European Commission

Combined Draft Renewal Assessment Report prepared according to

Regulation (EC) N° 1107/2009

and

Proposal for Harmonised Classification and Labelling (CLH Report)

according to Regulation (EC) N° 1272/2008

Rape oil

Volume 1

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Finland

Version History

When	What
March 2020	Initial RAR
September 2021	Draft final-RAR
December 2021	Final-RAR following the expert meeting TC64 (15-19 November 2021) (homework)
February 2023	Adaptions for the benefit of the CLH classification

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

Although the format for harmonised classification and labelling is used, the EFSA conclusions were published before this classification proposal had been finalised. Therefore, the sections relevant for classification purposes can differ in the current document compared to those in the published RAR . In this document the name rape oil is used instead of rape seed oil that is used in the published RAR.

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Level 1

Rape oil

1 STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1 CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1 Purpose for which the draft assessment report was prepared

This Renewal Assessment Report (RAR) is prepared for the renewal of the approval of the active substance rape oil. Rape oil is part of the AIR4 renewal programme for active substances (Commission Implementing Regulation (EU) No 844/2012).

1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State

The Netherlands conducted the full evaluation (RMS) and prepared the RAR for the active substance rape oil. The co-rapporteur Member State is Finland.

1.1.3 EU Regulatory history for use in Plant Protection Products

Rape oil is re-evaluated as an existing active substance by the Rapporteur Member State The Netherlands. The main data was submitted by the Task Force Rape Seed Oil (TF-RSO) consisting of the members

- W. Neudorff GmbH KG, Germany
- Evergreen Garden Care, Germany

Rape oil is approved since 1 September 2009 (Commission Directive 2008/127/EC of 18 December 2008)
The original extension of 31 August 2019 is extended to 31 August 2020 (Regulation (EU) 2017/195 of 3 February 2017).

The Review Report- Plant oils/Rape oil SANCO/2623/08 – rev. 1 is dated 25 July 2008.

The EFSA conclusion is published on 17 January 2013 (EFSA Journal 2013;11(1):3058) - Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/rape oil.

1.1.4 Evaluations carried out under other regulatory contexts

Not relevant.

1.2 APPLICANT INFORMATION

1.2.1 Name and address of applicant(s) for approval of the active substance

W. Neudorff GmbH KG
An der Mühle 3
D-31860 Emmerthal / Germany

Evergreen Garden Care Deutschland
Wilhelm-Theodor-Römheld-Str. 30.
D-55130 Mainz / Germany

1.2.2 Producer or producers of the active substance

Please refer to Vol. 4 for the sources of rape oil.

1.2.3 Information relating to the collective provision of dossiers

A joint dossier was submitted by the Task Force Rape Oil (TF-RSO) consisting of:
W. Neudorff GmbH KG, Germany
Evergreen Garden Care Deutschland GmbH.

1.3 IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1 Common name proposed or ISO-accepted and synonyms	ISO: Rape oil / LEAR / Canola oil[1] Synonyms: Rape oil: *Brassica napus* oil, rape oil, colza oil, turnip rape oil, ravison oil, sarson oil, toria oil. Canola oil: Low erucic acid Rape oil, canbra oil, low erucic acid colza oil, low erucic turnip rape oil.

[1] Rape seed versus Canola (see also definition according to CODEX-STAN 210): Canadian breeders successfully lowered the erucic acid content from as high as 40% (Polish rape seed) and 23.5% (Argentine rape seed) down to just 2%, and in 1986 the trademark "Canola" was altered to apply only to canola oil with less than 2% erucic acid. The word “canola” was derived from “**Can**adian **o**il, **l**ow **a**cid” in 1978. On the European market, it is better known as LEAR oil (for Low Erucic Acid Rape seed). Thus, although low in erucic acid the manufacturer named its product “Rape oil”.

Definition according to CODEX-STAN 210[2]	Rape oil: (turnip rape oil, colza oil, ravison oil, sarson oil, toria oil) is produced from seeds of Brassica napus L., Brassica campestris L., Brassica juncea L. and Brassica tournefortii Gouan.
	Rape oil - low erucic acid: (low erucic acid turnip rape oil, low erucic acid colza oil, canola oil) is produced from low erucic acid oil-bearing seeds of varieties derived from the *Brassica napus L.*, *Brassica campestris L.* and *Brassica juncea L.*, species.
1.3.2 Chemical name (IUPAC and CA nomenclature)	
IUPAC	Rape oil[3]
CA	Rape oil
1.3.3 Producer's development code number	None
1.3.4 CAS, EEC and CIPAC numbers	
CAS	8002-13-9 (Rape oil) 93165-31-2 (Fatty acids, rape-oil, erucic acid-low)
EC	232-299-0 (Rape oil) 296-916-5 (Fatty acids, rape-oil, erucic acid-low)
CIPAC	Not available
1.3.5 Molecular and structural formula, molecular mass	
Molecular formula	Not possible as it is a mixture of triglycerides of fatty acids.
Structural formula	
Molecular mass	
1.3.6 Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information - data provided separately in Volume 4

[2] Codex Standard for named vegetable oils, CODEX-STAN 210 (Amended 2003, 2005)

[3] ECHA required for the substance with EC 232-299-0 the name to be amended from 'Rape seed oil' to 'Rape oil'. The name was not amended by EFSA in the published RAR and the following was concluded there: *"Our phys-chem experts did not agree with the proposed name change from 'rape seed oil' to 'rape oil' as the active substance is manufactured from rape by crushing and extraction. In addition, since we have renewal 5 batch data showing that the active substance as manufactured contains low levels of erucic acid, it is proposed to keep only the CAS/EC number corresponding to the low erucic acid content. In any case, a note has been added in our conclusions indicating the ECHA name for this CAS/EC number."*. ECHA furthermore required for the substance with CAS number 93165-31-5 the name to be amended from 'Rape seed oil – low erucic acid' to 'Fatty acids, rape-oil, low erucic acid-low'. However, in line with the proposal by EFSA the name was not amended by the RMS in the published RAR. In this classification proposal the names have been amended as required by ECHA.

1.3.7 Specification of purity of the active substance in g/kg	The purity complies with the European Pharmacopeia 7.0 and Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 and ph. Eur. 5, 2005. Active substance is not a single compound but a mixture of triglycerides of fatty acids and the mode of action is mechanical rather than chemical: 100% of technical active substance is considered as active substance. The specifications is based on the composition as fatty acids and some physical and chemical parameters. No FAO specification.
1.3.8 Identity and content of additives (such as stabilisers) and impurities	
1.3.8.1 Additives	CONFIDENTIAL information - data provided separately in Volume 4
1.3.8.2 Significant impurities	CONFIDENTIAL information - data provided separately in Volume 4
1.3.8.3 Relevant impurities	None
1.3.9 Analytical profile of batches	CONFIDENTIAL information - data provided separately in Volume 4

1.4 INFORMATION ON THE PLANT PROTECTION PRODUCT

1.4.1 Applicant	W. Neudorff GmbH KG An der Mühle 3 D-31860 Emmerthal Germany Contact: [redacted]
1.4.2 Producer of the plant protection product	W. Neudorff GmbH KG An der Mühle 3 D-31860 Emmerthal Germany [redacted]
1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product	NEU 1160 I
1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product	
1.4.5 Composition of the plant protection product	CONFIDENTIAL information – data provided separately (Volume 4). For classification purposes, the data are also provided in the confidential Annex to this proposal

<table>
<tr><td>1.4.6 Information on the active substances</td><td>The purity is according to the values stated in German Drug Authoritiy Codex (Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994).

<table><tr><td>ISO:</td><td>Rape oil / LEAR / Canola oil[4]</td></tr><tr><td>Synonyms (English):</td><td>Rape Oil: Brassica napus oil, rape oil, colza oil, turnip rape oil, ravison oil, sarson oil, toria oil
Canola oil: Low erucic acid rape oil, canbra oil, low erucic acid colza oil, low erucic turnip rape oil</td></tr><tr><td>Rape oil:</td><td>CAS No.: 8002-13-9 (Rape seed oil)
93165-31-2 (Rape seed oil - low erucic acid)
EU Index: not applicable
EINECS: 232-299-0 (Rape seed oil)
296-916-5 (Rape seed oil - low erucic acid)
CIPAC: Not applicable</td></tr></table></td></tr>
<tr><td>1.4.7 Information on safeners, synergists and co-formulants</td><td>CONFIDENTIAL information – data provided separately (Volume 4)
For classification purposes, the data are also provided in the confidential Annex to this proposal</td></tr>
<tr><td>1.4.8 Type and code of the plant protection product</td><td>Emulsifiable concentrate [Code: EC]</td></tr>
<tr><td>1.4.9 Function</td><td>Insecticide and acaricide</td></tr>
<tr><td>1.4.10 Field of use envisaged</td><td>Pome and stone fruits, berry bushes, vegetables, potatoes and ornamental in field as well as in berries, vegetables, ornamentals and woody ornamentals in glasshouse.</td></tr>
</table>

1.4.11 Effects on harmful organisms	Contact action. The oil forms a film around the target species (translocation in plants is not relevant, since contact action is the main factor of controlling insects and spider mites).

[4] Rape versus Canola (see also definition according to CODEX-STAN 210): Canadian breeders successfully lowered the Erucic acid content from as high as 40% (Polish rape seed) and 23.5% (Argentine rape seed) down to just 2%, and in 1986 the trademark "Canola" was altered to apply only to canola oil with less than 2% Erucic acid. The word “canola” was derived from “Canadian oil, low acid” in 1978. On the European market, it is better known as LEAR oil (for Low Erucic Acid Rape seed). Thus, although low in Erucic acid the manufacturer named its product “Rape oil”.

1.5 DETAILED USES OF THE PLANT PROTECTION PRODUCT

GAP check SWA 20-04-2018, AKO 24-05-2019

PPP (product name/code)	**NEU 1160 I**	**Formulation type:**	**Emulsifiable Concentrate (EC)**
active substance 1	**Rape oil**	**Conc. of as 1:**	**883 g/L**
safener	**no**	**Conc. of safener:**	**no**
synergist	**no**	**Conc. of synergist:**	**no**
Applicant:	**NEU**	**professional use**	☒
Zone(s):	**EU all zones**	**non professional use**	☒

Verified by MS: **yes**

1	2	3	4	5	6	7	8 + 9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate***			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kgas/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Fruit trees												
1	All zones	Pome fruit	Fpn	Spider mites (all stages)	Knapsack sprayer, motor sprayer, hand sprayer	From end of leaf bud swelling to fruit ripe (BBCH 03 – 89) March-oct	a) 3 (7d) b) 3 (7d)	a) 30 b) 90	a) 26.49 b) 79.47	1500	n.a.	**Max. Application for RSO products for 3 m trees**
Berries												

2	All zones	Berry bushes (*Beerenstrauch)*	Gpn	Spider mites (all stages)	Knapsack sprayer, motor sprayer, hand sprayer	From Leaf tips above the bud scales: first leaves separating to fruit ripe (BBCH 10 to 87) April-oct	a) 3 (7d) b) 3 (7d)	a) 21.1 b) 63.3	a) 18.63 b) 55.89	1200	n.a.	**Max. Application for plants > 125 cm**
3	All zones	Berry bushes (*Beerenstrauch)*	Fpn	Spider mites (all stages)	Knapsack sprayer, motor sprayer, hand sprayer	From Leaf tips above the bud scales: first leaves separating to fruit ripe (BBCH 10 to 87) Approx. may-august	a) 3 (7d) b) 3 (7d)	a) 21.1 b) 63.3	a) 18.63 b) 55.89	1200	n.a.	**Max. Application for plants > 125 cm**
Vegetables												
4	All zones	Vegetables	Fpn	Spider mites	Knapsack sprayer, motor sprayer, hand sprayer	Cotyledon visible to fully ripe (BBCH 10 to 89) May-sept	a) 3 (5d) b) 3 (5d)	a) 23.1 b) 69.3	a) 20.40 b) 61.19	1200	n.a.	**Max. Application for plants > 125 cm**
5	All zones	Vegetables	Gpn	Spider mites	Knapsack sprayer, motor sprayer, hand sprayer	Cotyledon visible to fully ripe (BBCH 10 to 89) Jan-dec	a) 3 (5d) b) 3 (5d)	a) 23.1 b) 69.3	a) 20.40 b) 61.19	1200	n.a.	**Max. Application for plants > 125 cm**
Ornamentals												
6	All zones	Woody ornamentals	Gpn	Spider mites (all stages)	Knapsack sprayer and hand sprayer	In case of infestation	a) 3 (7d) b) 3 (7d)	a) 80 b) 240	a) 70.64 b) 211.9	4000	n.a.	**Max. Application for plants > 125 cm**
7	All zones	Ornamentals	Gpn	Spider mites (all stages)	Knapsack sprayer and hand sprayer	In case of infestation BBCH 10-89 Jan-dec	a) 4 (5d) b) 4 (5d)	a) 24.0 b) 96.0	a) 21.19 b) 84.77	1200	n.a.	**Max. Application for plants > 125 cm**
8	All zones	Ornamentals	Fpn	Spider mites (all stages)	Knapsack sprayer and hand sprayer	In case of infestation during vegetation period BBCH 10-89 during vegetation period may-sept	a) 4 (5d) b) 4 (5d)	a) 24.0 b) 96.0	a) 21.19 b) 84.77	1200	n.a.	**Max. Application for plants > 125 cm**

Agriculture												
9	All zones	Potatoes	Fpn	Colorado beetle	Knapsack sprayer, motor sprayer, hand sprayer	Cotyledon visible to fully ripe (BBCH 10 to 89) April-sept	a) 4 (7d) b) 4 (7d)	a) 7.5 b) 30.0	a) 6.62 b) 26.5	800-1200	n.a.	

*F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

1.5.1 Further information on representative uses

Development stages of the harmful organism concerned

The treatment is intended against all stages of spider mites in ornamentals, fruit trees, berries and vegetables, moreover against Colorado beetles in potatoes. In contrast to this, all developmental stages of target species will be affected by applications in the greenhouse; however, as NEU 1160 I is a contact insecticide/acaricide, hidden stages of the target species may be less affected, so that the treatment has to be repeated after about 7 days.

Duration of protection afforded by each application

NEU 1160 I is a contact acaricide/insecticide. Thus, duration of protection is dependent on the period of population recovery or re-infestations and cannot be estimated. A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. In greenhouses, it is recommended to repeat the treatment after about 7 days to interfere with the recovery of pest populations from hidden stages.

Duration of protection afforded by the maximum number of applications:

A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. This treatment should reduce the population of mites so far that protection should last for the next months to come. Up to 4 treatments are required to achieve an optimal control of all stages of spider mites. Protection then should last until a new population begins to develop. This re-infestation risk is highly dependent on conditions which are not connected with the effectiveness of NEU 1160 I.

1.5.2 Overview on authorisations in EU Member States

Note RMS: Many of the products listed below are combination products with other actives such as pyrethrins.

The task force member Neudorff GmbH KG has the following product registrations containing Rape oil within Europe:

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
AT	CZ	12.01.2012	3141	Spruzit Schädlingsfrei	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
AT	CZ	23.04.2014	3141-901	Compo Schädlings-frei plus				
AT	CZ	03.01.2013	3141-902	Spruzit Neu				
AT	CZ	22.09.2015	3141-903	Spruzit progress				
AT	CZ	24.01.2012	3148	Spruzit AF Schädlingsfrei	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
AT	CZ	13.07.2012	3148-901	Spruzit AF RosenSchädlingsFrei				
AT	CZ	13.07.2012	3148-902	Spruzit SchädlingsSpray				
AT	CZ	19.07.2012	3148-903	Spruzit OrchideenSchädlingsSpray				
AT	CZ	12.10.2012	3148-904	bellaflora biogarten Schädlingsfrei				
AT	CZ	27.08.2015	3148-907	Lizetan Zierpflanzenspray AF				
AT	CZ	13.12.2017	3148-908	Lizetan Zierpflanzen- und Rosen-Spray				
AT	CZ	18.01.2018	3148-909	Compo Schädlings-frei plus AF				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
AT	CZ	10.04.2015	3602	Neem Plus Schädlingsfrei	30 L/ha 60 L/ha	A: 0.035 R: 26.19 **A: 0.070** **R: 52.38**	2-6	A: 0.07 R: 52.38 **A: 0.421** **R: 314.28**
BE	CZ	09.08.2004	9390G/B	Pyrethro Pur	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
BE	CZ	01.07.2010	9853P/B	Raptol				
BE	CZ	09.08.2004	9391G/B	Pyrethro Pur Spray	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
CZ	CZ	04.09.2008	4526-1	Spruzit (Koncentrát proti škůdcům)	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
CZ	CZ	16.05.2016	4526-2	Natria proti škůdcům na rostlinách – koncentrát				
CZ	CZ	04.09.2008	4527-2	Spruzit AF (Přípravek proti škůdcům)	600 L/ha 1200 L/ha	P:0.025 R: 4.95	2-8	P: 0.055 R: 9.9
CZ	CZ	04.09.2008	4527-3	Raptol (Sprej proti škůdcům)				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
CZ	CZ	19.05.2016	4527-4	Natria proti škůdcům na rostlinách AL		**P: 0.06** **R: 9.9**		**P: 0.48** **R: 79.2**
DE	CZ	25.11.2002	024780-00	Spruzit Schädlingsfrei	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
DE	CZ	21.03.2003	024780-60	Spruzit Neu				
DE	CZ	03.03.2017	024780-61	Pyreth Natur-Insektizid				
DE	CZ	03.03.2017	024780-64	Compo Schädlings-frei plus				
DE	CZ	03.03.2017	024780-67	Herba-Vetyl flüssig				
DE	CZ	03.03.2017	024780-72	Bio Spinnmilben- & Schädlingsfrei				
DE	CZ	24.08.2005	024785-62	Raptol AF RosenSchädlingsfrei				
DE	CZ	***	024785-00	Spruzit AF Schädlingsfrei				
DE	CZ	25.05.2011	024785-64	Spruzit OrchideenSchädlingsSpray				
DE	CZ	05.05.2015	024785-71	Spruzit AF OrchideenSchädlingsFrei				
DE	CZ	25.05.2011	024785-65	Spruzit AF RosenSchädlingsFrei				
DE	CZ	05.05.2015	024785-70	Spruzit RosenSchädlingsSpray				
DE	CZ	25.05.2011	024785-66	Spruzit SchädlingsSpray				
DE	CZ	29.07.2016	024785-63	Bayer Garten Bio-Schädlingsfrei AF				
DE	CZ	01.08.2016	024785-69	Bayer Garten Bio Spinnmilben- & Schädlingsfrei AF				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
DE	CZ	29.07.2016	024785-67	Bayer Garten Bio-Schädlingsfrei Akut AF				
DE	CZ	29.07.2016	024785-72	Bayer Garten Orchideen-Spray Lizetan AF				
DE	CZ	29.07.2016	024785-73	Bayer Garten Zierpflanzen-&Rosen-Spray Lizetan AF				
DE	CZ	01.08.2016	024785-74	Bayer Garten Orchideen-& Zierpflanzen-Spray Lizetan				
DE	CZ	***	024785-75	Lizetan Orchideen-& Zierpflanzenspray				
DE	CZ	***	024785-76	Lizetan Orchideen-Spray AF				
DE	CZ	***	024785-77	Lizetan Zierpflanzen- & Rosen-Spray				
DE	CZ	***	024785-78	Bio Spinnmilben- & Schädlingsfrei AF				
DE	CZ	***	027485-79	COMPO Schädlings-frei plus AF				
DE	CZ	***	024785-68	Dr. Stähler Schädlings-Spray				
DE	CZ	19.03.2014	006892-00	Neem Plus Schädlingsfrei	30 L/ha 60 L/ha	A: 0.035 R: 26.19 **A: 0.070** **R: 52.38**	2-6	A: 0.07 R: 52.38 **A: 0.421** **R: 314.28**
IE	CZ	02.01.2012	PCS 04667	Pyrol Bug and Larvae Killer Concentrate		P: 0.027	2-8	P: 0.054

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
IE	CZ	24.08.2009	PCS 04752	Advanced Bug Killer	6 L/ha 12 L/ha	R: 4.95 **P: 0.055** **R: 9.9**		R: 9.9 **P: 0.44** **R: 79.2**
IE	CZ	12.07.2012	PCS 05244	Pyrol Bug and Larvae Killer for Roses	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
IE	CZ	24.08.2009	PCS 04753	Growing Success Advanced Bug Killer				
IE	CZ	08.05.2012	PCS 05243	Pyrol Bug and Larvae Killer				
IE	CZ	15.11.2017	PCS 05928	BugFree Bug and Larvae Killer				
IE	CZ	15.11.2017	PCS 05929	BugFree Bug and Larvae Killer for Roses				
LU	CZ	24.03.2003	L 01565-015	Spruzit Schädlingsfrei	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
LU	CZ	14.04.2017	L 02141-015	Spruzit Neu				
LU	CZ	24.03.2003	L 01566-015	Spruzit AF Schädlingsfrei	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
LU	CZ	03.11.2016	L 02062-015	Spruzit RosenSchädlingsSpray				
LU	CZ	18.02.2013	L 01948-015	Spruzit AF RosenSchädlingsFrei				
LU	CZ	17.11.2016	L 02061-015	Spruzit AF OrchideenSchädlingsFrei				
LU	CZ	18.02.2013	L 01949-015	Spruzit OrchideenSchädlingsSpray				
LU	CZ	24.03.2003	L 01569-015	Raptol SchädlingsSpray				

Existing Authorisations								
Country	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
LU	CZ	18.02.2013	L 01950-015	Spruzit SchädlingsSpray				
LU	CZ	10.12.2014	L 02024-015	Neem Plus Schädlingsfrei	30 L/ha 60 L/ha	A: 0.035 R: 26.19 **A: 0.070** **R: 52.38**	2-6	A: 0.07 R: 52.38 **A: 0.421** **R: 314.28**
NL	CZ	06.02.2009	13122 N	Spruzit-R concentraat	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
NL	CZ	18.11.2015	14997 N	Natria Insectenmiddel concentraat				
NL	CZ	29.05.2009	13202 N	Promanal-R concentraat				
NL	CZ	07.09.2009	13230 N	Raptol				
NL	CZ	06.03.2009	13154 N	Spruzit-R Gebruiksklaar	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
NL	CZ	24.11.2015	15003 N	Natria Insectenmiddel spray				
NL	CZ	29.05.2009	13201 N	Promanal-R Gebruiksklaar				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
PL	CZ	17.02.2010	Zezwolenie MRiRW nr R-13/2010 z dnia 17.02.2010 r. zmienione decyzią MRiRW nr R-288/2012d z dnia 31.10.2012 r. decyzią MRiRW nr R-671/2015d z dnia 05.08.2015 r. oraz decyzią MRiRW nr R-407/2016d z dnia 11.08.2016 r.	Spruzit Koncentrat na Szkodniki EC	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
PL	CZ	31.12.2009	Zezwolenie MRiRW nr R-134/2009 z dnia 31.12.2009 r. zmienione decyzią MRiRW nr R-287/2012d z dnia 31.10.2012 r. decyzią MRiRW nr R-670/2015d z dnia 05.08.2015 r. oraz decyzią MRiRW nr R-424/2016d z dnia 29.08.2016 r.	Spruzit Spray na Szkodniki AL	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
SI	CZ	08.08.2007	U34330-9/2015/3	Raptol Koncentrat	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
SI	CZ	25.07.2007	U34330-90/2016/**5**	Raptol Spray		P:0.025	2-8	P: 0.055

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
SI	CZ	07.07.2017	U34330-90/2016/**4**	Raptol Spray AE	600 L/ha 1200 L/ha	R: 4.95 **P: 0.06** **R: 9.9**		R: 9.9 **P: 0.48** **R: 79.2**
UK	CZ	17.04.2007	13438	Spruzit	6 L/ha 12 L/ha	P: 0.027 R: 4.95 **P: 0.055** **R: 9.9**	2-8	P: 0.054 R: 9.9 **P: 0.44** **R: 79.2**
UK	CZ	30.07.2004	15746	Advanced Bug Killer				
UK	CZ	13.09.2011	15844	Pyrol Bug and Larvae Killer Concentrate				
UK	CZ	05.12.2016	17897	Richard Jackson´s Pest Control				
UK	CZ	19.10.2015	17273	Guard´n´Aid for SpiderMite				
UK	CZ	19.10.2015	17276	Guard´n´Aid for Thrip				
UK	CZ	19.10.2015	17277	Guard´n´Aid PestOff Plus Concentrate				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
UK	CZ	24.11.2004	18015	Growing Success Advanced Bug Killer	600 L/ha 1200 L/ha	P:0.025 R: 4.95 **P: 0.06** **R: 9.9**	2-8	P: 0.055 R: 9.9 **P: 0.48** **R: 79.2**
UK	CZ	13.09.2011	18060	Pyrol Bug and Larvae Killer				
UK	CZ	12.12.2012	18061	Pyrol Bug and Larvae Killer for Roses				
UK	CZ	16.10.2017	18260	BugFree Bug and Larvae Killer				
UK	CZ	24.10.2017	18270	BugFree Bug and Larvae Killer for Roses				
DK	NZ	06.04.2016	364-67	Spruzit Neu	3.5 L/ha 12 L/ha	P: 0.016 R: 2.89 **P: 0.055** **R: 19.8**	2-8	P: 0.032 R: 5.78 **P: 0.44** **R: 79.2**
DK	NZ	13.06.2016	364-5	InsektFri Spruzit N Konzentrat				
DK	NZ	16.04.2007	364-6	InsektFri Spruzit N Klar-til-brug	1400 L/ha	**P: 0.069** **R: 12.38**	2-8	P: 0.138 R: 24.6 **P: 0.552** **R: 98.4**
FI	NZ	09.04.2008	2009	Spruzit	3.5 L/ha 12 L/ha	P: 0.016 R: 2.89 **P: 0.055** **R: 19.8**	2-8	P: 0.032 R: 5.78 **P: 0.44** **R: 79.2**
FI	NZ	10.04.2013	3154	Natria Hyönteisten torjunta-aine, tiiviste				
FI	NZ	21.03.2017	3388	Raptol				
FI	NZ	09.04.2008	2777	Spruzit RTU	1400 L/ha	**P: 0.069**	2-8	P: 0.138

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
FI	NZ	08.03.2017	3409	Spraits AF		**R: 12.38**		R: 24.6 **P: 0.552** **R: 98.4**
FI	NZ	10.04.2013	3155	Natria Hyönteisten torjunta-aine, spray				
NO	NZ	16.03.2007	2009.71.14	Konsentrat mot skadeinsekter og Bladlus	3.5 L/ha 12 L/ha	P: 0.016 R: 2.89 **P: 0.055** **R: 19.8**	2-8	P: 0.032 R: 5.78 **P: 0.44** **R: 79.2**
NO	NZ	22.08.2011	2012.21	Proff Skadeinsekter				
NO	NZ	03.04.2017	2017.20	Raptol				
NO	NZ	n.a.	2012.12.17	Natria Insektkonsentrat*				
NO	NZ	28.01.2007	2009.69.14	Spray mot skadeinsekter og Bladlus	1400 L/ha	**P: 0.069** **R: 12.38**	2-8	P: 0.138 R: 24.6 **P: 0.552** **R: 98.4**
NO	NZ	n.a.	2012.13.17	Natria Insektspray*				
SE	NZ	03.03.2003	4573	Raptol Insekt Effekt Koncentrat	3.5 L/ha 12 L/ha	P: 0.016 R: 2.89 **P: 0.055** **R: 19.8**	2-8	P: 0.032 R: 5.78 **P: 0.44** **R: 79.2**
SE	NZ	24.11.2010	4573	Natria Pyrsol				
SE	NZ	24.07.2006	5351	Raptol				
SE	NZ	17.07.2015	PHT-0012-4573	Stoppa insekter koncentrat				
SE	NZ	01.11.2017	5350	Raptol Insekt Effekt färdigblandad	1400 L/ha	**P: 0.069** **R: 12.38**	2-8	P: 0.138 R: 24.6 **P: 0.552**
SE	NZ	03.03.2003	4574**	Raptol Insekt Effekt				
SE	NZ	03.03.2003	4574**	Raptol Bladlöss Effekt				

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
SE	NZ	03.03.2003	4574**	Raptol Ros Effekt Spray				**R: 98.4**
SE	NZ	26.04.2012	PHT-0001-4574	Natria Pyrsol Spray				
SE	NZ	08.07.2015	PHT-0010-4574	Stoppa insekter				
SE	NZ	26.01.2018	PHT-0037-5350	Raptol Bladlöss Effekt färdigblandad				
SE	NZ	26.01.2018	PHT-0030-5350	Pyrsol Spray				
SE	NZ	17.10.2016	PHT-0029-5350	Spraits AF				
CY	SZ	09.08.2016	3270	Spruzit AF	1000 L/ha	P: 0.459 R: 8.253	2-3	P: 0.0918 R: 16.51 **P: 0.1377** **R: 24.76**
ES	SZ	09.01.2014	25.692	Spruzit EC	10 L/ha 15 L/ha	P: 0.459 R: 8.253 **P: 0.6885** **R: 12.38**	4 (x 10 L/ha) 2 (x 15 L/ha)	P: 0.1377 R: 24.76 **P: 0.1836** **P: 33.132**
ES	SZ	23.10.2017	25.692	Solabiol Insecticida Acaricida Natural EC				
ES	SZ	09.01.2014	25.693	Spruzit RTU	1000 L/ha	P: 0.18 R: 8.253	2-3	P: 0.36 R: 16.51 **P: 0.54** **R: 24.76**

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
FR	SZ	07.05.2010	2090199	Insecticide Spruzit EC	10 L/ha 15 L/ha	P: 0.459 R: 8.253 **P: 0.6885** **R: 12.38**	2	P: 0.0918 R: 16.51 **P: 0.1377** **R: 24.76**
FR	SZ	07.05.2010	2160608	Spruzit EC PRO***				
FR	SZ	07.05.2010	2090200	Insecticide Spruzit AF	1000 L/ha	P: 0.459 R: 8.253	2-3	P: 0.0918 R: 16.51 **P: 0.1377** **R: 24.76**
FR	SZ	07.05.2010	2160609	Spruzit AF PRO***				
FR	SZ	In finalisation	Not yet assigned	Neem Plus Insecticide	30 L/ha 60 L/ha	A: 0.035 R: 26.19 **A: 0.070** **R: 52.38**	2-6	A: 0.07 R: 52.38 **A: 0.421** **R: 314.28**
GR	SZ	25.05.2012	14398/25-05-2012	Spruzit EC	10 L/ha 15 L/ha	P: 0.459 R: 8.253 **P: 0.6885** **R: 12.38**	2	P: 0.0918 R: 16.51 **P: 0.1377** **R: 24.76**

Existing Authorisations								
Count-ry	**Zone**	**Since**	**Reg. No.**	**Product**	**Product Application rate per treatment** Min and **Max [l/ha]**	**Active Substance(s) [1] Application rate per treatment** Min and **Max [kg as/ha]**	**Number of treatments per Season Min and Max**	**Active substance(s) Max. total dose/ ha** Min and **Max [kg as/ha]**
GR	SZ	25.05.2012	14397/25-05-2012	Spruzit AF	1000 l/ha	P: 0.18 R: 8.253	2-3	P: 0.36 R: 16.51 **P: 0.54** **R: 24.76**
IT	SZ	26.05.2005	12692	Spruzit Insetticida	6 - 18 l/ha	P: 0.02754 R: 4.9518 **P: 0.08262** **R: 14.8554**	8	P: 0.22032 R: 39.6144 **P: 0.66096** **R: 118.8432**
IT	SZ	26.05.2005	12690/PPO	Spruzit Insetticida Concentrato				
IT	SZ	31.08.2015	16418/PPO	Natria Insetticida Abbattente	1000 l/ha	P: 0.459 R: 8.253	4	**P: 0.1836** **R: 33.01**
IT	SZ	26.05.2005	12691/PPO	Spruzit Insetticida Pronto Uso				
IT	SZ	26.11.2015	16521/PPO	Naturkraft Insetticida Pronto Uso				
IT	SZ	26.11.2015	16525/PPO	Naturkraft Insetticida per Afidi Pronto Uso				
IT	SZ	26.11.2015	16524/PPO	Naturkraft Insetticida per Cocciniglie Pronto Uso				

The task force member Evergreen Garden Care Deutschland GmbH has the following product registrations containing Rape oil within Europe:

MS	Product name	Product code	Active substance(s) and content (g/L or g/kg)	Crop(s))	Authorisation holder of registered product[5]	Authorisation number of registered product[3]
FR	Naturen Eradibug	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	Scotts France SAS	2110150
FR	Naturen Eradigun	CEL 32622	Rape oil (17 g/L)	Orchards, vineyards, vegetables, ornamentals	Scotts France SAS	2110149
BE	Naturen Eradibug	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	Evergreen Garden Care Belgium B.V.B.A.	9755G/B
BE	Naturen Eradigun	CEL 32622	Rape oil (17 g/L)	Orchards, vineyards, vegetables, ornamentals	Evergreen Garden Care Belgium B.V.B.A.	9756G/B
Lux	Naturen Eradibug	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	Scotts Benelux bvba	L01828-078
Lux	Naturen Eradigun	CEL 32622	Rape oil (17 g/L)	Orchards, vineyards, vegetables, ornamentals	Scotts Benelux bvba	L01829-078
AT	Naturen Bio Schädlingsfrei Obst und Gemüse Konzentrat	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	Evergreen Garden Care Österreich GmbH	2568
AT	Naturen Bio Schädlingsfrei Obst und Gemüse	CEL 32622	Rape oil (17 g/L)	Orchards, vinejards, vegetables, ornamentals	Evergreen Garden Care Österreich GmbH	2739/0

[5] For new products not yet authorised this field is not applicable.

MS	Product name	Product code	Active substance(s) and content (g/L or g/kg)	Crop(s))	Authorisation holder of registered product[5]	Authorisation number of registered product[3]
DE	MICULA	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	Evergreen Garden Care Deutschland GmbH	043743-00
DE	Schädlingsfrei Naturen AF	CEL 32622	Rape oil (17 g/L)	Orchards, vineyards, vegetables, ornamentals	Evergreen Garden Care Deutschland GmbH	024213-00
RoI	Bug Clear for Fruit & Veg	CEL 32601	Rape oil (777 g/L)	Orchards, vineyards, vegetables, ornamentals	The Scotts Company (UK) Ltd	92338
UK	Bug Clear Fruit & Veg	CEL 32601	Rape oil (777 g/L)	all edible crops, all non edible crops	Evergreen Garden Care UK Ltd	16910
UK	botanico BUGCLEAR Spray	S16881	Rape oil (10 g/L) Pyrethrins (0.100 g/L)	ornamental garden plants	Evergreen Garden Care UK Ltd	17867
UK	BugClear Ultra 2 Gun!	S16881	Rape oil (10 g/L) Pyrethrins (0.100 g/L)	ornamental garden plants	Evergreen Garden Care UK Ltd	18127
UK	BugClear Ecomax	NLS484A	Rape oil (700 g/L) Pyrethrins (7 g/L)	ornamental garden plants (outdoor), ornamental plant production (permanent protection with full enclosure)	Evergreen Garden Care UK Ltd	17834
UK	Bugclear Ultra 2	NLS484A	Rape oil (700 g/L) Pyrethrins (7 g/L)	ornamental garden plants (outdoor), ornamental garden plants (protected)	Evergreen Garden Care UK Ltd	18128

MS	Product name	Product code	Active substance(s) and content (g/L or g/kg)	Crop(s))	Authorisation holder of registered product[5]	Authorisation number of registered product[3]
IT	BIOPOLYSECT SL	CEL 32601	Rape oil (777 g/L)	ornamentals	Evergreen Garden Care France SAS	015967
IT	BIOPOLYSECT AL	CEL 32622	Rape oil (17 g/L)	ornamentals	Evergreen Garden Care France SAS	015968

Level 2

Rape oil

2 SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

Summary of methodology proposed by the applicant for literature review and for all sections

2.1 IDENTITY

2.1.1 Summary or identity

The active substance is Rape oil (CAS No. 8002-13-9, EC 232-299-0). Rape oil (turnip rape oil, colza oil, ravison oil, sarson oil, toria oil) is produced from seeds of *Brassica napus L.*, *Brassica campestris L.*, *Brassica juncea L.* and *Brassica tournefortii Gouan*.

Alternative is fatty acids,)rape-oil, erucic acid-low / Canola oil (CAS No. 93165-31-2, EEC 296-916-5):is produced from low erucic acid oil-bearing seeds of varieties derived from the Brassica napus L., Brassica campestris L. and Brassica juncea L., species.

The purity complies with the European Pharmacopeia 7.0 and Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 and ph. Eur. 5, 2005.

Active substance is not a single compound but a mixture of triglycerides of fatty acids and the mode of action is mechanical rather than chemical: 100% of technical active substance is considered as active substance. The specification is based on the composition as fatty acids and some physical and chemical parameters.

No relevant impurities are present in the technical material (see Volume 4).

2.2 PHYSICAL AND CHEMICAL PROPERTIES [EQUIVALENT TO SECTION 7 OF THE CLH REPORT TEMPLATE]

2.2.1 Summary of physical and chemical properties of the active substance

Table 1: Summary of physicochemical properties of the active substance

Property	**Value**	**Reference**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101,3 kPa	Slightly viscous clear liquid, yellowish.	[redacted] Report: SSL01308 KCA 2.3/01	Measured
Melting/freezing point	-29.5°C.	[redacted] Report: 20080160.01 KCA-2.1/01	Measured
Boiling point	Boiling range 412 – 418 °C, however the test item boiled under decomposition, therefore boiling range > decomposition range.	[redacted] Report: 20080160.01 KCA-2.1/01	Measured
Relative density	D_4^{20} : 0.9184 (NEU 1160 I, 96% Rape seed oil)	[redacted] KCP 2.6/01	Measured
Vapour pressure	Calculated from higher temperature 20°C: 6.2 x 10^{-7} Pa 25°C: 1.1 x 10^{-6} Pa 50°C: 1.3 x 10^{-5} Pa	[redacted] Report: 20080160.02 KCA-2.2/01	Measured
Surface tension	Not determined (Water solubility < 1mg/L) Both studies ([redacted]) were found not acceptable, however it is considered that rape oil does not dissolve in water and therefore the surface tension does not have to be determined.	-	-

Water solubility	The water solubility cannot be determined for Rape oil, as it is a mixture of triglycerides of fatty acids. The water solubility can only be determined for a pure compound. Below an estimation is provided for the main constituent Triolein (fatty acid Oleic acid), which can be considered as a rough estimation of the water solubility of Rape seed oil. Triolein (Glyceryl trioleate; CAS 122-32-7) 2.551 *10^{-20} mg/L by the log P_{ow} approach. (WSKOW v 1.40) 8.8546 * 10^{-7} mg/L by the increment approach. (Wat Sol v1.01)	[redacted] Report: SCF22442 KCA 2.5/01	Estimated
Partition coefficient n-octanol/water	The log K_{ow} (partition coefficient n-octanol/water) cannot be determined for Rape oil, as it is a mixture of triglycerides of fatty acids. The log K_{ow} can only be determined for a pure compound. Below a calculated log K_{ow} is provided for the main constituent, the triglyceride, Triolein, as well as, the fatty acid, Oleic acid. Considering that the other constituents of Rape oil are triglycerides of similar sized fatty acids, Rape oil can be considered a lipophilic substance. Triolein (Glyceryl trioleate; CAS 122-32-7) Log K_{ow} = 23.29 (KOWWIN v1.62)	[redacted] Report: SCF22442 KCA-2.7/01	Estimated
Henry's law constant	The Henry's Law constant can only be determined for the constituents, and not for Rape seed oil, which is a mixture of glycerides of different fatty acids. Below an estimated Henry's Law constant is provided for the main constituent Triolein (fatty acid Oleic acid). Triolein (fatty acid Oleic acid) 25°C: 1.49.10-10 Pa*m^3/mole (…)	[redacted] Report: SCF22442 KCA-2.2/02	Estimated

Flash point	187.5 °C 234.4 °C 261.5 °C	[redacted]KCA 2.10/03 [redacted]Report: SSL01308 KCA-2.10/01 [redacted]Report: 20160001.01 KCA 2.10/02	Measured
Flammability	Not determined (not a solid)	-	-
Explosive properties	Not explosive	Expert statement	Estimated
Self-ignition temperature	405°C (NEU 1160 I, 96% rape oil) 400°C (NEU 1160 I, 100% rape oil) 400°C (NEU 1160 I, 100% rape oil)	[redacted]Report: NOTOX Project 300329 KCA 2.9/03 [redacted]Report: SSL01308 KCA-2.9/01 [redacted]KCP 2.9/02	Measured
Oxidising properties	Not oxidising	Expert statement	Estimated
Granulometry	Not determined (Not a granule)	-	-
Solubility in organic solvents and identity of relevant degradation products	Solubility at 20 ºC: n-Heptane : > 250 g/L p-xylene: > 250 g/L 1,2-Dichloroethane: > 250 g/L Methanol: < 10 g/L Acetone: > 250 g/L Ethyl acetate : > 250 g/L	[redacted]Report: 20031238/01-PSBO KCA-2.6/02 [redacted]Report: SSL01308 KCA-2.6/01	Measured

Dissociation constant	Not relevant (As Rape oil is a mixture of triglycerides of fatty acids, no dissociation can occur).	-	-
Viscosity	Newtonian liquid, dynamic viscosity (NEU 1160 I, 96% Rape oil): 69.04 mPas at 20 °C (shear rates between 5 – 100 s-1) 31.61 mPas at 40 °C (shear rates between 5 – 100 s-1)	[redacted] KCP 2.5/01	Measured
Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	Maxima are found at 206 nm (2-propanol)/210 nm (methanol) Ɛ = 1070 L × mol–1 × cm–1 and at 218.5 nm (methanol+10% NaOH) Ɛ = 141 L × mol–1 × cm–1 (100%). No absorption maxima (molar extinction coefficient Ɛ<10 L × mol–1 × cm–1) between 290-750 nm , therefore no phototoxicity expected.	[redacted] Report: SSL01308 KCA 2.4/01 [redacted] Report: SCF22442 KCA 2.4/02	Measured

2.2.1.1 Evaluation of physical hazards [equivalent to section 8 of the CLH report template]

2.2.1.1.1 Explosives *[equivalent to section 8.1 of the CLH report template]*

Table 2: Summary table of studies on explosive properties

Method	Results	Remarks	Reference
Not provided	-	-	-

2.2.1.1.1.1 Short summary and overall relevance of the provided information on explosive properties

No study provided, evaluation based on expert statement, based on the nature of the active substance. Rape seed oil consists of aliphatic chains with ester groups. The structural properties exclude explosive properties.

2.2.1.1.1.2 Comparison with the CLP criteria

According to CLP Annex I, 2.1.4.3, no classification if any of the following (a-c) is met:

a. there are no chemical groups associated with explosives properties, see table A6.1 UN-Manual of Tests and Criteria 7th revised ed. (UN-MTC) Appendix 6 (p. 494), OR

Such groups are present and

b. the substance contains groups associated with explosive properties which include oxygen and the oxygen balance is less than -200 °C OR

c. the substance is an organic substance and

- the exothermic decomposition energy is below 500 J/g, OR
- onset of exothermic decomposition is 500 °C or above.

Rape seed oil meets criteria 'a' and as such does not have to be classified as an explosive liquid.

2.2.1.1.1.3 Conclusion on classification and labelling for explosive properties

Not explosive.

2.2.1.1.2 Flammable gases (including chemically unstable gases) *[equivalent to section 8.2 of the CLH report template]*

Table 3: Summary table of studies on flammable gases (including chemically unstable gases)

Method	Results	Remarks	Reference
-			

2.2.1.1.2.1 Short summary and overall relevance of the provided information on flammable gases (including chemically unstable gases)

Active substance is not a gas, therefore not applicable.

2.2.1.1.2.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.2.3 Conclusion on classification and labelling for flammable gases

Not applicable.

2.2.1.1.3 Oxidising gases *[equivalent to section 8.3 of the CLH report template]*

Table 4: Summary table of studies on oxidising gases

Method	Results	Remarks	Reference
-			

2.2.1.1.3.1 Short summary and overall relevance of the provided information on oxidising gases

Active substance is not a gas, therefore not applicable.

2.2.1.1.3.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.3.3 Conclusion on classification and labelling for oxidising gases

Not applicable.

2.2.1.1.4 Gases under pressure *[equivalent to section 8.4 of the CLH report template]*

Table 5: Summary table of studies on gases under pressure

Method	Results	Remarks	Reference
-			

2.2.1.1.4.1 Short summary and overall relevance of the provided information on gases under pressure

Active substance is not a gas, therefore not applicable.

2.2.1.1.4.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.4.3 Conclusion on classification and labelling for gases under pressure

Not applicable.

2.2.1.1.5 Flammable liquids *[equivalent to section 8.5 of the CLH report template]*

Table 6: Summary table of studies on flammable liquids

Method	Results	Remarks	Reference
EC A.9, ISO3679, Equilibrium method ASTM 7236-07	Flashpoint: 234.4 °C	Accepted by RMS Rape seed oil (100%)	[redacted] Report: SSL01308 KCA-2.10/01
EC A.9,	Flashpoint: 261.5 °C	Accepted by RMS	[redacted]

Method	Results	Remarks	Reference
ISO 3679, ISO 3680 Equilibrium method		Rape seed oil (100%)	Report: KCA 2.10/02
EC A.2, OECD 103, OECD 113 DSC method	Boiling point > 350 °C (Decomposition temperature: 350 °C)	Accepted by RMS Rape oil (100%)	[redacted] Report: 20030778.01 KCA-2.1/02
EC A.2, OECD 103 DSC + capillary method	Boiling range: 412 – 418 °C Decomposition range: 330 – 445 °C	Accepted by RMS Measured, the test item boiled under decomposition, therefore boiling range > decomposition range Rape oil (100%)	[redacted] Report: 20080160.01 KCA-2.1/01

2.2.1.1.5.1 Short summary and overall relevance of the provided information on flammable liquids

The flash-point and boiling point were determined for Rape seed oil (100%) and have been accepted by the RMS.

2.2.1.1.5.2 Comparison with the CLP criteria

A flammable liquid shall be classified in one of the three categories in accordance with the following criteria:

1. Flash point < 23 °C and initial boiling point ≤ 35 °C
2. Flash point < 23 °C and initial boiling point > 35 °C
3. Flash point ≥ 23 °C and ≤ 60 °C

Rape oil does not meet any of the above criteria and as such does not have to be classified as a flammable liquid.

2.2.1.1.5.3 Conclusion on classification and labelling for flammable liquids

Not (highly) flammable.

2.2.1.1.6 Flammable solids *[equivalent to section 8.6 of the CLH report template]*

Table 7: Summary table of studies on flammable solids

Method	Results	Remarks	Reference
-			

2.2.1.1.6.1 Short summary and overall relevance of the provided information on flammable solids

Active substance is not a solid, therefore not applicable.

2.2.1.1.6.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.6.3 Conclusion on classification and labelling for flammable solids

Not applicable.

2.2.1.1.7 Self-reactive substances *[equivalent to section 8.7 of the CLH report template]*

Table 8: Summary table of studies on self-reactivity

Method	Results	Remarks	Reference
Not provided.	.	.	.

2.2.1.1.7.1 Short summary and overall relevance of the provided information on self-reactive substances

No study provided, evaluation based on expert judgement, considering the structural composition of the active substance. Rape seed oil consists of aliphatic chains with ester groups. The structural properties exclude self-reactivity.

2.2.1.1.7.2 Comparison with the CLP criteria

Self-reactive substances or mixtures are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances and mixtures classified according to this part as explosives, organic peroxides or as oxidising. According to the CLP Regulation, self-reactive properties are tested using UN test series A to H, the hazard class can be assessed also based on the screening criteria in CLP Annex I, 2.8.4.2, see below.

The classification procedures for self-reactive substances and mixtures need not be applied if:

(a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.3 in Appendix 6 of the UN-MTC 7th revised ed. (on p. 494 and p. 496); or
(b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT for a 50 kg package is greater than 75 °C or the exothermic decomposition energy is less than 300J/g. The onset temperature and decomposition energy can be estimated using a suitable calorimetric technique (see Part II, sub-section 20.3.3.3 of the UN-MTC).

The majority of the screening criteria for no classification in CLP are met for Rape oil. The content of any free olefins (alkenes) can be excluded, as based on the 5-batch data such compounds were not found. Therefore no classification as a self-reactive substance is proposed.

2.2.1.1.7.3 Conclusion on classification and labelling for self-reactive substances

Not self-reactive.

2.2.1.1.8 Pyrophoric liquids *[equivalent to section 8.8 of the CLH report template]*

Table 9: Summary table of studies on pyrophoric liquids

Method	Results	Remarks	Reference
Not provided			

2.2.1.1.8.1 Short summary and overall relevance of the provided information on pyrophoric liquids

No study provided, based on the experience in manufacturing and handling of the active substance which shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures.

2.2.1.1.8.2 Comparison with the CLP criteria

Pyrophoric liquid means a liquid substance or mixture which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. According to the CLP Regulation, pyrophoric properties are tested using UN N.3 method (results from test method EU A.13 are acceptable as the two methods are considered equivalent, see Chapter R.7a: Endpoint specific Guidance, R.7.1.10.5). Alternatively, an assessment can be made based on experience in handling, see criteria in CLP Annex I, 2.9.4.1. The classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)).

2.2.1.1.8.3 Conclusion on classification and labelling for pyrophoric liquids

Not pyrophoric.

2.2.1.1.9 Pyrophoric solids *[equivalent to section 8.9 of the CLH report template]*

Table 10: Summary table of studies on pyrophoric solids

Method	Results	Remarks	Reference
-			

2.2.1.1.9.1 Short summary and overall relevance of the provided information on pyrophoric solids

Active substance is not a solid, therefore not applicable.

2.2.1.1.9.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.9.3 Conclusion on classification and labelling for pyrophoric solids

Not applicable.

2.2.1.1.10 Self-heating substances *[equivalent to section 8.10 of the CLH report template]*

Table 11: Summary table of studies on self-heating substances

Method	Results	Remarks	Reference
92/69/EEC A.1 OECD 102 DIN ISO 3013	Melting/ Freezing range. -12.0 °C – -30.6 °C	Accepted by RMS Rape seed oil (100%)	[redacted] Report: 20031238/01-PCFP KCA-2.1/03
92/69/EEC A.15 DIN 51794	auto-ignition temperature: 400 °C	Accepted by RMS Rape seed oil (100%)	[redacted] Report: SSL01308 KCA-2.9/01
92/69/EEC A.15 DIN 51794	auto-ignition temperature: 400 °C	Accepted by RMS Rape seed oil (100%)	[redacted] Report: KCA 2.9/02

2.2.1.1.10.1 Short summary and overall relevance of the provided information on self-heating substances

The active substance is not to be classified as self-heating in the sense of Reg. (EC) 1272/2008 since liquids are not classified as self-heating. Furthermore, the melting point determined is < 160 °C and thus the substance is not to be considered for classification. The auto-ignition temperature was determined in two studies for Rape seed oil (100%), both have been accepted by the RMS.

2.2.1.1.10.2 Comparison with the CLP criteria

According to the CLP Regulation, self-heating properties are tested using methods N4 given in Part III, sub-section 33.3.1.6 of the UN RTGD; or see also the criteria for the screening tests, CLP Annex I 2.11.4.2 below.
The classification procedure for self-heating substances or mixtures need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied. Examples of screening tests are:
(a) The Grewer Oven test (VDI guideline 2263, Part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80 K above the reference temperature for a volume of 1 l;
(b) The Bulk Powder Screening Test (Gibson, N. Harper, D.J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60 K above the reference temperature for a volume of 1 l.
In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. However, if liquids are adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered.

2.2.1.1.10.3 Conclusion on classification and labelling for self-heating substances

Not self-heating.

2.2.1.1.11 Substances which in contact with water emit flammable gases *[equivalent to section 8.11 of the CLH report template]*

Table 12: Summary table of studies on substances which in contact with water emit flammable gases

Method	Results	Remarks	Reference
Not provided			

2.2.1.1.11.1 Short summary and overall relevance of the provided information on substances which in contact with water emit flammable gases

No study provided, evaluation based on expert judgement considering the structural composition of the active substance. Rape seed oil consists of aliphatic chains with ester groups with no metals or metalloids present in the chemical structure.

2.2.1.1.11.2 Comparison with the CLP criteria

A substance or mixture shall be classified as a substance or mixture which in contact with water emits flammable gases if spontaneous ignition takes place in any step of the test procedure. According to the CLP Regulation, substances which, in contact with water, emit flammable gases are tested using UN test series N.5, in accordance with Table 2.12.1. The hazard class can be assessed also based on the screening procedure see criteria in CLP Annex I, 2.12.4.1, see below.
The classification procedure for this class need not be applied if:
(a) the chemical structure of the substance or mixture does not contain metals or metalloids; or
(b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or
(c) the substance or mixture is known to be soluble in water to form a stable mixture.

2.2.1.1.11.3 Conclusion on classification and labelling for substances which in contact with water emit flammable gases

Not a substance which in contact with water will emit flammable gases.

2.2.1.1.12 Oxidising liquids *[equivalent to section 8.12 of the CLH report template]*

Table 13: Summary table of studies on oxidising liquids

Method	Results	Remarks	Reference
Not provided.			

2.2.1.1.12.1 Short summary and overall relevance of the provided information on oxidising liquids

No study provided, evaluation based on expert statement considering the structural composition of the active substance. Rape seed oil consists of aliphatic chains with ester groups with oxygen only chemically bonded to carbon and hydrogen.

2.2.1.1.12.2 Comparison with the CLP criteria

For organic substances or mixtures the classification procedure for this class shall not apply if:
(a) the substance or mixture does not contain oxygen, fluorine or chlorine; or

(b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen

2.2.1.1.12.3 Conclusion on classification and labelling for oxidising liquids

Not oxidising.

2.2.1.1.13 Oxidising solids *[equivalent to section 8.13 of the CLH report template]*

Table 14: Summary table of studies on oxidising solids

Method	Results	Remarks	Reference
-			

2.2.1.1.13.1 Short summary and overall relevance of the provided information on oxidising solids

Active substance is not a solid, therefore not applicable.

2.2.1.1.13.2 Comparison with the CLP criteria

Not applicable.

2.2.1.1.13.3 Conclusion on classification and labelling for oxidising solids

Not applicable.

2.2.1.1.14 Organic peroxides *[equivalent to section 8.14 of the CLH report template]*

Table 15: Summary table of studies on organic peroxides

Method	Results	Remarks	Reference
Not provided			

2.2.1.1.14.1 Short summary and overall relevance of the provided information on organic peroxides

No study provided, evaluation based on expert judgement considering the structural composition of the active substance. The active substance is not an organic peroxide (or contains compounds which are organic peroxides) as it consists of aliphatic chains with ester groups.

2.2.1.1.14.2 Comparison with the CLP criteria

Organic peroxides means liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide. Organic peroxides are thermally unstable substances or mixtures, which can undergo exothermic self-accelerating decomposition. In addition, they can have one or more of the
following properties:
(i) be liable to explosive decomposition;
(ii) burn rapidly;
(iii) be sensitive to impact or friction;
(iv) react dangerously with other substances.

2.2.1.1.14.3 Conclusion on classification and labelling for organic peroxides

Not an organic peroxide.

2.2.1.1.15 Corrosive to metals *[equivalent to section 8.15 of the CLH report template]*

Table 16: Summary table of studies on the hazard class corrosive to metals

Method	Results	Remarks	Reference
Not provided.			

2.2.1.1.15.1 Short summary and overall relevance of the provided information on the hazard class corrosive to metals

No study provided, evaluation based on expert judgement considering the structural composition of the active substance. Rape seed oil consists of aliphatic chains with ester groups. The active substance is not corrosive to metals.

2.2.1.1.15.2 Comparison with the CLP criteria

A substance or a mixture that is corrosive to metals means a substance or a mixture which by chemical action will materially damage, or even destroy, metals. According to the CLP Regulation, this hazard class should be evaluated based on the results from the test method in Part III, sub-section 37.4, C.1 of the UN-MTC. In the CLP Guidance 2.16.4.1., a screening procedure is also proposed. Screening procedure for Liquids: Solids and liquids: substances having acid or basic functional groups, containing halogens or able to form complexes with metals should be considered for this hazard class. E.g. usually extreme pH points towards the likelihood of corrosivity.

Considering that all the above named conditions are not satisfied, a test should have been conducted. However, as Rape seed oil does not possess any characteristics as being a strong acid/base based on the functional groups in the mixture, does not contain any halogens or is able to form any complexes with metals, the need for testing is waived based on expert judgement and as such no further data is required. Therefore, Rape seed oil is not classified as corrosive to metals.

2.2.1.1.15.3 Conclusion on classification and labelling for corrosive to metals

Not corrosive to metals.

2.2.2 Summary of physical and chemical properties of the plant protection product

The formulation NEU 1160 I is an clear homogenous, pale yellow oil with no explosive, no oxidising, no flammable and self-heating properties. The pH of a 1% emulsion is 5.6 (however no temperature was provide and is required according CIPAC MT 75.3 and should be provided) and the viscosity was determined to be 69.04 mPa.s (at 20°C) and 31.61 mPa.s (at 40°C) indicating an Newtonian liquid. The kinematic viscosity at 40°C is 34.09 mm^2/s (calc.) and no H304 classified components are present in the formulation and therefore the product does not have to be classified as an aspiration hazard. The surface tension of the neat formulation was 33.2 mN/m and at a 4% emulsion 31.7 mN/m and therefore the formulation is considered to be surface active. The relative density is 0.9184 and the density is 0.9184 g/cm^3 (at 20°C). The storage stability in the commercial packaging has not been adequately demonstrated, as the studies for the accelerated storage stability for 1 month at 54°C and 2 year shelf-life at ambient temperature were not accepted, however the formulation is considered to be physically, chemically and technically stable after 8 weeks at 40°C in HDPE packaging. The 2 year shelf-life study at ambient temperature in HDPE packaging is found to be acceptable, as all physical, chemical and technical properties were stable after 2 years at ambient temperature in HDPE packaging. The study for low temperature storage for 7 days at 0°C was accepted and showed stability over the storage period at 0°C. The technical properties were all within the criteria and therefore no problems are anticipated when the product handled normally. It should be mentioned that based on the emulsion stability and re-emsulsifiability results it is recommended to include the following phrase on the product label “continuous agitation during application” to prevent any separation/formation of cream/froth and oil on top of the spray liquid (tank mixture).

2.3 DATA ON APPLICATION AND EFFICACY

2.3.1 Summary of effectiveness

Formulated products containing the active substance rape oil have been authorized at member state level for > 10 years and has therefore been assessed in line with Uniform Principles. For a renewal of an active substance no new efficacy data is required.

2.3.2 Summary of information on the development of resistance

No reported cases of resistance are known. The mode of action of rape oil is mechanical. Therefore the risk for development of resistance is considered to be very low.

2.3.3 Summary of adverse effects on treated crops

The representative product has been authorised at Member State level for > 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable adverse effects on treated crops are known

2.3.4 Summary of observations on other undesirable or unintended side-effects

The representative product has been authorised at Member State level for > 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable side effects are known

2.4 FURTHER INFORMATION

2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire

Active substance

The recommended precautions concerning handling, storage, transport and fire are collected in the safety data sheet.

Formulation NEU 1160 I

See Volume 3 CP section B.4 or the safety data sheet.

2.4.2 Summary of procedures for destruction or decontamination

Active substance

Rape oil is an active substance without any halogens. A study on pyrolytic behaviour, therefore, is not required. Further information in the safety data sheet.

Formulation NEU 1160 I

See Volume 3 CP section B.4 or the safety data sheet.

2.4.3 Summary of emergency measures in case of an accident

Active substance

Dike spill: Prevent from entering sewers, waterways, or low areas. Sweep up and place in suitable containers for later disposal. Further information in the safety data sheet.

Formulation NEU 1160 I

See Volume 3 CP section B.4 or the safety data sheet.

2.5 METHODS OF ANALYSIS

2.5.1 Methods used for the generation of pre-authorisation data

Active substance

1) Technical material:

Active substance: The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3030/99 rev. 4 for the determination of fatty acids with GC-FID and found to be acceptable.

Non-significant-impurity: The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3030/99 rev. 4 for the determination of the relevant impurity free Erucic acid with an LOQ of 0.05% w/w (12.5 mg/L) with GC-FID and confirmation with GC-MS.

2) Residues:

One pre-registration analytical method for the determination of fatty acids in soil has been provided in support of the risk-assessment of fate. No pre-registration analytical methods in support of risk-assessment for ecotoxicology, toxicology, residues, efficacy and physical, chemical properties were provided and are required.

B.5.1.2. (a) Methods in soil, water, sediment, air and any additional matrices used in support of environmental fate studies.

One study was provided, however it was not fully validated according to SANCO/3029/99 rev. 4, pending information which need to be provided by the applicant on the raised issues. Moreover, after the commenting round no further information/data was presented for the raised issues and as such the analytical method is still considered to be not acceptable.

B.5.1.2. (b) Methods in soil, water and any additional matrices used in support of efficacy studies

Not required, fatty acids occur naturally resulting from plant metabolism and by formation by microbial organisms.

B.5.1.2. (c) Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicological studies

Not required, since the active substance is not regarded as toxic or very toxic.

B.5.1.2. (d) Methods in body fluids, air and any additional matrices used in support of operator, worker, resident and bystander exposure studies

Not required, since the active substance is not regarded as toxic or very toxic.

B.5.1.2. (e) Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies

Not required. Rape oil is used as an edible food without indication of deleterious effect.

B.5.1.2. (f) Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies

One analytical method was provided in support of bee study. The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3029/99 rev. 4 for the determination of methylated oleic acid in pure water and 50% sucrose solution with GC-MS with an LOQ of 140 mg/L (pure water) and 12 mg/L (50% sucrose solution).

B.5.1.2. (g) Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests

Not required.

<u>NEU 1160 I</u>

1) Formulation:

Active substance: The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3030/99 rev. 4 for the determination of fatty acids (as methylesters of palmitic acid, stearic acid, oleic acid, linoleic acid and linolenic acid) in the formulation NEU 1160 I with GC-FID and confirmation GC-MS and found to be acceptable.

Non-significant impurity: The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3030/99 rev. 4 for the determination of Erucic acid in the formulation NEU 1160 I with GC-FID and confirmation GC-MS and found to be acceptable.

2) Residues:

An pre-registration analytical method for the determination of Oleic acid in water and 50% aqueous sucrose solution has been provided in support of the risk-assessment of ecotoxicology. No pre-registration analytical methods in support of risk-assessment for fate, toxicology, residues, efficacy and physical, chemical properties were provided and are required.

B.5.1.2. (a) Methods in soil, water, sediment, air and any additional matrices used in support of environmental fate studies.

See Volume 3 CA section B.5.

B.5.1.2. (b) Methods in soil, water and any additional matrices used in support of efficacy studies
Not required, fatty acids occur naturally resulting from plant metabolism and by formation by microbial organisms.

B.5.1.2. (c) Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicological studies
Not required, since the active substance is not regarded as toxic or very toxic.

B.5.1.2. (d) Methods in body fluids, air and any additional matrices used in support of operator, worker, resident and bystander exposure studies
Not required, since the active substance is not regarded as toxic or very toxic.

B.5.1.2. (e) Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies
Not required. Rape oil is used as an edible food without indication of deleterious effect.

B.5.1.2. (f) Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies
The analytical method is fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3029/99 rev. 4 for the determination of oleic acid in 50 % (w/v) aqueous sucrose solution samples and water samples with an LOQ of 1400 mg/L and 100 mg/L respectively with GC-MS.

B.5.1.2. (g) Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests
Not required.

2.5.2 Methods for post control and monitoring purposes

Fatty acids occur naturally in the soil resulting from plant metabolism and by formation by microbial organisms. They also are common constituents in every living cell, being normally used for structural integrity of cells, as building blocks for more complex compounds and as a high energy food source. Plants, soil microorganisms or animals will utilise fatty acids to meet their nutritional requirements. Fatty acids are an excellent substrate for microbial growth, serving both as carbon sources, and as energy sources.

Rape oil does not volatilize. Therefore, the presentation of an analytical method for the determination of the a.s. or metabolites in air is not required.

Any contamination of this substance to drinking water or ground water is unlikely to occur. Even if the oil may be washed off treated plants by rain, it will rapidly degrade in the environment.

In addition, the US EPA consider that, since people are exposed to this substance from food or other sources, the incremental exposure derived from non-dietary exposure such as drinking water or ground water should be minimal (US EPA 1998). Thus, a method to quantify Rape oil residue in waters from applications as an insecticide or acaricide, is considered not necessary.

Therefore for food and feed commodities of plant and animal origin and the environmental matrices soil, water and air and for body fluids and tissues no residue definition(s) are proposed (and no MRL's are in place, as the active substance is included in Annex IV of Reg. (EU) 396/2005). As a consequence there is no need to monitor this/these compound(s) in these compartments and no analytical post-registration methods for monitoring/enforcement are required. However an analytical method for the determination of fatty acids in soil was provided (under pre-registration methods), nevertheless could not be fully evaluated as the study report was interim and not finally signed.

2.6 EFFECTS ON HUMAN AND ANIMAL HEALTH

More detailed results of the studies are presented in Volume 3, section B.6.

2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals *[equivalent to section 9 of the CLH report template]*

Rape oil is a dietary vegetable oil derived from seeds of *Brassica napus.* Fats and oils nor fatty acids do pose any health problem, and no Acceptable Daily Intake (ADI) has been set for any of the fatty acids, including Stearic, Palmitic, Oleic and Linoleic acids, or oils and fats. Rape oil is, like all vegetable oils, metabolized by hydrolysis of glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β-oxidation. An oral absorption percentage of 100% should be considered suitable.

2.6.1.1 Short summary and overall relevance of the provided toxicokinetic information on the proposed classification(s)

The provided data on absorption, distribution, metabolism and excretion is literature data. There is no influence on the classification proposal.

2.6.2 Summary of acute toxicity

Based on the studies performed with NEU 1160/1 (90% Rape seed oil, 2% Pyrethrum extract) rape oil has no acute oral nor dermal toxicity (LD50>2000 mg/kg b.w. in both cases). The endpoint for acute inhalation is LC50, 4h > 2.36 mg/L (mist). Rape oil was found to be not irritating to eyes and skin and also to be no sensitizer. Although NEU 1161 I has a second active substance which is pyrethrin and this active substance has the following EU harmonised classifications (CLP00: H302 harmful if swallowed, H312 harmful in contact with skin and H332 harmful if inhaled) no acute toxicity effects were found with NEU 1161 I. Therefore the acute toxicity studies performed with NEU 1161 I can be considered as worst case and the bridging possibilities based on the composition of the two formulations were accepted by the RMS.

According to the CLP Guidance, classification in Acute Tox. 4 (the lowest classification) is required for substances with oral LD50 of 200-2000 mg/kg bw. The LD50 for oral toxicity was above 2000 mg/kg bw and rape oil thus does not fulfil the CLP classification criteria for acute oral toxicity.

According to the CLP Guidance, classification in Acute Tox. 4 (the lowest classification) is required for substances with dermal LD50 of 400-2000 mg/kg bw. The LD50 for dermal toxicity was above 2000 mg/kg bw and rape oil thus does not fulfil the CLP classification criteria for acute oral toxicity.

According to the CLP Guidance, classification in Acute Tox. 4 (the lowest classification) is required with inhalation

LC50 for mists of 1-5 mg/litre/4h. The LC50 for inhalation was above 2.36 mg/L (mist) (highest technical achievable concentration) and rape oil thus not fulfil the CLP classification criteria for inhalation toxicity.
Consequently, there is no proposed classification.

2.6.2.1 Acute toxicity - oral route [equivalent to section 10.1 of the CLH report template]

Table 17: Summary table of animal studies on acute oral toxicity

Method, guideline, deviations[1] if any	Species, strain, sex, no/group	Test substance	Dose levels, duration of exposure	Value LD_{50}	Reference
OECD Guideline 401 (1987), EEC Directive 92/69/EEC B.1	Wistar rats 5/sex	NEU 1161 I	2000 mg/kg (gavage)	Oral LD50 > 2000 mg/kg bw	KCP 7.1.1/01

[1]*study is acceptable*

2.6.2.1.1 Short summary and overall relevance of the provided information on acute oral toxicity

The test substance, NEU1161 I was administered by oral gavage to five Wistar strain Crl:(WI) BR (outbred, SPF-Quality) rats of each sex at a dose of 2000 mg/kg bw. No mortality occurred, no clinical signs of toxicity were observed and no abnormalities were found in the animals upon macroscopic post mortem examination.
The oral LD_{50} value of NEU 1161 I in rats was established as exceeding 2000 mg/kg bw.

2.6.2.1.2 Comparison with the CLP criteria regarding acute oral toxicity

According to the CLP Guidance, classification in Acute Tox. 4 (the lowest classification) is required for substances with oral LD50 of 200-2000 mg/kg bw. Rape oil thus does not meet the criteria for classification for acute oral toxicity because the LD50 for oral toxicity was above 2000 mg/kg bw.

2.6.2.1.3 Conclusion on classification and labelling for acute oral toxicity

No acute oral toxicity. No classification proposed.

2.6.2.2 Acute toxicity - dermal route [equivalent to section 10.2 of the CLH report template]

Table 18: Summary table of animal studies on acute dermal toxicity

Method, guideline, deviations[1] if any	Species, strain, sex, no/group	Test substance	Dose levels, duration of exposure	Value LD_{50}	Reference
OECD 402, limit test (1987) EC Directive 92/69/EEC B.3	SD Rats 5/sex	NEU 1161 I	2000 mg/kg for 24h to 10% of body surface	Dermal LD50 > 2000 mg/kg	KCP 7.1.2/01

[1]*study is acceptable*

2.6.2.2.1 Short summary and overall relevance of the provided information on acute dermal toxicity

In an acute dermal toxicity study groups of young adult Sprague-Dawley rats (5/sex) were exposed by the dermal route to NEU1161 I (90% Rape seed oil, 2% Pyrethrum extract). Test material was applied for 24 hours to 10% of each animal's body surface at a dose of 2000 mg/kg body weight. Animals were observed for the following 15 days. No mortality occurred. Red staining on the head or in the neck was noted in one female from day 2 onwards.
The mean body weight gain during the observation period was within the range expected for rats used in this type of study. No abnormalities were found at macroscopic post mortem examination of the animals.

2.6.2.2.2 Comparison with the CLP criteria regarding acute dermal toxicity

According to the CLP Regulation, classification in Acute Tox. 4 (the lowest classification) is required for substances with dermal LD50 of 400-2000 mg/kg bw. Rape oil thus does not meet the criteria for classification for acute dermal toxicity because the LD50 for dermal toxicity was above 2000 mg/kg bw.

2.6.2.2.3 Conclusion on classification and labelling for acute dermal toxicity

No acute dermal toxicity. No classification proposed.

2.6.2.3 Acute toxicity - inhalation route [equivalent to section 10.3 of the CLH report template]

Table 19: Summary table of animal studies on acute inhalation toxicity

Method, guideline, deviations[1] if any	Species, strain, sex, no/group	Test substance, form and particle size (MMAD)	Dose levels, duration of exposure	Value LC_{50}	Reference
OECD 403, limit test (1981)	SD Rats 5/sex	NEU 1161 I, MMAD: 1.102 - 1.696	2.36 mg /L for 4hr, nose only	LC50 for four hours was >2.36 mg/L	KCP 7.1.3/01

[1]*study is acceptable*

2.6.2.3.1 Short summary and overall relevance of the provided information on acute inhalation toxicity

In an acute inhalation toxicity study, groups of young adult Sprague Dawley rats (5/sex) were exposed by the inhalation route to an aerosol of NEU 1161 I (90% Rape seed oil, 2% Pyrethrum Extract) for 4 hours on the head-nose only at an actual concentration of 2.36 mg/L (highest technical achievable concentration) Animals then were observed for 14 days.

The 4-hour inhalation LC_{50} for males was > 50 mg/L nominal, i.e. > 2.36 mg/L measured
for females was > 50 mg/L nominal, i.e. > 2.36 mg/L measured
combined was > 50 mg/L nominal, i.e. > 2.36 mg/L measured

Body weights were recorded prior to exposure and on days 8 and 15. All animals were necropsied and subjected to gross macroscopic examination.
Under the conditions of this experiment NEU 1161 I caused no mortality. Acute toxicological symptoms were not observed over a 14-day observation period. The post-mortem findings after euthanasia did not show any macroscopic organ changes.

Exposure conditions:

Concentrations		% particles < 4 µm*	Temperature (°C)
Nominal	Measured		
50 mg/L	2.36 mg/L air	> 95	19.8-21.5

* MMAD 1.102 (SD 1.395) - 1.696 (SD 1.522)

The obtained LC50 for four hours is above 2.36 mg/L (mist).

2.6.2.3.2 Comparison with the CLP criteria regarding acute inhalation toxicity

According to the CLP Guidance, classification in Acute Tox. 4 (the lowest classification) is required with inhalation LC50 for mists of 1-5 mg/litre/4h. Rape oil thus does not meet the criteria for classification for acute inhalation toxicity because the LC50 for inhalation was above 2.36 mg/L (mist) (highest technical achievable concentration).

2.6.2.3.3 Conclusion on classification and labelling for acute inhalation toxicity

No acute inhalation toxicity. No classification proposed.

2.6.2.4 Skin corrosion/irritation [equivalent to section 10.4 of the CLH report template]

Table 20: Summary table of animal studies on skin corrosion/irritation

Method, guideline,	**Species, strain,**	**Test substance**	**Dose levels,**	**Results - Observations and time point of onset[2]**	**Reference**

deviations[1] if any	**sex, no/group**		**duration of exposure**	**- Mean scores/animal - Reversibility**	
OECD 404 EC Directive 92/69/EEC B.4	3 young adult male New Zealand rabbits	NEU 1161 I	0.5 mL	Non Irritant: Very slight erythema (mean score 24 – 72h 0.78) and slight oedema (mean score 24 – 72h 0.34) in the treated skin-areas of the rabbits, resolved within 3-7 days after exposure. Greasy remnants of the test substance present on the skin on day 1. No symptoms of systemic toxicity and no mortality.	KCP 7.1.4/01

[1]*study is acceptable*

2.6.2.4.1 Short summary and overall relevance of the provided information on skin corrosion/irritation

In a primary dermal irritation study, 3 young adult male New Zealand rabbits were exposed *via* the dermal route to 0.5 mL of NEU 1161 I (90% Rape oil, 2% Pyrethrum Extract) each. The test material was applied undiluted for 4 hours to the clipped skin of one flank, using a semi-occlusive dressing. Observations were made 1, 24, 48 and 72 hours and 7 days after exposure. Very slight erythema and slight oedema in the treated skin-areas of the rabbits, which had resolved within 3-7 days after exposure was observed. Greasy remnants of the test substance were present on the skin on day 1. No symptoms of systemic toxicity were found and no mortality occurred.

Table 6.1.4-1: Individual and mean skin irritation scores

	Erythema			**Oedema**		
Animal no	**1021**	**1023**	**1025**	**1021**	**1023**	**1025**
After 1 hr	1	1	1	2	2	2
After 24 hr	1	1	1	1	1	1
After 48 hr	1	1	1	0	0	0
After 72 hr	1	0	0	0	0	0
After 7 d	0	0	0	0	0	0
Mean score 24 – 72 h	0.78			0.34		

The skin irritation study did not show an irritating potential.

2.6.2.4.2 Comparison with the CLP criteria regarding skin corrosion/irritation

A substance is classified as corrosive to skin (Category 1) when it produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis in at least one tested animal after exposure for up to 4 hours. Three sub-categories are provided within the corrosion category: subcategory 1A, where corrosive responses are noted following up to 3 minutes exposure and up to 1 hour observation; sub-category 1B, where corrosive responses are described following exposure greater than 3 minutes and up to 1 hour and observations up to 14 days;

and sub-category 1C, where corrosive responses occur after exposures greater than 1 hour and up to 4 hours and observations up to 14 days. Corrosive substances may be classified in Category 1 where data are not sufficient for sub-categorisation

According to Regulation No. (EC) 1272/2008 a substance should be classified as skin irritant (Category 2) when it produces reversible damage to the skin following its application for up to 4 hours. Reversible damage is defined as if:

(1) Mean score of ≥ 2,3 - ≤ 4,0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or

(2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or

(3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

Rape oil thus does not meet the criteria for classification for skin corrosion/irritation because the *in vivo* skin irritation study did not show an irritating potential.

2.6.2.4.3 Conclusion on classification and labelling for skin corrosion/irritation

No skin corrosion/irritation. No classification proposed.

2.6.2.5 Serious eye damage/eye irritation [equivalent to section 10.5 of the CLH report template]

Table 21: Summary table of animal studies on serious eye damage/eye irritation

Method, guideline, deviations[1] if any	**Species, strain, sex, no/group**	**Test substance**	**Dose levels duration of exposure**	**Results** **- Observations and time point of onset[2]** **- Mean scores/animal** **- Reversibility**	**Reference**
OECD Guideline 405 EU Directive 92/69 EEC B.5 (1992)	3 young adult male albino rabbits	NEU 1161 I	0.1 mL	Non Irritant: No acute systemic toxicological signs or mortality. Slight irritation of the conjunctival tissue, resolved within 24 hours.	KCP 7.1.5/01

[1]*study is acceptable*

2.6.2.5.1 Short summary and overall relevance of the provided information on serious eye damage/eye irritation

In a primary eye irritation study 0.1 mL of undiluted NEU 1161 I (90% Rape oil and 2% Pyrethrum Extract) was instilled into the conjunctival sac of one eye of each of 3 young adult male albino rabbits. Eye irritation was scored using the Draize scheme for eyes. The test substance did not cause any acute systemic toxicological signs or mortality. Instillation of the test substance resulted in slight irritation of the conjunctival tissue, which had resolved within 24 hours.

Mean values of eye irritation scores (24, 48 and 72 h after instillation)

Animal no.	Mean 24-72 hours				
	Corneal opacity	Iris	Conjunctivae		
			Redness	Chemosis	Discharge
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0

The eye irritation study did not show an irritating potential.

2.6.2.5.2 Comparison with the CLP criteria regarding serious eye damage/eye irritation

According to Regulation No. (EC) 1272/2008 a single hazard category (Category 1) is adopted for substances that have potential to seriously damage the eyes. For such substances the following criteria apply:

A substance that produces:

(a) in at least one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or

(b) in at least 2 of 3 tested animals, a positive response of:

(i) corneal opacity ≥ 3 and/or

(ii) iritis > 1,5

calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material.

According to Regulation No. (EC) 1272/2008 a single hazard category (Category 2) is adopted for substances that have potential for eye irritation. For such substances the following criteria apply:

Substances that produce in at least in 2 of 3 tested animals, a positive response of:

(a) corneal opacity ≥ 1 and/or

(b) iritis ≥ 1, and/or

(c) conjunctival redness ≥ 2 and/or

(d) conjunctival oedema (chemosis) ≥ 2

calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material, and which fully reverses within an observation period of 21 days

Rape oil thus does not meet the criteria for classification for eye damage/irritation because the eye damage/irritation

study did not show an irritating potential.

2.6.2.5.3 Conclusion on classification and labelling for serious eye damage/eye irritation

No eye damage/irritation. No classification proposed.

2.6.2.6 Respiratory sensitisation [equivalent to section 10.6 of the CLH report template]

No data available.

2.6.2.7 Skin sensitisation [equivalent to section 10.7 of the CLH report template]

Table 22: Summary table of animal studies on skin sensitisation

Method, guideline, deviations[1] if any	**Species, strain, sex, no/group**	**Test substance**	**Dose levels duration of exposure**	**Results**	**Reference**
OECD Guideline 406 (1992), GPMT EU Directive 96/54 EEC B.6 (1996)	10 young adult female Himalayan strain guinea pigs	NEU 1160 I	20% for intradermal injection and 100% for topical induction and challenger	No sensitizer: Mild skin reactions (using 10% sodium dodecyl sulfate 24 hours before epidermal induction) after challenge exposure in experimental and control animals. No evidence of skin hypersensitivity	KCP 7.1.6/01

[1]*study is acceptable*

2.6.2.7.1 Short summary and overall relevance of the provided information on skin sensitisation

Test substance concentrations selected for the main study were based on the results of a preliminary study. In the main study, 10 young adult female Himalayan strain guinea pigs were intradermally injected with 20% NEU 1160 I (v/v in water) and epidermally exposed to undiluted NEU 1160 I (96% Rape oil). Five control animals (females) were similarly treated, but with vehicle alone (water). No positive control was included. Two weeks after the epidermal application all animals were challenged with undiluted test substance.

Mild skin reactions (using 10% sodium dodecyl sulfate 24 hours before epidermal induction) were evident after the challenge exposure in the experimental and control animals. There was no evidence that the test substance had caused skin hypersensitivity in the guinea pig. On the basis of this study, NEU 1160 I does not warrant classification as being a dermal sensitiser.

The skin sensitisation study did not show a sensitising potential.

2.6.2.7.2 Comparison with the CLP criteria regarding skin sensitisation

A skin sensitiser is a substance that will lead to an allergic response following skin contact. Where data are sufficient, guidance allows the allocation of skin sensitisers into Sub-category 1A, strong sensitisers, or Sub-category 1B for other skin sensitisers. Sub-category 1A is appropriate for substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitisation in humans. Severity of reaction may also be considered. Sub-category 1B is appropriate for substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitisation in humans. Severity of reaction may also be considered.

Rape oil thus does not meet the criteria for classification for skin sensitisation because the skin sensitisation study did not show a sensitising potential.

2.6.2.7.3 Conclusion on classification and labelling for skin sensitisation

No skin sensitisation. No classification proposed.

2.6.2.8 Phototoxicity

No study was submitted. Considering the nature of the active substance and its use in cosmetics no *in vitro* phototoxicity study is required. Furthermore, no absorption maxima (molar extinction coefficient Ɛ<10 L × mol–1 × cm–1) between 290-750 nm is found, therefore no phototoxicity is expected (see 2.2.1).

2.6.2.9 Aspiration hazard [equivalent to section 10.13 of the CLH report template]

Table 23: Summary table of evidence for aspiration hazard

Type of study/data	Test substance	Relevant information about the study (as applicable)	Observations	Reference
No data available				

An acute inhalation toxicity study is available (see section on acute toxicity - 2.6.2.3)

2.6.2.9.1 Short summary and overall relevance of the provided information on aspiration hazard

The kinematic viscosity at 40°C is 34.09 mm^2/s and no H304 classified components are present in the formulation. In addition, no signs of aspiration hazard were seen in the acute inhalation study (section 2.6.2.3).

2.6.2.9.2 Comparison with the CLP criteria regarding aspiration hazard

According to CLP, Aspiration hazard means severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.
No such effects were observed after acute inhalation exposure to the product (96% rape oil, EC-formulation). In addition, a substance may be classified for aspiration hazard based on the kinematic viscosity. However the kinematic viscosity is above the limit value of 20,5 mm^2 and therefore rape oil does not meet any of thew criteria for classification as aspiration hazard.

2.6.2.9.3 Conclusion on classification and labelling for aspiration hazard

No classification proposed.

2.6.2.10 Specific target organ toxicity-single exposure (STOT SE) [equivalent to section 10.11 of the CLH report template]

Table 24: Summary table of animal studies on STOT SE (specific target organ toxicity-single exposure)

Method, guideline, deviations[1] if any, species, strain, sex, no/group	**Test substance, route of exposure, dose levels, duration of exposure**	**Results** **- NOAEL/LOAEL** **- target tissue/organ** **- critical effects at the LOAEL**	**Reference**
OECD Guideline 401 (1987), EEC Directive 92/69/EEC B.1 Wistar Rats 5/sex	NEU 1161 I Oral (gavage, single dose), 2000 mg/kg. Single dose	No mortality occurred, no clinical signs of toxicity were observed and no abnormalities were found in the animals upon macroscopic post mortem examination.	KCP 7.1.1/01
OECD 402, limit test (1987) EC Directive 92/69/EEC B.3 Sprague Dawley Rats 5/sex	NEU 1161 I Test material was applied for 24 hours to 10% of each animal's body surface at a dose of 2000 mg/kg body weight.	No mortality occurred, no clinical signs of toxicity were observed and no abnormalities were found in the animals upon macroscopic post mortem examination.	KCP 7.1.2/01
OECD 403, limit test (1981) Sprague Dawley Rats 5/sex	NEU 1161 I Exposed by the inhalation route to an aerosol of NEU 1161 I for 4 hours on the head-nose only at an actual concentration of 2.36 mg/L	No mortality occurred, no clinical signs of toxicity were observed and no abnormalities were found in the animals upon macroscopic post mortem examination.	KCP 7.1.3/01

[1]*studies are acceptable*

2.6.2.10.1 Short summary and overall relevance of the provided information on specific target organ

toxicity – single exposure (STOT SE)

The acute studies are performed with the product NEU 1161 I (90% Rape oil, 2% Pyrethrum Extract). No mortality occurred, no clinical signs of toxicity were observed and no abnormalities were found in the animals upon macroscopic post mortem examination after single oral, dermal and inhalatory exposure.

2.6.2.10.2 Comparison with the CLP criteria regarding STOT SE (specific target organ toxicity-single exposure)

Substances should be classified for STOT-SE when specific target organ toxicity (Cat 1 or 2) or narcotic effects or respiratory tract irritation (Cat 3) are observed following a single exposure.

Rape oil thus does not meet the criteria for classification for STOT SE cat 1, 2 or 3 because the acute oral, dermal and inhalation studies and the open literature on Rape oil and fatty acids screened for neurotoxicity did not show specific target toxicity, narcotic effects or respiratory tract irritation.

2.6.2.10.3 Conclusion on classification and labelling for STOT SE (specific target organ toxicity-single exposure)

No specific target toxicity, narcotic effects or respiratory tract irritation. No classification proposed.

2.6.3 Summary of repeated dose toxicity (short-term and long-term toxicity) [section 10.12 of the CLH report]

2.6.3.1 Specific target organ toxicity-repeated exposure (STOT RE) [equivalent to section 10.12 of the CLH report template]

Table 25: Summary table of animal studies on repeated dose toxicity (short-term and long-term toxicity) STOT RE (specific target organ toxicity - repeated exposure). *The studies are open literature studies. As the active substance is rape oil only the relevant effects are presented.*

Method, guideline, deviations if any, species, strain, sex, no/group	**Test substance, route of exposure, dose levels, duration of exposure**	**Results** **- NOAEL/LOAEL** **- target tissue/organ** **- critical effects at the LOAEL**	**Reference**
Non guideline study (no GLP) public literature 25 male Wistar rats, 5 groups *The aim of the present study was to determine the effect of long-term optional intake of vegetable oils (canola, grape seed, corn) and yogurt butter on the serum, liver and muscle cholesterol status.*	Control Canola oil (rape oil), corn oils and grape oil, manually prepared yogurt butter 10 weeks, 24 h two bottle choice (oil and water) tests. Dose level not clear as intake was optional for the animals.	Critical (relevant) effect: Beneficial effects of canola (36% decrease serum TC levels) and corn oils (21% decrease serum TC levels) on the serum cholesterol status and grape oil on the liver cholesterol values without adverse effects on HDL-C and BMI status in rats. Decrease in LDL-C values (about 64%) for canola oil	Asadi et al. (2010) KCA 5.1.1/01
Non guideline study (no GLP) public literature Male Wistar rats *The aim of the study was to determine changes in the blood lipid profile of rats fed with Rape seed, strawberry and raspberry oils and their effects on selected parameters of oxidative status.*	Rape oil, strawberry and raspberry oils 0.8 ml, oral gavage for 5 weeks once daily	Critical (relevant) effect: Beneficial effect as facilitation of the process of maintenance of suitable redox state in the body for strawberry and raspberry oils. Lower total cholesterol in the blood plasma for rape oil. However, total cholesterol was not statistically significant compared to the control in rats fed with rapeoil.	Pieszka et al. (2013) KCA 5.1.1/02
Non guideline study (no GLP) public literature 15 male Wistar rats, 3 groups *This study aimed to assess the nutritional effects of Rape oil and sunflower oil on ponderal and biochemical parameters in rats.*	Rape oil and sunflower oil 4 weeks, daily 1.5 ml	Critical (relevant) effect: Statistically significant lowering effects on the HDL cholesterol and triglyceride levels for rape oil.	Berroukche et al. (2015) KCA 5.1.1/03
Non guideline study (no GLP) public literature 30 male Wistar Kyoto (WKY) rats *This study intended to examine whether or not fatty acid composition unique to CO participates in the adverse effect of blood pressure increase.*	canola oil (obtained from a low erucic acid and low glucosinolate variant of Rape seed), Fed as dietary fat for 13 weeks	Critical (relevant) effect: An increase in blood pressure, neutrophil count, white blood cell count, plasma levels of total protein, total cholesterol, free cholesterol, triglycerides and phospholipids after rape oil. A decrease of platelet counts.	Ohara (2009) KCA 5.1.1/04

Non guideline study (no GLP) public literature 16 male Wistar rats *In this study Wistar rats were fed a diet containing 10% (dietary Rape (canola) oil (CO) or soybean oil (SO) as the sole fat nutrient for 10 weeks, and changes in clinical signs, urinalysis, blood biochemistry and pathology were compared.*	Canola oil and soybean oil diet (Oriental Yeast, Tokyo, Japan) supplemented with 10 w/w% CO or with10 w/w% SO. 10 weeks	Significant increased plasma concentrations of aldosterone and Na+.	Ohara (2008) KCA 5.1.1/06)
Non guideline study (no GLP) public literature 30 two-month old male Wistar-Han rats *Aiming at correlating diet with alterations of mitochondrial membrane composition and bioenergetics.*	a Rape oil-based diet n=11 (11 days n=8 (22 days) n=15 (33 days)	Critical (relevant) effect: Alterations in mitochondrial membrane composition and bioenergetics with decreased hepatic mitochondrial state 3 respiration and higher susceptibility to Ca2+ - induced transition pore opening. A decrease in hydroperoxide production by the respiratory chain, although a simultaneous decrease in vitamin E content.	Monteiro (2013) KCA 5.1.1/05
Non guideline study (no GLP) public literature Pigs *Myocardial changes in newborn piglets fed sow milk or milk replacer diets containing different levels of erucic acid were determined in this study.*	Canola oil (cv. Westar) and high erucic acid Rape (HEAR) oil (cv. S80514)	Significant correlation of the myocardial lipidosis scores to the content of erucic acid in the diet after 6, 9 and 12 days on the Rape oil diet. Increased myocardial lipidosis noticeable from 900 mg/kg bw/day and greatest in piglets fed in excess of 1100 mg erucic acid/kg bw/day for 4 to 9 days.	Kramer 1990 KCA 5.3.2/02
Non guideline study (no GLP) public literature Male Sprague-Dawley rats Effects of dietary saturated fat on erucic acid induced myocardial lipidosis in rats were determined in this study.	A Rape oil-based diet with different percentages of erucic acid 2 weeks	Critical (relevant) effect: Increase myocardial lipidosis with Oils with about 9% erucic acid.	Kramer 1990 KCA 5.3.1/01
Non guideline study (no GLP) public literature Male CF1 mice Effect of conjugated linoleic acid mixtures and different edible oils in body composition and lipid regulation in mice were determined in this study.	Diets containing olive, maize and Rape oils supplemented with an equimolecular mixture of CLA (mix-CLA) or a rumenic acid (RA)-rich oil for 30 days	Rape oil-fed animals increased the body weight gain. The higher body weight of R oil-mice was associated with a higher fat retention in carcasses, as well as in epididymal white adipose tissue (EWAT) pads. Rape oil prevented the hepatic steatosis observed with mix-CLA supplementation to olive and maize oils by increasing TG secretion.	Scalerandi 2014 KCA 5.1.1/07

Non guideline study (no GLP) public literature Weanling Male Sprague-Dawley strain rats *The effects of high erucic acid Rape oil on fatty acid oxidation in rat liver were determined.*	HEAR* (48% erucic acid) and LEAR* (1% erucic acid) 4 weeks	Critical (relevant) effect: Feeding HEAR led to an increase in the weight of liver and a decrease in hepatic oxidation of palmitic acids in rats.	Zhang et al. 1991 KCA 5.3.1/02
Non guideline study (no GLP) public literature 40 Albino rats (Sprague-Dawley strain) 5 groups of 8 rats *Biochemical and toxicological studies on the effect of high and low erucic acid Rape oil on rats.*	Diet of high erucic acid Rape oil or low erucic acid Rape oil or hydrogenated rapeoil or partially hydrogenated rapeoil	Critical (relevant) effect: Reduced body weight gain (HEAR), Increased serum triglycerides (LEAR).	Badawy et al. 1994 KCA 5.3.1/03
Non guideline study (no GLP) public literature Male and female Sprague-Dawley strain rats *The effects of the inclusion of 15 % of the newly available low erucic acid Rape oils in the diet of rats on body weight and the histological appearance of heart, liver and spleen tissues were determined.*	Oil of refined, edible quality 1. SBO Soybean oil 2. SPO Low erucic acid Rape oil 3. HSPO Commercially hydrogenated oil 4. ZEO Low erucic acid Rape oil 5. RSO High erucic acid Rape oil 10 weeks	Critical (relevant) effect: Focal lesions were found in cardiac tissue of the rats, but not in liver and spleen tissue. The incidence of lesions was similar on all ration treatments. A significantly ($P < 0.01$) higher incidence of cardiac lesions was found in male rats than in female rats.	Vogtmann et al. (1975) KCA 5.3.1/04

Non guideline study (no GLP) public literature 80 Male Wistar rats *The purpose of this feeding study was to compare the effects of feeding mustard oil (MUST), high erucic acid rape (HEAR) oil, low erucic acid rape (LEAR) oil and corn oil, with or without Selenium (Se) addenda.*	1. mustard oil (2. high erucic acid rape (HEAR 46% erucic acid), 3. low erucic acid rape (LEAR 1% erucic acid), 4.corn oil Half of each group received Selenium supplement 8 weeks	Critical (relevant) effect: Difference in serum cholesterol levels between LEAR oil fed animals compared to the HEAR oil fed animals. HEAR values are higher.	Watkins 1995 KCA 5.3.2/01
Non guideline study (no GLP) public literature 80 Pigs *In this study the performance of myocardial and blood seral changes in pigs fed diets containing high or low erucic acid Rape oils were determined.*	1.high erucic acid Rape (HEAR) oil, 2. low erucic acid Rape (LEAR) oil, 3. low erucic acid rape oil (Tower), 4. low erucic acid rape oil (1788), Groups of crossbred pigs (16/group, 8 females and 8 males)) diets containing 15% Rape oil comprising 0.3, 1.2, 4.9, or 34.2% erucic acid content, or a control diet 23 weeks.	Critical (relevant) effect: Pig carcass “fatness” (no significant effect of Rape oil on the incidence of cardiac lipidosis and myopathy). Serum cholesterol levels were significantly elevated in all animals that received oil in the diet, irrespective of the erucic acid concentration	Aherne et al. 1976 KCA 5.3.2/04
Non guideline study (no GLP) public literature Yorkshire piglets *In this study ultra structural changes in the liver parenchymal cells of Rape oil–fed animals were determined.*	Rape oil (Tower RO), Brassica napus, 0.4 % erucic acid (EA) content 8 weeks	Critical (relevant) effect: Liver dysfunction (hepatocytes from the animals fed tower RO were altered).	Cullen 1996 KCA 5.3.2/03

Non guideline study (no GLP) public literature Female SV 129 mice *The aim of this study was to determine whether increasing n-3 PUFA and reducing n-6 PUFA by using canola oil instead of corn oil in the maternal diet might reduce the risk for breast cancer in female offspring.*	two groups and placed on diets containing either 10% w/w corn oil (which is 50% n-6 PUFA, control diet) or 10% w/w canola oil (which is 20% n-6 PUFA, 10% n-3 PUFA, test diet)	No adverse effects. Beneficial effects observed as suppressed mammary gland tumorigenesis.	Ion et al. 2010 KCA 5.5/01
Non guideline study (no GLP) public literature Kunming mice *In this study, the effects of two cooking oils (pork oil and canola/Rape oil) on the pH and the cholic acid content in feces, in addition to colon tumorigenesis, were studied in mice.*	Rape seed/ Canola oil and pork oil	No adverse effects. Beneficial effects observed as the results showed that canola oil significantly decreased faecal pH in female mice ($P<0.05$), but had no influence on feces pH in male mice ($P>0.05$). Pork oil significantly increased the feces pH in both male and female mice ($P<0.05$). Canola oil significantly promote an increase in faecal pH. Deducting from the pH change it is inferred that increased bile excretion occurred in the pork oil group and thus changing the intestine environment for colon tumorigenesis.	He et al. 2015 KCA 5.5/02
Non guideline study (no GLP) public literature Kunming mice *In this study plasma lipid and glucose concentrations were investigated in Kunming mice.*	Rape seed/ Canola oil and pork oil	Consumption of the two cooking oils increased plasma total cholesterol level in both male and female mice, and pork oil showed stronger TC promotion effect than canola oil.	He et al. 2014 KCA 5.5/03
Non guideline study (no GLP) public literature 60 female athymic nu/nu mice (Harlan Sprague Dawley) *This study was designed to determine whether removing corn oil and substituting with canola oil in the diet would provide the cancer growth suppressive benefits linked to long chain omega 3 fatty acids.*	Corn oil and canola oil	No adverse effects. Beneficial effects observed as the mean (± SEM) tumor growth rate of the mice that consumed the com oil diet was 7.5 ± 0.8 mm3/day, whereas the mean tumor growth rate of mice that consumed the canola oil diet was 3.2 ± 0.4 mm3/day.	Hardman et al. KCA 5.5/05

Non guideline study (no GLP) public literature Male Fischer rats *The purpose of the study was to determine the chemopreventive effects of dietary canola oil rich in ω・3 fatty acids on azoxymethane-induced colon tumor development in rats and to compare the effects of a com oil diet rich in w-6 fatty acids on colon tumor development.*	Corn oil and canola oil	The canola oil group had a significantly ($P < 0.05$) decreased number of colon tumors	Bhatia et al. 2011 KCA 5.5/04
Non guideline study (no GLP) public literature 20 female rats *The effect of maternal (pregnancy plus lactation) dietary canola oil was investigated on the susceptibility of female Sprague-Dawley rat offspring to mammary carcinogenesis.*	Soybean oil and canola oil	No adverse effects. Beneficial effects observed for mammary carcinogenesis as the offspring of canola-fed dams showed significantly decreased tumor multiplicity (1.0 ± 0.3 vs. 1.9 ± 0.3, respectively; $P = 0.04$) and tumor volume (1232.5 ± 771.0 mm3 vs. $6,302.5 \pm 1,747.4$ mm3, respectively; $P = 0.01$), along with increased survival rate (87 % vs. 47%, respectively; $P = 0.01$).	Mabasa et al. 2013 KCA 5.5/06
Non guideline study (no GLP) Public literature Young Sprague-Dawley rats 260 animals in total, both sexes *Morphological effects of Rape oil in rats after long-term exposure (160 days) was investigated.*	1 Conventional Rape oil containing 40 to 50 % erucic acid 2 Arachis oil – Rape oil mixtures 3 Rape oil from the Canadian cultivar Oro (ORO-FRI-72-1 RKD) containing only 0.3 erucic acid	1 Growth retardation Myocardial lipidosis in predominantly male rats after 10 days on the diet Heart lesions after 40 days (small foci of histiocytes in-between muscles fibres and macrophages with lipid droplets 2 No specific effects found 3 No specific effects found	Engfeldt et al. 1975 KCA 5.5/07
Non guideline study (no GLP) Public literature Specific Pathogen Free (SPF) Wistar rats 220 rats of each sex *A combined chronic oral toxicity and carcinogenicity study with in-utero phase*	Hydrogenated fish oils, hydrogenated soybean oil and LEAR (refined Rape oil – low erucic acid Rape oil)	Various effects in LEAR diet group: higher total white cell count in males, ascribable to higher lymphocyte counts, and lower plasma triglyceride levels. No cardiac lipidosis.	Duthie et al. 1988 KCA 5.5/08

Non guideline study (no GLP) Public literature Male and female mice of Crj:CD-1 (ICR) strain. 30 male and 30 female mice. *Effects of lard, palm and Rape oil diets on the survival and fatty acid composition of liver and brain lipids were studied in male and female mice for 15 months.*	Palm oil (n-3 PUFA deficient) diet, lard diet, or Rape oil (n-3 PUFA sufficient) diet.	The results of fatty acid analyses seem to reveal that intensity of n-3 PUFA deficiency is ranking in the following order; the palm oil diet fed-male>the female mice>the lard diet fed-male and female mice>the Rape oil diet fed male and female mice. Group fed with a diet deficient in n-3 PUFA had a decrease in survival rate.	Suzuki et al., 1991 KCA 5.5/09
Non guideline study (no GLP) Public literature 60 male Sprague-Dawley rats Myocardial ultrastructure of rats fed high and low erucid acid rape oils	diets containing 20% (w/w) soybean oil, low erucic acid Rape oil, or high erucic acid Rape oil	Long-term feeding of high erucic acid Rape oil (30.9%) resulted in alteration of mitochondrial morphology, disorganization of myofibrils, and degeneration or necrosis of the cardiac muscle fiber. Low erucic acid Rape oil (0.9%) induced less severe cardiopathologic changes but the nature of the alterations was similar to that high levels of erucic acid	Yamashiro et al., 1980 KCA 5.5/10

** Low and High erucic acid Rape seed*

2.6.3.1.1 Short summary and overall relevance of the provided information on specific target organ toxicity – repeated exposure (short-term and long-term toxicity)

Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation.

The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). There is no indication for a short-term toxic potential. In a study performed by Kramer 1990/1992 a significant correlation of the myocardial lipidosis scores to the content of erucic acid in the Rape oil diet was found in rats/piglets. Less liver dysfunction (Zhang et al. 1991 ; Cullen 1996) was found with the low erucic rape oil compared to the high erucic rape oil.

As no erucic acid is found in the batch analysis < 1.25 mg/L (< LOD, 0.005 % w/w) the concentration of erucic acid will be very low in the TGAI (LOQ of the method is 12.5 mg/L (0.05% w/w)) and as a consequence the effects related to liver dysfunction and myocardial lipidosis won't be relevant for this application. Therefore, no further details are summarized in this paragraph.

2.6.3.1.2 Comparison with the CLP criteria regarding STOT RE (specific target organ toxicity-repeated exposure)

The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents.

Considering the low amount of erucic acid in the TGAI the adverse effects observed with high erucic acid rape are not relevant for the active substance.

STOT-RE is assigned on the basis of a substance demonstrating evidence of significant (Category 1) or severe (Category 2) toxicity, generally at or below the oral guidance value of 100 mg/kg bw/d (for a classification in category 2) obtained in a 90-day rat study. The oral guidance value for a classification in category 1 is ≤ 10 mg/kg bw/d from a 90-day study. The equivalent guidance values for a 28-day study are ≤ 300 mg/kg bw/d and ≤ 30 mg/kg bw/d, respectively; for a one-year study, they are ≤ 25 mg/kg bw/d and 2.5 mg/kg bw/d, respectively. 'Significant' toxicity is taken to mean changes that clearly indicate functional disturbance or morphological changes that are toxicologically relevant. 'Severe' toxicity is considered to be more profound or serious and indicates changes that are of a considerably adverse nature with a significant impact on health.

Rape oil thus does not meet the criteria for classification for STOT RE cat 1 or 2 because the repeated dose toxicity studies did not show effects.

2.6.3.1.3 Conclusion on classification and labelling for STOT RE (specific target organ toxicity-repeated exposure)

No specific target organ toxicity after repeated exposure. No classification proposed.

2.6.4 Summary of genotoxicity / germ cell mutagenicity [equivalent to section 10.8 of the CLH report template]

Table 26: Summary table of genotoxicity/germ cell mutagenicity tests *in vitro*

Method, guideline, deviations[1] if any	**Test substance**	**Relevant information about the study including rationale for dose selection (as applicable)**	**Observations /Results**	**Reference**
Non-Guideline public literature Ames test	Rape oil I group exposed to oil cooking fume, volatilized in gas fuel II gas fuel control group III control group, exposed to room air IV positive control group	Salmonella typhimurium TA98 and TA100 Doses ranging from 1.0 to 10.0 mg/plate	Revertants induced by cooking oil fume A, B, C, D are the samples from each household. TA98: -S9: positive A +S9: positive A+ B + C (cytotoxicity at 10 mg/plate) TA100: -S9: negative +S9: positive A+ IB (only highest concentrations)	Chen H, (1992) KCA 5.4.1/03
Non-Guideline public literature sister chromatid exchange (SCE)	Rape oil I group exposed to oil cooking fume, volatilized in gas fuel II gas fuel control group III control group, exposed to room air IV positive control group	V79 cells Doses ranging from 0.05 to 0.5 mg.ml-1	-S9: positive +S9: positive All samples induced SCE in a dose-dependent manner (including control groups) in V79 cells in the range of 0.05-0.25 mg/ml with or without S9 mix. Doses more than 0.25 mg/ml of the samples were cytotoxic as observed by reduced yield of	Chen H, (1992) KCA 5.4.1/03

Method, guideline, deviations[1] if any	**Test substance**	**Relevant information about the study including rationale for dose selection (as applicable)**	**Observations /Results**	**Reference**
			second division metaphase and SCEs in V79 cells.	
Non-Guideline public literature Testing in vitro on fibroblast cells	Rape oil (oleic acid was the most abundant species) and lin rich in α-linolenic acid (ALA) Fibroblasts were treated for 24 h with 0.1% oils.	Mouse embryo fibroblasts (NIH3T3, ATCC, Manassas, VA, USA)	Fatty acids were taken up by the cells and promoted cell proliferation. No oxidative stress-mediated cytotoxic or genotoxic effects were observed after oil stimulation. ALA-rich LO exhibited the most potent wound healing activity, ALA may be considered a candidate for promoting the observed effect.	Lewinska A., (2015) KCA 5.4.1/01
OECD 471 AMEStest	Oil of H. annuus L. (sunflower) seeds (	Bacterial strains of S. typhimurium TA97a, TA98, TA100, TA102 and TA1535	Dose dependent cytotoxicity is observed (no dose dependent mutagenicity)	KCA 5.4.1 /02

Table 27: Summary table of genotoxicity/mutagenicity tests in mammalian somatic or germ cells *in vivo*

Method, guideline, deviations[1] if any	**Test substance**	**Relevant information about the study (as applicable)**	**Observations/Results**	**Reference**
Non-Guideline public literature	Rape oil I group exposed to oil	Inhalation exposure 4 groups of mice were	Frequency of mice bone marrow MN-PCE was increased and it showed a remarkable time-dose-response relationship	Chen H, .(1992) KCA 5.4.1/03

Method, guideline, deviations[1] if any	Test substance	Relevant information about the study (as applicable)	Observations/Results	Reference
	cooking fume, volatilized in gas fuel II gas fuel control group III control group, exposed to room air IV positive control group	exposed directly to fresh oil cooking fume, 3 h/day, 6 days/week, 4 weeks in total. 6 animals were sacrificed every week	during the 4 weeks exposure. The increase was statistically significantly different from the control groups.	

2.6.4.1 Short summary and overall relevance of the provided information on genotoxicity / germ cell mutagenicity

Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation.
Marzin (1999) carried out an Ames test in accordance with OECD Guideline 471 with five strains of Salmonella enterica var. Typhimurium. Up to 5000 microgram/plate showed no mutagenic activity with and without metabolic activation.
The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents and there is no indication for a genotoxic potential.
Only the cooking fume of Rape oil contained mutagenic activity in Ames test, the sister chromatid exchange (SCE) frequencies of V79 cell and mouse micronucleus assay. However, this is considered not relevant for the use of Rape oil as plant protection product as the Rape oil will not be cooked before using as a plant protection product.

According to the applicant repeated heating of edible oils can generate a number of compounds, including polycyclic aromatic hydrocarbons (PAH) and aldehydes which have been reported to have carcinogenic potential. The nature of the gas fuel can be indicated as volatiles from burned gas fuel but no cooking oil fume. The compounds formed by cooking oil are generated only during certain heating processes so possible genotoxic potential is not relevant if using the PPP under the given conditions. The product “grill flavour concentrate”, derived from heat-treated canola oil is very far away from the exposure from rape oil as plant protection product, even very far away from rapes oil as such. However, the applicant did not provide an overview of the constituents in Grill flavour concentrate (vegetable) derived from rape oil (obtained from Brassica napus, low in erucic acid (< 2%) subjected to a heating process and subsequent distillation steps) compared to the rape oil mixture to be used in PPPs. “The flavouring is intended to be used in meats and meat products, sauces and similar products (ketchups, BBQ sauces), processed cheese and cream cheese, as well as snacks.”

After RMS checking the ingredients of the Grill flavour concentrate (vegetable) a lot of different ingredients were found compared to rape oil used as PPP. Therefore, the BMDL05 value of 12.8 mg/kg bw/day for rape oil (low in erucic acid < 2%) subjected to a heating process and subsequent distillation steps cannot be used in the risk assessment. Although the BMDL05 value is not a value that should be used for rape oil as a PPP the total information presented in the Scientific Opinion on Flavouring Group Evaluation 501 (FGE.501): Grill flavour concentrate (vegetable) supported the knowledge that no genotoxic or carcinogenic properties of the Grill flavour concentrate (vegetable) are present. A high BMDL05 has been be derived.
In addition, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) found in their scientific opinion that fatty acids (E 570) used as a food additive did not raise a concern for genotoxicity. The Panel concluded that the food additive fatty acids (E 570) was of no safety concern at the reported uses and use levels.

During the Pesticide Peer Review TC64 (15-19 November 2021) all available information on rape oil including its nature (food grade quality) and EFSA's assessment on similar substances was taken into account by the experts for the weight of evidence approach on genotoxicity. All the experts agreed with the RMS that rape oil is unlikely to be genotoxic. The experts also agreed that if the EFSA Panel on Food Additives and Flavourings (FAF) assessment on some components of grill flavour concentrate (vegetable), common to some components of rape oil, is finalised and raised concerns for genotoxicity, the relevance of these findings for rape oil as a PPP should be further considered.

2.6.4.2 Comparison with the CLP criteria regarding genotoxicity / germ cell mutagenicity

For potential classification as a germ cell mutagen, criteria from the CLP Regulation were considered:
Comparison with Category 1 criteria

- *The classification in Category 1A is based on positive evidence from human epidemiological studies*

Rape oil thus does not meet the criteria for classification for germ cell mutagen Category 1A because there are no epidemiological data to support classification of rape oil in Category 1A.

- *The classification in Category 1B is based on positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals*

No *in vivo* studies with heritable germ cell are available for rape oil.

- *Classification in Category 1B can also be based on "positive result(s) from in vivo somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. It is possible to derive this supporting evidence from mutagenicity/genotoxicity tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells".*

Rape oil thus does not meet the criteria for classification for germ cell mutagen Category 1B because there is no relevant data from *in vivo* experiments in mammals, only from *in vitro* experiments (Chen et al. 1992).

Comparison with Category 2 criteria

- *Classification in category 2 is based on:*

  — positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:

  — somatic cell mutagenicity tests in vivo, in mammals; or

  — other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays.

Rape oil thus does not meet the criteria for classification for germ cell mutagen Category 2 because there is no relevant data from *in vivo* experiments in mammals, only from *in vitro* experiments (Chen et al. 1992). This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth. The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 200lz1). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents. Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage.

2.6.4.3 Conclusion on classification and labelling for genotoxicity / germ cell mutagenicity

No classification proposed based on a lack of (positive) data.

2.6.5 Summary of long-term toxicity and carcinogenicity [equivalent to section 10.9 of the CLH report template]

Data on animal carcinogenicity studies are summarized in Table 25.

2.6.5.1 Short summary and overall relevance of the provided information on long-term toxicity and carcinogenicity

Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituens or degraded via β -oxidation.

The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). Therefore, long term toxicity and carcinogenicity studies deemed not necessary. There is no indication for a long-term or carcinogenic effect. This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth (Ion et al. 2010; He et al. 2015; Hardman et al 2007; Bhatia et al. 2011; Mabasa et al. 2013). Furthermore, the beneficial effects of low erucic rape oil versus high erucic rape oil was observed considering the less severe cardiopathologic changes (Yamashiro et al. 1980). As no erucic acid is found in the batch analysis < 1.25 mg/L (< LOD, 0.005 % w/w) the concentration of erucic acid will be very low in the TGAI (LOQ of the method is 12.5 mg/L (0.05% w/w)) and as a consequence the effects related to cardiopathology won't be relevant for this application. Therefore, no further details are summarized in this paragraph.

2.6.5.2 Comparison with the CLP criteria regarding carcinogenicity

The criteria for classification as a carcinogen under Regulation 1272/2008 are as followed:

Category 1: Known or presumed human carcinogen.

A substance is classified in Category 1 for carcinogenicity on the basis of epidemiological and/or animal data. A substance may be further distinguished as:

Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or

Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animals evidence.

Category 2: Suspected human carcinogens

The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animals studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B.

Rape oil thus does not meet the criteria for classification for carcinogenicity because there is no indication for a long-term or carcinogenic effect. Rape oil did not lead to any treatment related neoplastic finding. However no relevant carcinogenicity studies are available.

The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents. Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage.

Table 28: Compilation of factors to be taken into consideration in the hazard assessment

Species and strain	Tumour type and background incidence	Multi-site responses	Progression of lesions to malignancy	Reduced tumour latency	Responses in single or both sexes	Confounding effect by excessive toxicity?	Route of exposure	MoA and relevance to humans
	None							

2.6.5.3 Conclusion on classification and labelling for carcinogenicity

In the absence of relevant carcinogenicity data, classification is not proposed.

2.6.6 Summary of reproductive toxicity [equivalent to section 10.10 of the CLH report template]

2.6.6.1 Adverse effects on sexual function and fertility – generational studies [equivalent to section 10.10.1 of the CLH report template]

2.6.6.1.1 Short summary and overall relevance of the provided information on adverse effects on sexual function and fertility – generational studies

Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage. Accordingly, reproduction toxicity tests with Rape oils are not deemed necessary. There is no indication for a reprotoxic effect. This is confirmed by results of open literature data showing that the female fertility index, the number and the weight of fetuses were not affected after rape oil administration in rats and hamsters (Reyes et al. 1995) (see table 29). In addition, fetuses were macroscopically considered as normal. No further details are summarized in this paragraph.

2.6.6.1.2 Comparison with the CLP criteria regarding adverse effects on sexual function and fertility

The criteria for classification as reproductive toxicant under Regulation 1272/2008 is as follows:

Category 1: Known or presumed human reproductive toxicant

Substances are classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility, or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of

whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 2: Suspected human reproductive toxicant

Substances are classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, and where the evidence is not sufficiently convincing to place the substance in Category 1. If deficiencies in the study make the quality of evidence less convincing, Category 2 could be the more appropriate classification.
Such effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects.

Rape oil thus does not meet the criteria for classification for reproductive toxicant because no evidence has been found for adverse effects on sexual function and fertility. This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth. The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 200l). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents. Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage.

2.6.6.2 Adverse effects on development [equivalent to section 10.10.4 of the CLH report template]

2.6.6.2.1 Short summary and overall relevance of the provided information on adverse effects on development

Table 29: Summary table of animal studies on adverse effects on development

Method, guideline, deviations if any, species, strain, sex, no/group	**Test substance, dose levels duration of exposure**	**Results - NOAEL/LOAEL (for sexual function and fertility, parents) - target tissue/organ - critical effects at the LOAEL**	**Reference**
Non-Guideline (no GLP) public literature	Rape oil containing a high concentration of erucic acid or corn oil.	No adverse effects	Reyes et al. 1995 KCA 5.6.1/02

Method, guideline, deviations if any, species, strain, sex, no/group	Test substance, dose levels duration of exposure	Results - NOAEL/LOAEL (for sexual function and fertility, parents) - target tissue/organ - critical effects at the LOAEL	Reference
Rat and hamsters Rats and hamsters were studied on the last day of pregnancy and compared with age-and diet-matched nonpregnant animals.			

Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage. Accordingly, developmental toxicity tests with Rape oils are not deemed necessary. There is no indication for a developmental effect. This is confirmed by results of open literature data showing that fetuses were not affected and were macroscopically considered as normal after rape oil administration in rats and hamsters (Reyes et al. 1995). No further details are summarized in this paragraph.

2.6.6.2.2 Comparison with the CLP criteria regarding adverse effects on development

The criteria for classification as reproductive toxicant under Regulation 1272/2008 is as follows:

Category 1: Known or presumed human reproductive toxicant

Substances are classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility, or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 2: Suspected human reproductive toxicant

Substances are classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, and where the evidence is not sufficiently convincing to place the substance in Category 1. If deficiencies in the study make the quality of evidence less convincing, Category 2 could be the more appropriate classification.

Such effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects.

Rape oil thus does not meet the criteria for classification for reproductive toxicant because no evidence has been found for adverse effects on development. This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth. The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 200l). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents. Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage.

2.6.6.3 Adverse effects on or via lactation [equivalent to section 10.10.7 of the CLH report template]

2.6.6.3.1 Short summary and overall relevance of the provided information on effects on or via lactation

Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage. Accordingly, adverse effects on or via lactation with Rape oils has not been found. No further details are summarized in this paragraph.

2.6.6.3.2 Comparison with the CLP criteria regarding effects on or via lactation

The criteria for classification as reproductive toxicant under Regulation 1272/2008 is as follows:

EFFECTS ON OR VIA LACTATION
Effects on or via lactation are allocated to a separate single category. It is recognised that for many substances there is no information on the potential to cause adverse effects on the offspring via lactation. However, substances which are absorbed by women and have been shown to interfere with lactation, or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified and labelled to indicate this property hazardous to breastfed babies. This classification can be assigned on the:
(a) human evidence indicating a hazard to babies during the lactation period; and/or
(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or
(c) absorption, metabolism, distribution and excretion studies that indicate the likelihood that the substance is present in potentially toxic levels in breast milk.

Rape oil thus does not meet the criteria for classification for reproductive toxicant because no evidence has been found for adverse effects on or via lactation. This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth. The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 200l). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents. Fat, oils and fatty acids are essential components of our daily food. Fatty acids – including unsaturated fatty acids – can be metabolized or used for energy storage.

2.6.6.4 Conclusion on classification and labelling for reproductive toxicity

No reproductive toxicity. No classification proposed.

2.6.7 Summary of neurotoxicity

Rape oil thus does not meet the criteria for classification for neurotoxicity because the mode of action of Rape oil as a plant protection product does not target the nervous system. No open literature on Rape oil and fatty acids dealing with neurotoxicity within the last ten years before the date of submission of this dossier has been found. This is confirmed by results of open literature data showing the beneficial effects of rape oil as suppression of tumor growth. The quality of Rape oil is accepted as food according to Codex Alimentarius (FAO-WHO 2001). Rape oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents.

2.6.8 Summary of other toxicological studies

2.6.8.1 Toxicity studies of metabolites and impurities

Rape oil is, like all vegetable oils, metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are an integral part of mammalian metabolism (incorporated as normal body constituents or degraded via β-oxidation). No toxicity tests deemed necessary on glycerol or fatty acids.
No open literature on Rape oil and fatty acids dealing with increased hazard to human health within the last ten years before the date of submission of this dossier has been found.

2.6.8.2 Supplementary studies on the active substance

Open literature data showed several other beneficial effects of canola oil/Rape oil. A preventive effect of Brassica napus L. oil/canola oil/Rape oil was found on pathophysiological changes of respiratory system in experimental asthmatic rat suggesting that B. napus could be useful as adjuvant therapy in rat model of asthma. This effect was

probably related to its anti-inflammatory and antioxidants components. The effects of oil mimetics in ratios found in two common cooking oils (canola and corn) were explored on Jurkat T leukemia cells. At high concentrations (100 and 150 µM) both types of oils induced apoptosis. At a non-toxic dose (75 µM) the different oil mimetics displayed differences in their action on pro-inflammatory molecules with canola oil being anti-inflammatory whereas corn oil was pro- inflammatory.

2.6.8.3 Endocrine disrupting properties

Please refer to point 2.14 ED Assessment for other Non-target vertebrates.

2.6.9 Summary of medical data and information

No clinically relevant health problems associated with Rape oil have been observed.

2.6.10 Toxicological end points for risk assessment (reference values)

2.6.10.1 Toxicological end point for assessment of risk following long-term dietary exposure – ADI (acceptable daily intake)

Rape oil is a dietary vegetable oil derived from seeds of *Brassica napus.* Fats and oils nor fatty acids do pose any health problem, and no Acceptable Daily Intake (ADI) has been set for any of the fatty acids, including Stearic, Palmitic, Oleic and Linoleic acids, or oils and fats. Rape oil is, like all vegetable oils, metabolized by hydrolysis of glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β-oxidation. No ADI has been set.

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) set a tolerable daily intake (TDI) of 7 mg/kg body weight (bw) per day for erucic acid a scientific opinion on the risks for animal and human health related to the presence of erucic acid in feed and food (https://doi.org/10.2903/j.efsa.2016.4593). As no erucic acid is found in the batch analysis < 1.25 mg/L (< LOD, 0.005 % w/w) the concentration of erucic acid will be very low in the TGAI (LOQ of the method is 12.5 mg/L (0.05% w/w)). Due to the low concentration in the TGAI and an TDI of 7 mg/ kg bw/day no risk will be expected for the operator, worker, bystanders and residents.

2.6.10.2 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

Rape oil is a dietary vegetable oil derived from seeds of *Brassica napus.* Fats and oils nor fatty acids do pose any health problem, and no Acceptable Daily Intake (ADI) has been set for any of the fatty acids, including Stearic, Palmitic, Oleic and Linoleic acids, or oils and fats. Rape oil is, like all vegetable oils, metabolized by hydrolysis of glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β-oxidation. No ARfD has been set.

2.6.10.3 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL (acceptable operator exposure level)

Rape oil is assumed to be of very low toxicity and its content in NEU 1160 I does not warrant operator exposure estimations. No AOEL has been set.

2.6.10.4 Toxicological end point for assessment of occupational, bystander and residents risks – AAOEL (acute acceptable operator exposure level)

Rape oil is assumed to be of very low toxicity and its content in NEU 1160 I does not warrant operator exposure estimations. No AAOEL has been set.

2.6.11 Summary of product exposure and risk assessment

Rape oil is assumed to be of very low toxicity and its content in NEU 1160 I does not warrant operator exposure estimations. No (A)AOEL is set.

2.7 RESIDUE

Rape oil is naturally occurring oil of food grade quality derived from seeds of rape (*Brassica napus*). It is a mixture of esters (triglycerides) of different fatty acids. The main fatty acids in rape oil are: oleic acid ($C_{18:1}$), linoleic acid ($C_{18:2}$) and linolenic acid ($C_{18:3}$). Fatty acids are an integral part of the cell membranes of every living organism. They also occur as food substrate in the form of their triglycerides, i.e. fats and oils. Linoleic and linolenic acid are essential fatty acids in humans.
As a plant protection product rape oil is used as a contact insecticide/acaricide against spider mites.
Since rape oil is rapidly degraded or converted into other compounds by the crop plant and in animal tissues, it is expected that residues cannot be distinguished from endogenous plant compounds at harvest after application of rape oil as plant protection product. Since rape oil is a natural product and toxicological values are not considered necessary (see Volume 1, 2.6.10.1, 2.6.10.2), a consumer risk assessment is considered not relevant.

2.7.1 Summary of storage stability of residues

Rape oil is a food grade commodity and fatty acids are naturally present in plants and animals. No residue trials have been performed, therefore, no storage stability study is required.

2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

Plants

No specific metabolism studies with rape oil in plants were performed. Literature about the metabolism of triglycerides and fatty acids in plants was submitted. The C_{18} fatty acids, which are the major fatty acids in rape oils

are commonly found in many plant seeds and plant tissues. It is known that plants will either degrade the components of rape oil to provide energy for other metabolism processes, or they will use the fatty acids to synthesize phospholipids, other fatty acids or lipids depots. Degradation of triacylglycerol starts with the removal of the fatty acids residues from glycerol by hydrolysis by acyl hydrolases. Fatty acids are further incorporated or metabolised in plant tissues by various oxidative pathways (for example α-oxidation, β-oxidation). The enzymatic pathway of α-oxidation proceeds with free fatty acids. Thus it can play an important part in the further degradation of free fatty acids released from glycerolipids by acyl hydrolases or exogenously applied fatty acids. β-Oxidation is the principal mechanism for the degradation of the fatty acids into CO_2 and water in plants and animals. It is associated with the mitochondria and the main respiration functions of living cells. β-oxidation of fatty acids is presented in Figure 2.7.2-1.

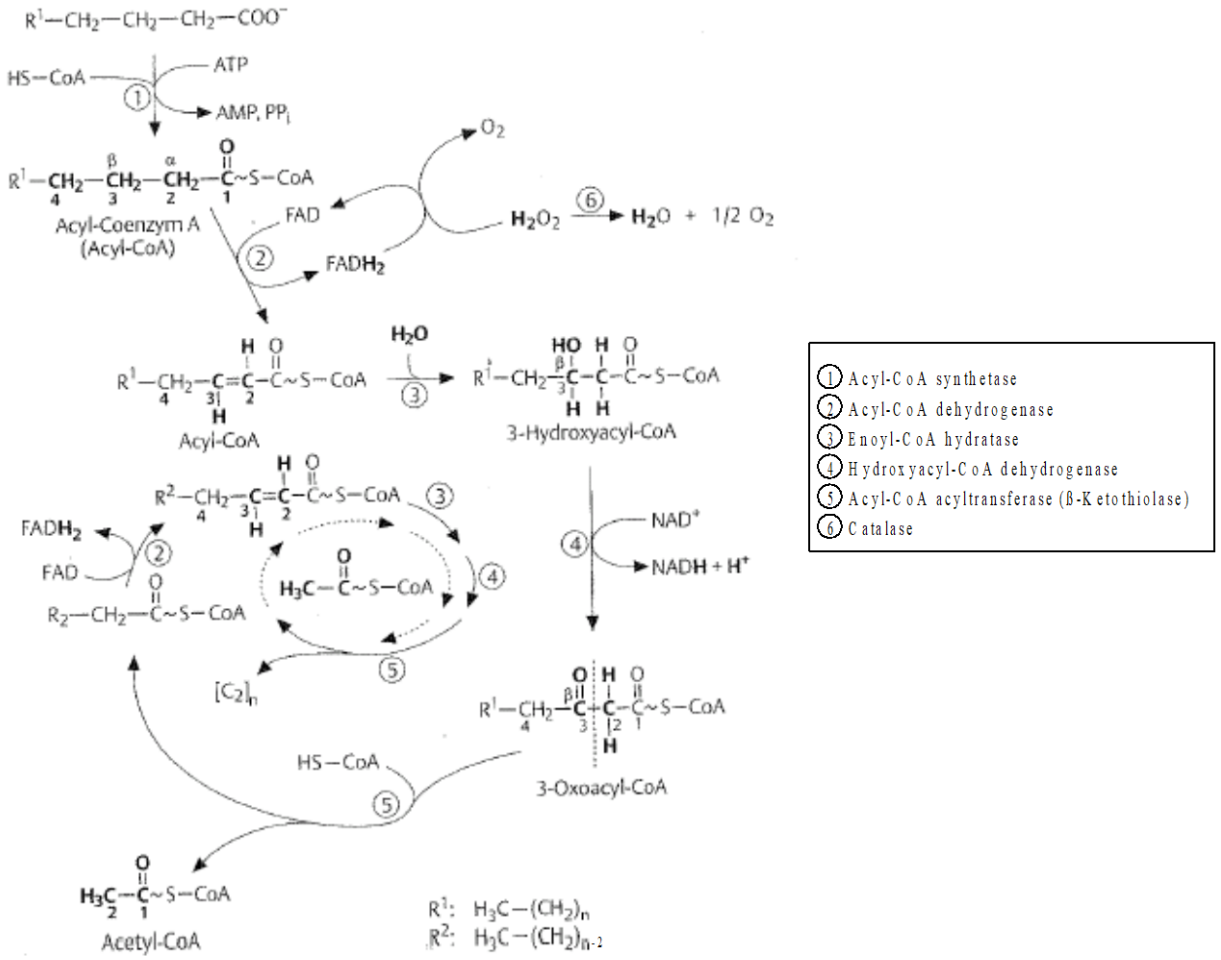

Figure 2.7.2-1: β-oxidation of fatty acids

Besides degradation fatty acids are also interconverted during biosynthesis. Synthesis takes place in the cytosol up to a chain length of C_{16}. The overall reaction in this fatty acid synthetase system involves the acyl carrier proteins acetyl ACP and malonyl ACP. Fatty acids longer than C_{16} can be formed through the action of fatty acid elongation systems which occur in the endoplasmic reticulum and the mitochondria. Double bonds can be introduced into the molecules by oxidative reactions catalyzed by fatty acid-CoA. Further transformations can occur by ω-oxidation and in-chain hydroxylation to form the complex polymers of cutin or suberin. Reaction can also lead to the triacylglycerols and phospholipids of the membranes. In the figure 2.7.2-2 biosynthesis of fatty acids is presented.

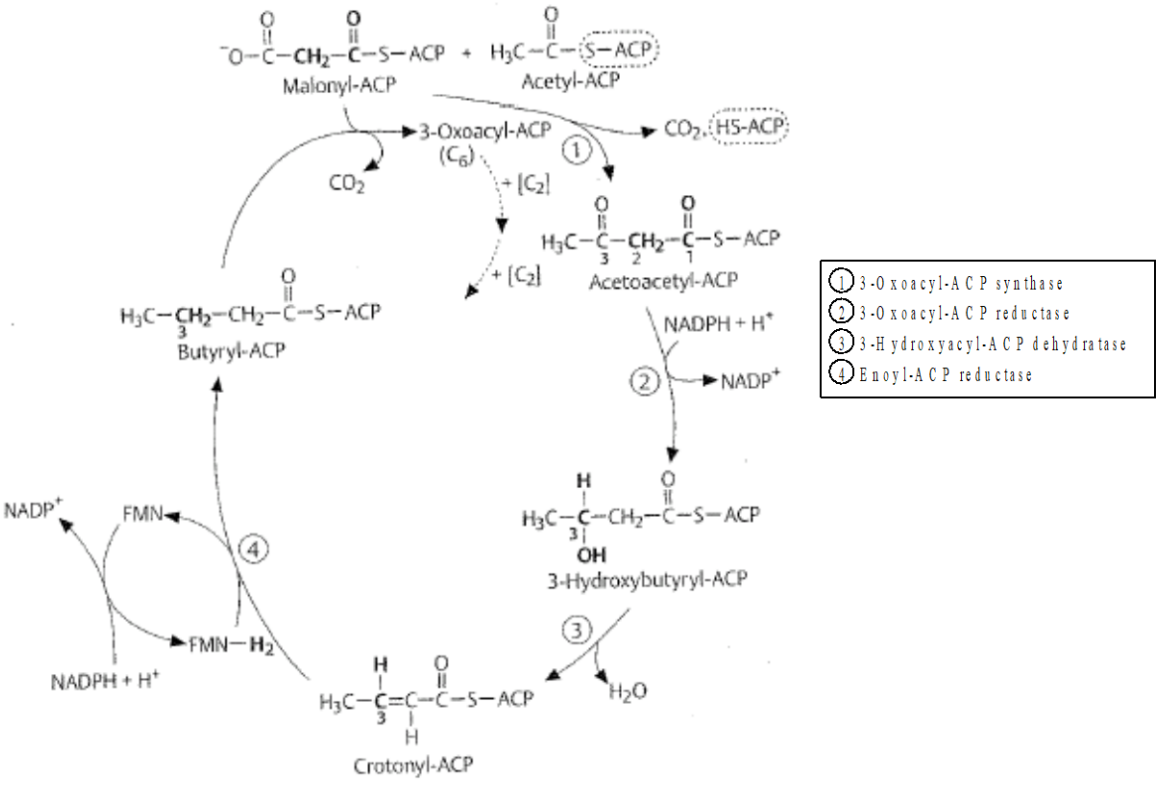

Figure 2.7.2-2: Biosynthesis of fatty acids

Fatty acids are absorbed by the leaf where they are used in the normal metabolic processes of the plant. Bacteria that inhabit the leaf surface will interact with the exogenous fatty acid substrate and begin to utilise it as a nutrient source using the pathways described above. Ionized fatty acid and non-dissociated fatty acid molecules will penetrate through the lipophilic layer of the cuticle and enter the cytoplasm of the cells (Rivera and Penner 1979), KCA 6.2.1/04. Once inside the cells, the lipids will be metabolized similar to the endogenous fatty acids and either broken down for energy or used to synthesize the more complex triacylglycerols or phospholipids.

Livestock

No specific metabolism studies with rape oil were performed in livestock, nor are these studies required, since the fatty acids comprised in rape oil occur naturally in animal tissues and their degradation pathway is well known. Recent open peer reviewed literature on the metabolism of fats in animals (ruminants and pigs) was submitted as supplementary information (Volume 3, B.7.2.3, B.7.2.4).

The first step in ingestion of fats by animals is to break the compounds into molecules small enough to pass the cell membranes of the tissues lining the gastrointestinal tract. About 40-50% of the ingested fat is reduced to fatty acids and glycerol and a similar portion is reduced to monoacylglycerols with short chain fatty acids. The rest is absorbed as di- and triacylglycerols. A more detailed pathway of degradation and use of fatty acids in animal tissues is described in Volume 3, B.7.2.

2.7.3 Definition of the residue

No residue definition is required, and rape oil is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

2.7.4 Summary of residue trials in plants and identification of critical GAP

Rape oil is naturally occurring oil. It is a mixture of esters (triglycerides) of different fatty acids. The main fatty acids in rape oil are: oleic acid ($C_{18:1}$), linoleic acid ($C_{18:2}$) and linolenic acid ($C_{18:3}$). Fatty acids included in rape oil are degraded or converted into other compounds by the crop plants. It is expected that the residues from applied rape oil cannot be distinguished from endogenous plant compounds at harvest. Moreover, fatty acids are part of plants and animal tissues, and are part of food and feed. Residue trials are therefore considered not required.

2.7.5 Summary of feeding studies in poultry, ruminants, pigs and fish

The fatty acids comprised in rape oil are part of plants and animal tissues, and are part of food and animal feed, and their metabolism is well known. Livestock feeding studies are considered not required. Recent open peer reviewed literature on feeding of fats in animals was submitted as supplementary information (Volume 3, B.7.4).

2.7.6 Summary of effects of processing

Rape oil is rapidly degraded or converted into other compounds by the crop plant. It is expected that residues cannot be distinguished from endogenous plant compounds at harvest. Furthermore, rape oil is also used as a food commodity and the degradation pathways are well known. Therefore, additional studies on the nature or magnitude of residues in processed commodities are considered not required.

2.7.7 Summary of residues in rotational crops

Rape oil will be degraded rapidly by soil micro-organisms and the fatty acids contained in rape oil occur naturally in the soil, resulting from degradation of organic substances or formed by micro-organisms. It is therefore not expected that rape oil will have any adverse effects on succeeding crops. Therefore, additional studies with rotational crops are considered not required.

2.7.8 Summary of other studies

No other data available or submitted, not required.

2.7.9 Estimation of the potential and actual exposure through diet and other sources

Rape oil is a food commodity and fatty acids are naturally present in the plants. Additionally, toxicological reference values (ADI, ARfD) are considered not necessary. No MRLs are proposed. Therefore, a quantitative consumer risk assessment is considered as not required and rape oil can be considered as a candidate for Annex IV of Regulation (EC) No 396/2005.

Rape oil is a food item, which may contain erucic acid (being a natural plant toxin). The maximum levels for erucic acid are regulated by Reg. (EU) No 2019/1870. Importantly, during the peer review, it has been concluded that erucic acid is no longer included in the amended reference specification for rape oil. No further residue data are deemed necessary, nor are they available for erucic acid. Furthermore, recital 5 of Reg. (EU) No 2019/1870 states that *"Given that the maximum level for vegetable oils and fats applies also to vegetable oils used as ingredient in food, there is no need to establish a maximum level for erucic acid in foods containing added vegetable oils and fats."*. Since risk managers considered the use of rape oil with a max. 2% content of erucic acid to sufficiently ensure safety of consumers, without the need to set specific levels for food items, this reasoning could also be applied to rape oil used as an active substance in plant protection products. Notwithstanding that, still it has been requested to conduct an indicative consumer risk assessment for erucic acid. An EFSA publication is available from the Contamination Panel in which the risk to erucic acid present in food and feed has been evaluated (EFSA Journal 2016;14(11):4593). The pesticide use of rape oil has not been explicitly considered in this publication. In addition, erucic acid was generally not reported to be present in most crop occurrence data in that publication.

Since no residue data are available for erucic acid, several worst-case assumptions are required to conduct an indicative consumer risk assessment. As a very worst-case, the max. total application rate needs to be taken into consideration, together with the maximum worst-case regulated level of 2% erucic acid in rape oil. However, using the maximum level of 2% (which is no longer set out in the specification) would lead to unrealistically high estimations of exposure to erucic acid. The 5 batch analysis did not even show any erucic acid (for food grade rape oil, LEAR is used: Low Erucic Acid Rape seed); the levels were below the LOD of 0.005% w/w. Therefore, in our calculations, we consider it more appropriate to use a level of erucic acid at the LOQ of 0.05% w/w, which still is a worst-case level since no erucic acid was observed in the tested batches (and erucic acid is no longer indicated as an relevant impurity, and as such no longer included in the specification of rape oil). In addition, also the max. total application rate can be considered unrealistically worst-case, since by using this max. rate no decline of residues between applications, and at harvest is anticipated. On the contrary, rapid degradation of erucic acid is expected.
For the indicative calculations, FAOSTAT data on the yield of diverse crops is being used. The yield of a crop can differ a lot between countries. Since these calculations concern chronic consumer intake calculations, it is considered most appropriate to take the average yield from all European countries, and not as another worst-case to take the lowest

yield from a specific European country.

Pome fruit: max. total application rate is 79.47 kg/ha.

Apple:

When considering the average yield of approximately 19,200 kg/ha (FAOSTAT, 2019), 79.47 kg of rape oil is applied on 19,200 kg apples, which is similar to 4,1 g rape oil/kg apple, and 2.1 mg erucic acid/kg apples.

Pear:

An average yield of approximately 17,000 kg/ha, leads to 2.3 mg erucic acid/kg pears.

Berry bushes: max. total application rate is 55.89 kg/ha.

It is considered that this use includes all fruits from the 'other small fruits and berries', such as currants, gooseberry, blueberry and cranberry. As a worst-case, currants are being used for the intake calculations, since their consumption is among the highest in PRIMo 3.1 compared to all other berries from this group.

Currants:

Based on an average yield of approximately 4,400 kg/ha, 6.4 mg erucic acid/kg currants can be calculated.

Since the calculated worst-case exposure for currants contributes for maximally 0.03% to the TDI (see below for further information on the consumer exposure calculations), the other berries are not taken further into account as their contribution is expected to be even lower.

Vegetables: max. total application rate is 61.19 kg/ha.

Since tomatoes are among the vegetables with clearly the highest consumption according to PRIMo 3.1 (excluding potatoes; root and tuber crops are considered separately below), they are considered for the current indicative exposure calculations.

Tomatoes:

Based on an average yield of approximately 156,000 kg/ha, 0.2 mg erucic acid/kg tomatoes can be calculated.

Since the calculated worst-case exposure for tomatoes contributes for maximally 0.01% of the TDI (GEMS/food, see below for further information on the consumer exposure calculations), the other vegetables are not further considered in detail as their contribution is expected to be even lower (i.e. for vegetables which are consumed in much smaller quantities), or in a similar range (e.g. spinach has been checked, and its contribution would be maximally 0.024% of the TDI for NL toddler; watermelons have been checked, leading to max. 0.016% of the TDI for GEMS/food; dry beans have been checked, which would lead to max. 0.16% of the TDI for UK toddlers).

Furthermore, vegetables growing in soil (e.g. root and tuber vegetables such as potatoes) are not further considered for their possible consumer exposure to erucic acid, since erucic acid degrades rapidly in soil, and therefore, residues can be expected to be negligible.

In addition, possible exposure of erucic acid to livestock when treated crops are being used as feed is considered not relevant. Rape meal is an important feed item for livestock. Therefore, the direct erucic acid exposure via rape meal is considered to cover the possible indirect exposure via feed crops treated with rape oil.

A tolerable daily intake (TDI) of 7 mg/kg bw/day for erucic acid was established in the scientific opinion from the

EFSA Contam Panel (EFSA Journal 2016;14(11):4593). When this value of 7 mg/kg bw/day is taken as the ADI in PRIMo 3.1, and the worst-case estimated levels of erucic acid for apples, pears, currants and tomatoes are inserted as input values, then the calculated exposure would be 0.50% of the TDI. When, for example, spinach is added, the calculated exposure would increase to 0.52% of the TDI, showing that including additional input for other vegetables will only have a very small effect on the percentage of the TDI. Based on the exposure calculations for these rather highly consumed crops, in combination with still very worst-case assumptions (in particular the assumption that all erucic acid has accumulated on the crops and nothing has degraded, and the assumption that all consumed crops have been treated with rape oil), the additional exposure to erucic acid due to its pesticide use is considered negligible. Consequently, the additional uses from the MRL-review are expected to only have a marginal effect on the calculated exposure, expressed as percentage of the TDI.
In conclusion, these indicative worst-case calculations show that the exposure to erucic acid due to the use of rape oil as active substance in plant protection products can be considered negligible.

More information was requested on the qualitative composition/alteration of rape oil once applied to the plant. However, the composition of rape oil is well known, and no alteration is expected when used as a plant protection product. Oxidation is the major metabolic pathway for fatty acids (β-oxidation). There are no genotoxic or carcinogenic compounds. When oxidation occurs, this results in rancidification, leading to a bad taste and odour. This is a quality aspect for food, not a risk for humans. As the active substance rape oil is of food grade quality, and its constituents are also naturally present in plants, no new/other harmful compounds are expected to be formed when applied as plant protection product. Heating of edible oils could potentially lead to compounds with carcinogenic potential, but this is considered to be not relevant when used as plant protection product (see also Vol. 1, 2.6.4.1). The applicant also submitted a paper from Maszewska from 2018 on the oxidative stability of selected edible oils. In addition, phototoxicity has been searched for in the literature search. The applicant provided the following information from this search:
In order to identify possible phototoxic properties (including photo sensibilization and photomutagenicity) of rapeoil, large international toxicological databases were searched (ECHA, PubChem, CompTox Chemical Dashboard USEPA and the OECD QSAR Toolbox). The search was for rapeoil, Canola oil, CAS 8002-13-9, Rape oil and the main fatty acid components oleic acid, linoleic acid and linolenic acid.
For rapeoil/canola oil itself, there are entries in the large international databases, but only very few toxicological data records are stored there. In principle, they can be regarded as low-toxic substances. There were no indications of possible phototoxicity in any of the databases.
For the main fatty acid components there are remarkably more toxicological data records in the databases. But here, too, there were no indications of phototoxic properties of the fatty acids mentioned.
In the OECD QSAR Toolbox 4.4, about 40 databases with information on human health hazards are implemented. No hits were found for any of the search terms entered. For all of the given search terms, the data base entries did not give any indications of phototoxic properties. However, it should be mentioned that there is no database that provides explicit data on photo-induced toxicity.
Importantly, phototoxicity has also been addressed in the tox section (see Vol. 3, B.6.2.7).
In conclusion, there are no indications for phototoxic properties of rapeoil.

2.7.10 Proposed MRLs and compliance with existing MRLs

No MRLs are proposed within the renewal assessment. Rape oil is considered as a candidate for Annex IV of Commission Regulation (EC) No 396/2005.

2.7.11 Proposed import tolerances and compliance with existing import tolerances

Not relevant for this application.

2.8 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Rape oil is an edible oil that is composed mainly of triglycerides (the ester of one molecule of glycerol and three fatty acid tails). The main fatty acids are: oleic acid (55-60 %), linoleic acid (23-28 %), linolenic acid (10 %), palmitic acid and stearic acid. This section will address both triglycerides and fatty acids (as breakdown products of triglycerides).

The assessment of the environmental fate and behaviour should be performed in the context of the natural occurrence of triglycerides, being common and abundant building materials of cells. In addition, they are a source of easily-degradable carbon for microorganisms.

The applicant has not provided a summary of natural background concentrations of triglycerides or fatty acids. However, some information can be found in the submitted open literature. The concentrations of the main fatty acids of rape oil in three forest soils range from 0.8 – 1.5 g fatty acid/kg soil (sum of oleic, linoleic, linolenic, palmitic and stearic acid). High background concentrations of oleic, linoleic, linolenic and erucic acid were also detected in the German standard soil LUFA 2.4 soil that had been selected for soil degradation tests. These concentrations were higher than 30% of the LOQ, which ranges from 7 mg/kg for oleic acid to 0.1 mg/kg for erucic acid.

2.8.1 Summary of fate and behaviour in soil

This section covers the information necessary under Regulation (EC) 1107/2009 (the placing of plant protection products on the market; PPP). When soil degradation data are needed to conclude on the rapid degradability of the substance under Regulation (EC) 1272/2008 (classification, labelling and packaging of substances and mixtures; CLP), these data can be found in section 2.8.2.2.4.

Rape oil is a mixture of triglycerides of fatty acids. Degradation routes of triglycerides and fatty acids are well known. Degradation intermediates are long- and short-chain fatty acids with a chain length up to C24 (mainly carbon chains with even numbers). Rape oil is a readily available source of energy and carbon for microorganisms. Soil photolysis is not considered to be a relevant degradation pathway for rape oil.

2.8.1.1 Rate of degradation in soil, laboratory studies and modelling endpoint

Based on the results of a preliminary aerobic soil degradation study with rape oil a conservative estimate of the DT_{50} of 3 days was used for the risk assessment. Subsequently, the report of the final GLP-compliant aerobic soil degradation study has become available (Andre, 2018; see Vol. 3MA B.8; for a summary see Section 2.8.1.2 below). Based on this final report, the geomean normalised DT_{50} value of rape oil is 1.01 days (normalised to 20°C; pF2), with the highest non-normalised DT_{50} value being 1.75 days (20 °C). As anaerobic (flooded) conditions are unlikely to occur for the intended uses of rape oil, no studies on the anaerobic degradation of rape oil in soil have been performed. No field studies are required and none have been performed.

Regarding the aerobic soil degradation of fatty acids, a DT_{50} value of 2.8 days has been determined for the potassium salts of fatty acids present in the plant protection product Neudosan (highest value). This DT_{50} value of 2.8 days is used for the degradation rate of the fatty acids resulting from the degradation of rape oil. This value is supported by supplementary information available in the above mentioned soil degradation study, where the geomean normalised DT_{50} value for oleic acid was determined to be lower than 1.91 days (20 °C).

A GLP-compliant aerobic soil degradation study with rape oil is available conducted according to OECD TG 307 (Andre, 2018; see Vol. 3MA B.8). Amounts of 100 g dry weight soil were used per incubation, with soil moisture content of 45% MWHC. The target amendment concentration of 100 mg unlabeled rape oil/kg dry weight soil. The concentration of rape oil and of the fatty acids oleic acid, linoleic acid, linolenic acid and erucic acid in four soils (pH range 5.11 – 7.4) was monitored during 7-day incubations at 20 °C in the dark with continuous airflow. The concentration of rape oil was indirectly determined by the analysis of its three main constituent fatty acids (acids oleic acid, linoleic acid and linolenic acid). To be able to determine the concentrations of fatty acids bound in rape oil as well as the concentrations of free fatty acids, soil extracts containing both free fatty acids and rape oil were eluted with different solvents over a separation column thereby separating the free fatty acids from the rape oil. The rape oil fraction and the fatty acid fraction were esterified and the individual fatty acids were analysed by gas chromatography with mass spectrometric detection (GC-MS). To determine the concentrations of rape oil based on the concentrations of three fatty acids (oleic acid, linoleic acid and linolenic acid), the GC-MS peak areas of the three fatty acids were directly calibrated to the rape oil concentration. The microbial biomass of the soils at the start and end of the incubations was determined. The recoveries of rape oil for the initial time specimens ranged from 86.5 to 93.2 % of the applied test item. The recoveries of rape oil decreased with time and ranged from 3.5 to 7.4 % at experimental end.

All investigated fatty acids, i.e. oleic acid, linoleic acid, linolenic acid and erucic acid, were present at zero time in each of the soils. Oleic acid and linoleic acid were most represented in the soils (oleic acid: 1.01 to 2.76 mg/kg dry weight, linoleic acid: 0.28 to 0.79 mg/kg dry weight) and showed an increase of their concentration at the first sampling (day 1, oleic acid: 3.61 to 9.48 mg/kg dry weight, linoleic acid: 0.74 to 1.94 mg/kg dry weight), due to the degradation of rape oil, followed by a decrease to the initial level or below (LUFA 2.4 and RefeSol 03-G) at experimental end. Except of a slight increase at the first sampling event, erucic acid showed no change in its amount. The geomean normalised DT_{50} value of rape oil is 1.01 days (normalised to 20°C; pF2), with the highest non-normalised DT_{50} value being 1.75 days (20 °C). This corresponds to a geomean DT_{50} value of 2.2 days and a maximum DT_{50} of 3.7 days at 12 °C (Q10 of 2.58). The study and results are considered reliable by the RMS.
It can be concluded that rape oil and several fatty acid constituents are quickly biodegraded in soil.

2.8.1.2 Adsorption in soil

The triglycerides of rape oil are considered to be essentially immobile in soil. This assumption is based on a QSAR (quantitative structure activity estimate) estimate for triglyceride esters of oleic acid (Koc = 1×10^{10} mL g-1). The Koc values of the most abundant fatty acids of rape oil have been calculated based on experimental Log(Pow) values. The calculated Koc values of these fatty acids are:

Fatty acid		***Water solubility (mg/L)***	***Log Pow***	***Koc***
Palmitic acid	C16:0	0.04 (exp.)	7.17 (exp.)	3431 (calc.)
Stearic acid	C18:0	0.6 (exp.)	8.23 (exp.)	11670 (calc.)
Oleic acid	C18:1	0.01 (calc.)	7.64 (exp.)	11670 (calc.)
Linoleic acid	C18:2	0.04 (calc.)	7.05 (exp.)	11670 (calc.)
Linolenic acid	C18:3	0.1 (calc.)	6.46 (exp.)	11670 (calc.)

To calculate Koc values, the Log(Pow) values of the experimental database contained in EPI v3.11 were used as input for the PCKOCWIN (v1.66) subroutine in EPI Suite. The calculation of Koc values based on experimental Log Pow values for these simple molecules is highly reliable.

2.8.2 Summary of fate and behaviour in water and sediment [equivalent to section 11.1 of the CLH report template]

This section covers the information necessary under Regulation (EC) 1107/2009 (the placing of plant protection products on the market; PPP), as well as Regulation (EC) 1272/2008 (classification, labelling and packaging of substances and mixtures; CLP). It should be noted that the CLP regulation sets out the criteria for classification. Guidance on the evaluation of information is provided in the REACH guidance of information requirements. When a conclusion on rapid degradability can be drawn based on the preferred aquatic fate data, i.e. hydrolysis, ready biodegradability and/or surface water simulation data (CLP guidance, section 4.1.3.2.3.2.), only these studies will be considered for CLP purposes. If the conclusion on rapid degradability is to be based on water/sediment simulation degradation data, NER formation and how NER was dealt with in the calculation of degradation/dissipation half-live values will be indicated. Generally, half-live values derived from simulation degradation studies will for CLP purposes be reported with and without normalization to 12°C, i.e. the temperature that is regarded as a reasonable alleged average temperature for the European Union under REACH (Guidance on Information Requirements and Chemical Safety Assessment; Chapter R.7b; section R.7.9.4.1; p 219).

As rape oil is practically insoluble, it is expected that most rape oil reaching an aquatic system through spray drift will be present on the water layer. As rape oil consists of naturally occurring triglycerides that are common and abundant building materials of cells and are a source of easily-degradable carbon for microorganism, it is expected that any rape oil present on the water layer will be quickly degraded.

Rape oil can be biodegraded under both oxic and anoxic conditions (Li et al., 2010; KCA 7.2.2.3/01; Li et al., 2007; KCA 7.2.2.3/02; Li et al., 2005; KCA 7.2.2.3/03). Hydrolytic and photochemical degradation of rape oil are not considered to be relevant pathways in natural waters. Similar to the degradation of rape oil in soil, a range of long and medium length fatty acids are produced during microbial degradation in aquatic media (Salam et al 2012; KCA 7.2.2.2/02). Based on four biodegradability screening studies of which two are GLP compliant, rape oil is considered readily biodegradable (see Section 2.8.2.1). The 10-day window was passed in one out of two GLP-compliant studies with 70% degradation (based on oxygen demand) after 8 days. The results of the second GLP-compliant study also demonstrate that rape oil is readily biodegradable; however, in this study the pass level for the 10-day window was

not reached (i.e., readily biodegradable, but failing 10-day window. However, the pass level for multi-constituent substances such as rape oil may be extended to 28 days (CLP guidance document, Annex I, 4.1.2.9.5). Therefore, the RMS proposed in the RAR to classify the active substance rape oil as 'biodegradable, passing 10-day window' even though in one of the studies this criterion was not met. Based on this classification, the default value for half-live for biodegradation in surface water is 15 days (ECHA, 2017[6]).

No readily biodegradable test is available for oleic acid, the model fatty acid of rape oil. Pelargonic acid (C9) is biodegradable (passing 10-day window). Based on this fact, the RMS proposes to use the default half half-live for biodegradation in surface water of 15 days for the metabolites of rape oil.

No whole-system or sediment degradation test is available for rape oil. However, biodegradation of rape oil in sediments is considered to be similar to degradation in soil. In experiments with high concentrations of rape oil (reflecting oil-spill situations), mineralization of rape oil was almost complete after 25 days of incubation under anoxic conditions. Although these incubations were performed with sediments enriched using rape oil amendments, the almost complete degradation of high concentrations of rape oil within a 25-day period warrants the use of a sediment DT_{50} of 25 days in sediments.

2.8.2.1 Rapid degradability of organic substances

Table 30: Summary of relevant information on rapid degradability

Method	**Results**	**Key or Supportive study**	**Remarks**	**Reference**
Ready biodegradability OECD 301F GLP	Readily biodegradable 89.2% degradation of NEU 1160 I after 28 days; 10-day window passed	Key study	Conducted with formulated product (NEU 1160 I) consisting for 96% (w/w) of rape oil. At least 60% of the degradation can be attributed to rape oil within the 10-day window. Formulated product and active substance rape oil	Brunswik-Titze 2017; KCP 10.5/03

[6] ECHA; Guidance on the biocidal products regulation. Volume IV Environment – Assessment and evaluation (Parts B + C), Version 2.0, October 2017.

Method	Results	Key or Supportive study	Remarks	Reference
			are considered readily biodegradable, passing 10-day window Valid study	
Ready biodegradability OECD 301F GLP	Readily biodegradable, failing 10-day window	**Key study**	Conducted with refined rape oil (purity not reported). Valid study	Feil 2008; KCA 7.2.2.1/03
Ready biodegradability OECD 310CEC L-33-A-93 not GLP	Rape oil is biodegradable. Unclear if 10-day window pass level was achieved.~80% degradation after 28 days	Supportive study	Conducted with the substance fatty acids, rape-oil, erucic acid-low. Minor deviations (e.g. larger test volume, but recommended volume to headspace ratio applied) Valid study (reliable with limitations)	Beran 2008, KCA 7.2.2/01
Ready biodegradability OECD 301F not GLP	Readily biodegradable, failing 10-day window 65.8% degradation after 28 days	-	Conducted with rape oil (purity not reported).Pressed for this study at the test facility. Not considered for classification purposes as	Vauhkonen et al., 2011, KCA 7.2.2.1/02

Method	Results	Key or Supportive study	Remarks	Reference
			insufficient details reported to assess the reliability	
biodegradation test CEC-L-33-T-82not GLP	87.5% degradation after 7 days 92% degradation after 21 days	Supportive study-	Substance: rape oil (crude, unsaponified; 1-2% erucic acid) Purity: not reported. Using the CEC-L-33-T-82 test guidelines, biodegradability is determined by monitoring the decrease in CH_3-CH_2-moieties in the liquid phase. This is not a ready biodegradability test. Valid study	Fabig et al. 1989; KCA 7.2.2.1/07

2.8.2.1.1 Ready biodegradability

There are four biodegradability screening studies available for rape seed oil of which two studies are GLP compliant, and two studies were derived from public literature. All four studies showed that rape seed oil is readily biodegradable. However, only in one of the GLP-compliant studies, the 10-day window was passed with 70% degradation after 8 days (based on oxygen demand), while degradation after 28 days amounted to 89.2% (Brunswik-Titze, 2017). In the second GLP-compliant study the 10-day window was failed, but degradation amounted to 76% after 28 days (based on oxygen demand) (Feil et al. 2008). Regarding the public literature studies, for one study 80% degradation was observed after 28 days, but it is unclear whether sufficient degradation was achieved during the 10-day window (Beran 2008). The second public literature study did not reach the pass level within the 10-day window with 65.8% degradation after 28 days (Vauhkonen et al., 2011). That the 10-day window was not met in all studies is not considered an issue, as for a multi-constituent substances with structurally similar constituents, such as rape seed oil, the 10-day window condition may be waived and the pass level can be

applied at day 28 (as specified in Annex I, 4.1.2.9.5 of the CLP guidance document). Overall, the RMS considers the active substance rape seed oil as 'readily biodegradable, passing the 10-day window'. Please see below for more details on the individual studies.

Brunswik-Titze (2017) conducted a GLP-compliant manometric respirometry test according to OECD TG 301F with the formulated product NEU 1160 I (consisting for 96% of rape seed oil). The formulated product final test concentration was 40 mg/L, corresponding to a 100 mg/L theoretical oxygen demand. The mineral medium was inoculated with microorganisms (30 mg dry solid/L) derived from a sample of activated sludge not previously intentionally exposed to the test substance. Test vessels were incubated in darkness at 21.9 – 22.4 °C for 28 days in diffuse light and stirred continuously. The consumption of oxygen was determined by measuring the negative pressure in the flasks after absorption of the evolved carbon dioxide in sodium hydrochloride.
Blank controls, reference substance (sodium acetate) and toxicity control test (containing the test substance and sodium acetate) systems were used to assess the validity of the test conditions and whether rape oil was inhibitory to microorganisms at the test concentration. The mean total oxygen uptake in the blank control vessels was 27.2 mg/L at the end of the test, satisfying the validity criterion of <60 mg/L in 28 days.
Mean biodegradation of the reference substance (sodium acetate) exceeded 60% by Day 8 and reached an average of 86.1% by the end of the test. The rate of biodegradation of sodium acetate in the toxicity control systems was 41.7% on Day 8 and 74.9 % by the end of the test indicating that rape oil is not inhibitory to microorganisms under the test conditions.
The pH value in the test and blank bottles was 7.5 – 7.6 at the end of the test and the difference between extremes of replicate values was less than 20%. All validity criteria were therefore satisfied and the results of the study are considered valid. The biodegradation of the test item reached 89.2% within 28 days. On Day 8 biodegradation of the test item was above 70%. As a result, the formulated product is considered to be readily biodegradable.
The results of this study can be translated to the degradability of the active substance. The average degradation determined on day 12 (which is the approximate end of the 10-day window) is 78.1% of ThOD. As a result, it can be concluded that not only the formulated product, but also the active substance rape oil is biodegradable and passing the 10-day window. The formulated product consists of 96% (w/w) rape oil. Even when making the worst-case (non-realistic) assumption that the remaining 4% consists purely of hydrogen, which would result in the largest oxygen demand per unit of weight, and that this hydrogen would be completely oxidised within the 10-day window, only approximately 11% of the degradation (in % ThOD) can be attributed to this remaining fraction. The degradation caused by rape oil would then still be more than 60% within the 10-day window. Results are considered reliable without restriction (Ri=1), and are used for conclusions.

Feil (2008) conducted a GLP-compliant manometric respirometry test according to OECD TG 301F with refined rape seed oil. The final test concentration was 102 mg/L, corresponding to a 292 mg/L theoretical oxygen demand. The medium (reconstituted test water) was inoculated with microorganisms (1.5 g dry material/L) derived from a sample of activated sludge not previously intentionally exposed to the test substance. Test vessels were incubated in darkness at 22 °C for 28 days in darkness and stirred continuously. The consumption of oxygen was determined by measuring the negative pressure in the flasks after absorption of the evolved carbon dioxide in potassium hydrochloride.

Blank controls, reference substance (sodium benzoate) and toxicity control test (containing the test substance and sodium benzoate) systems were used to assess the validity of the test conditions and whether rape oil was inhibitory to microorganisms at the test concentration. The mean total oxygen uptake in the blank control vessels was 25 mg/L at the end of the test, satisfying the validity criterion of <60 mg/L in 28 days.
Mean biodegradation of the reference substance (sodium benzoate) exceeded 60% by Day 3 and reached 110% by the end of the test. The rate of biodegradation of sodium benzoate in the toxicity control systems was 63% by the end of the test indicating that rape oil is not inhibitory to microorganisms under the test conditions.
The pH value in the test and blank bottles was within the range of pH 6 to 8.5 at the end of the test and the difference between extremes of replicate values was less than 20%. All validity criteria were therefore satisfied and the results of the study are considered valid. The mean biodegradation of the test item was 76% at the end of the study. The 10-day window failed. As a result, the test item is considered readily biodegradable, but failing the 10-day window. Results are considered reliable without restriction (Ri=1), and are used for conclusions.

In addition to these two GLP-compliant studies, two studies from public literature are available in which the test item ‘rape oil’ (low-erucic rape oil and cold-pressed rape seed; no conclusion can be made regarding the similarity between the test items and the active substance) was determined to be readily biodegradable. These studies are considered as supportive information. In the first study, an average biodegradation of 80% was reached within 28-days for low-erucic rape oil (concentration between 30 and 40 mg C/L) in a headspace test according to OECD TG 310 (Beran, 2008). Data on biodegradation were only given for day 28; it is not known if the pass-level of 70% biodegradation was reached within a 10-day window. Aniline was used as reference substance. The RMS considers this substance conservative compared to the use of 1-octanol as prescribed by OECD 310 for poorly soluble test substances. No data is presented on the biodegradation of the control. The study by (Beran) 2008 is considered valid, but with restrictions. In the second study, 65.8% biodegradation was determined for the substance ‘cold-pressed rape oil’ (purity not indicated) in a manometric respiratory test according to OECD TG 301F (Vauhkonen et al., 2011). The test substance concentration was not specified. Controls were not included. The pass level was not reached within the 10-day window. The study by Vauhkonen et al. (2011) is not considered suitable for classification purposes, as insufficient details are available to assess the reliability.
In conclusion, the active substance rape oil is readily biodegradable. The 10-day window was passed in one out of two GLP-compliant studies. That the 10-day window was not met in the other GLP-compliant study and the supporting public literature study, is not considered an issue, as for a multi-constituent substances with structurally similar constituents, such as rape seed oil, the 10-day window condition may be waived and the pass level can be applied at day 28 (as specified in Annex I, 4.1.2.9.5 of the CLP guidance document). Overall, the RMS considers the active substance rape seed oil as ‘readily biodegradable, passing the 10-day window’.

2.8.2.1.2 BOD5/COD

No studies submitted.

2.8.2.2 Other convincing scientific evidence

Rape oil is an edible oil that is composed mainly of triglycerides (the ester of one molecule of glycerol and three fatty acid tails). In rape oil the main fatty acids are: oleic acid (55-60 %), linoleic acid (23-28 %), linolenic acid (10 %), palmitic acid and stearic acid. These compounds are common and abundant building materials of cells.

Fatty acids are a source of easily-degradable carbon for microorganisms. Under nutrient-limiting conditions, microorganisms commonly convert fatty acids to storage compounds such as polyhydroxybutyrates.

There are test guidelines specifically developed to assess the biodegradation of aliphatic carbohydrates, e.g. CEC-L-33-T-82 (Co-ordinating European Council). In this test, biodegradability is determined by monitoring the decrease in CH_3-CH_2-moieties by infra-red spectroscopy. Fabig et al. (1989) assessed the biodegradability of rape seed oil (crude, unsaponified; 1-2% erucic acid) using the CEC-L-33-T-82 guideline. The reference substance was diisotridecyl adipate ($C_{32}H_{62}O_4$) which reached a degradation of 27 and 78% after 7 and 21 days. Rape seed oil showed an average of 87.5% biodegradation at day 7 of the incubations, and 92% after 21 days. These results suggest a higher biodegradation than observed in the reported manometric respiratory test (OECD TG 301F) where O_2 consumption amounted to 76 and 78.1% after 28 days. However, it is important to realize that ready biodegradability tests (OECD TG 301) determine ultimate degradation by measuring the O_2 consumption/ CO_2 evolution / Dissolved Organic Carbon (DOC) removal. The pass level for readily biodegradable substances is set at a degree of degradation of 60% (ThOD or $ThCO_2$) or 70% DOC, and it is thus assumed that a fraction (30-40%) of the substance is either assimilated into biomass or converted into products of biosynthesis. Fabig et al. (1989) is considered supportive in both frameworks, but as reliable ready biodegradability tests are available that demonstrate that rape seed oil is readily biodegradable its use is limited for classification purposes.

2.8.2.2.1 Aquatic simulation tests

No studies submitted.

2.8.2.2.2 Field investigations and monitoring data (if relevant for C&L)

No studies submitted, not relevant.

2.8.2.2.3 Inherent and enhanced ready biodegradability tests

No studies submitted.

2.8.2.2.4 Soil and sediment degradation data

Not assessed for classification purposes, as reliable aquatic fate date are available that allow a conclusion on the rapid degradability of rape seed oil.

2.8.2.2.5 Hydrolysis

Hydrolytic degradation is not a relevant pathway for rape oil, since rape oil is practically not soluble in water.

2.8.2.2.6 Photochemical degradation

No data is available on direct photochemical degradation of rape oil.

2.8.2.2.7 Other / Weight of evidence

Please refer to Section 2.8.2.2.

2.8.3 Summary of fate and behaviour in air

Not assessed in this dossier.

2.8.3.1 Hazardous to the ozone layer

Not assessed in this dossier.

2.8.3.1.1 Short summary and overall relevance of the provided information on hazards to the ozone layer

Not assessed in this dossier.

2.8.3.1.2 Comparison with the CLP criteria

Not assessed in this dossier.

2.8.3.1.3 Conclusion on classification and labelling for hazardous to the ozone layer

Not assessed in this dossier.

2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

No monitoring data are available; rape oil and metabolites, degradation and reaction products occur naturally.

2.8.5 Definition of the residues in the environment requiring further assessment

For soil, surface water, ground water and sediment compartments: saturated and multi-unsaturated triglycerides of long-chain fatty acids and long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers).

For the air compartment: saturated and multi-unsaturated triglycerides of long-chain fatty acids.

2.8.6 Summary of exposure calculations and product assessment

2.8.6.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} of rape oil were calculated for all proposed uses of the plant protection product NEU 1160 I (see Volume 3 CP B.8.2). The calculations were based on the maximum intended application rates of the active substance. The minimum application interval according to the GAP was used. Persistence in soil is not taken into account, as the DT_{50} value of 1.75 days for rape oil (highest non-normalised value) and 2.8 days for the metabolite fatty acids do not exceed the trigger.

The following input parameters were used in the calculation.

Parent : Rape oil

Method of calculation	Single 1st order kinetics	
$DT_{50\ soil}$	DT_{50} (d): 3 (conservative approach; actual DT_{50} is 1.75 days)	
Application rate	Crop:	Pome-, stone fruit
	Application rate:	26490 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	50
Application rate	Crop:	Berry bushes

	Application rate:	18630 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	60
Application rate	Crop:	Vegetables
	Application rate:	20400 g a.i./ha
	Number of applications:	3
	Interval (d):	5
	% plant interception:	10
Application rate	Crop:	Woody ornamentals
	Application rate:	70640 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	25
Application rate	Crop:	Ornamentals
	Application rate:	21190 g a.i./ha
	Number of applications:	4
	Interval (d):	5
	% plant interception:	10
Application rate	Crop:	Potatoes
	Application rate:	6620 g a.i./ha
	Number of applications:	4
	Interval (d):	7
	% plant interception:	15

The following tables give the initial, short- and long-term PEC_{soil} and time-weighted average PEC_{soil}.

Table 2.8.6.1-1 PEC_{soil} of rape oil after application of NEU 1160 I in critical GAP

$PEC_{(s)}$		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
Pome-, stone fruit					
Initial		**17.660**	-	**21.860**	-
Short term	24 h	14.017	15.768	17.350	19.518
	2d	11.125	14.142	13.771	17.505
	4d	7.008	11.525	8.675	14.266
Long term	7 d	3.504	8.753	4.337	10.834
	14d	0.695	5.245	0.861	6.492
	21d	0.138	**3.611**	0.171	**4.470**
	28d	0.027	2.726	0.034	3.374

PEC(s)		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
	50d	0.000	1.529	0.000	1.892
	100d	0.000	0.764	0.000	0.946
Berry bushes					
Initial		**9.936**	-	**12.299**	-
Short term	24 h	7.886	8.872	9.762	10.981
	2d	6.259	7.957	7.748	9.849
	4d	3.943	6.484	4.881	8.026
Long term	7 d	1.972	4.924	2.440	6.095
	14d	0.391	2.951	0.484	3.652
	21d	0.078	**2.032**	0.096	**2.515**
	28d	0.015	1.533	0.019	1.898
	50d	0.000	0.860	0.000	1.065
	100d	0.000	0.430	0.000	0.532
Vegetables					
Initial		**24.480**	-	34.619	-
Short term	24 h	19.430	21.858	27.477	30.911
	2d	15.421	19.603	21.809	27.723
	4d	9.715	15.976	13.739	22.593

PEC(s)		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
Long term	7 d	4.857	12.133	6.869	17.158
	14d	0.964	7.270	1.363	10.281
	21d	0.191	**5.006**	0.270	**7.079**
	28d	0.038	3.778	0.054	5.343
	50d	0.000	2.119	0.000	2.997
	100d	0.000	1.060	0.000	1.498
Woody ornamentals					
Initial		**70.640**	-	**87.438**	-
Short term	24 h	56.067	63.073	69.400	78.072
	2d	44.500	56.567	55.083	70.019
	4d	28.034	46.101	34.700	57.064
Long term	7 d	14.017	35.010	17.350	43.335
	14d	2.781	20.978	3.443	25.967
	21d	0.552	**14.445**	0.683	**17.880**
	28d	0.110	10.902	0.136	13.495
	50d	0.001	6.115	0.001	7.569
	100d	0.000	3.057	0.000	3.784
Ornamentals					
Initial		**25.428**	-	**36.755**	-
Short term	24 h	20.182	22.704	29.172	32.818
	2d	16.019	20.362	23.154	29.432
	4d	10.091	16.595	14.586	23.987
Long term	7 d	5.046	12.602	7.293	18.216
	14d	1.001	7.552	1.447	10.915
	21d	0.199	**5.200**	0.287	**7.516**
	28d	0.039	3.924	0.057	5.673
	50d	0.000	2.201	0.000	3.182
	100d	0.000	1.101	0.000	1.591
Potatoes					
Initial		**7.503**	-	**9.345**	-
Short term	24 h	5.955	6.699	7.417	8.344
	2d	4.726	6.008	5.887	7.484
	4d	2.977	4.896	3.709	6.099
Long term	7 d	1.489	3.718	1.854	4.632
	14d	0.295	2.228	0.368	2.775
	21d	0.059	**1.534**	0.073	**1.911**
	28d	0.012	1.158	0.014	1.442

PEC(s)	**mg a.i./kg soil at 5 cm**			
	Single application		**Multiple application**	
	Actual	**TWA**	**Actual**	**TWA**
50d	0.000	0.649	0.000	0.809
100d	0.000	0.325	0.000	0.404

Table 2.8.6.2-2 Overview of environmental fate parameters of the metabolites for PEC_{soil} calculations

Parameter	**Oleic acid**
Molecular weight [g/mol]	282.47
Molar correction factor [-]	0.96
DT_{50} in soil [d]	2.8
Maximum occurrence in soil [%]	300*

*worst case value based on 3 oleic acid tails in triolein

Metabolite: Oleic acid

Method of calculation	Single 1st order kinetics	
$DT_{50\ soil}$	DT_{50} (d): 2.8 maximum occurrence in soil: 300% (worst-case value) molar correction factor: 0.32	
Application rate	Crop:	Pome-, stone fruit
	Application rate:	26490 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	50
Application rate	Crop:	Berry bushes
	Application rate:	18630 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	60
Application rate	Crop:	Vegetables
	Application rate:	20400 g a.i./ha
	Number of applications:	3
	Interval (d):	5
	% plant interception:	10

Application rate	Crop:	Woody ornamentals
	Application rate:	70640 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	25
Application rate	Crop:	Ornamentals
	Application rate:	21190 g a.i./ha
	Number of applications:	4
	Interval (d):	5
	% plant interception:	10
Application rate	Crop:	Potatoes
	Application rate:	6620 g a.i./ha
	Number of applications:	4
	Interval (d):	7
	% plant interception:	15

The following tables give the initial, short- and long-term PEC_{soil} and time-weighted average PEC_{soil}.

Table 2.8.6.2-3 PEC_{soil} of oleic acid after application of NEU 1160 I in critical GAP

$PEC_{(s)}$		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
Pome-, Stone fruit					
Initial		16.902	-	20.418	-
Short term	24 h	13.194	14.973	15.939	18.087
	2d	10.302	13.329	12.444	16.104
	4d	6.279	10.728	7.584	12.96
Long term	7 d	2.988	8.028	3.609	9.699
	14d	0.528	4.725	0.639	5.706
	21d	0.093	3.234	0.114	3.906
	28d	0.018	2.436	0.021	2.943
	50d	0	1.365	0	1.65
	100d	0	0.684	0	0.825
Berry bushes					
Initial		9.51	-	11.487	-
Short term	24 h	7.425	8.424	8.967	10.176
	2d	5.796	7.5	7.002	9.06
	4d	3.534	6.036	4.266	7.29

PEC(s)		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
Long term	7 d	1.68	4.518	2.031	5.457
	14d	0.297	2.658	0.36	3.21
	21d	0.054	1.818	0.063	2.196
	28d	0.009	1.371	0.012	1.656
	50d	0	0.768	0	0.927
	100d	0	0.384	0	0.465

PEC(s)		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
Vegetables					
Initial		23.427	-	32.193	-
Short term	24 h	18.291	20.754	25.134	28.518
	2d	14.28	18.477	19.623	25.392
	4d	8.703	14.871	11.961	20.433
Long term	7 d	4.143	11.13	5.691	15.294
	14d	0.732	6.549	1.005	9
	21d	0.129	4.482	0.177	6.159
	28d	0.024	3.378	0.03	4.641
	50d	0	1.893	0	2.601
	100d	0	0.945	0	1.299
Woody ornamentals					
Initial		67.605	-	81.669	-
Short term	24 h	52.779	59.886	63.759	72.345
	2d	41.205	53.319	49.776	64.413
	4d	25.116	42.909	30.339	51.837
Long term	7 d	11.952	32.115	14.436	38.799
	14d	2.112	18.897	2.553	22.827
	21d	0.372	12.933	0.45	15.624
	28d	0.066	9.744	0.081	11.772
	50d	0	5.463	0	6.597
	100d	0	2.73	0	3.3
Ornamentals					
Initial		24.336	-	34.035	-
Short term	24 h	18.999	21.558	26.571	30.15
	2d	14.832	19.194	20.745	26.844
	4d	9.042	15.447	12.645	21.603
Long term	7 d	4.302	11.562	6.015	16.167
	14d	0.759	6.801	1.065	9.513
	21d	0.135	4.656	0.189	6.51
	28d	0.024	3.507	0.033	4.905
	50d	0	1.965	0	2.751
	100d	0	0.984	0	1.374
Potatoes					
Initial		7.179	-	8.715	-
Short term	24 h	5.607	6.36	6.804	7.719
	2d	4.377	5.664	5.31	6.873

PEC(s)		**mg a.i./kg soil at 5 cm**			
		Single application		**Multiple application**	
		Actual	**TWA**	**Actual**	**TWA**
	4d	2.667	4.557	3.237	5.532
Long term	7 d	1.269	3.411	1.539	4.14
	14d	0.225	2.007	0.273	2.436
	21d	0.039	1.374	0.048	1.668
	28d	0.006	1.035	0.009	1.257
	50d	0	0.579	0	0.705
	100d	0	0.291	0	0.351

2.8.6.2 Predicted environmental concentrations in groundwater (PEC_{GW})

PEC groundwater calculations were performed using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 for a triglyceride consisting of glycerine and oleic acid (i.e., triolein) being degraded to the respective fatty acid, oleic acid. Oleic acid was selected as representative fatty acid since it is the predominant fatty acid (ca. 55-60 %) of rape oil (see Volume 3 CP B.8.2).

Summary of substance-related parameters of rape oil and oleic acid for PEC_{GW} calculations

Parameter	**Rape oil /Triolein**		**Oleic acid**	
Molecular Mass [g/mol]	885.46		282.47	
Water solubility (25°C) [mg/L]	2.551×10^{-20}	calculated with EPI Suite v4.11. For PEARL 4.4.4 a value of 2.551×10^{-9} mg/L was used due to input limitations.	0.01151	calculated with EPI Suite v4.11.
Saturated vapour pressure (25°C) [Pa]	6.86×10^{-15}		0.00684	
K_{OC} [mL/g]	1×10^{10}	calculated with EPI Suite v4.11. For PELMO 5.5.3 a value of 1×10^{6} mL/g was used due to input limitations.	11670	calculated with EPI Suite v4.11.

Parameter	Rape oil /Triolein		Oleic acid	
K_{OM} (K_{OC} / 1.724) [mL/g]	5.8 x 10^9	calculated with EPI Suite v4.11. For PEARL 4.4.4 a value of 5.8 x 10^8 mL/g was used due to input limitations.	6786.54	calculated with EPI Suite v4.11.
Freundlich sorption exponent (1/n)	1	not determined; default value used for modelling	1	not determined; default value used for modelling
DT_{50} soil [d] 20°C pF2/10kPa	3	conservative value (actual value is 1.01 days; geomean, n = 4)	1.87	geometric mean lab values of fatty acids, potassium salt (n = 2)
Plant uptake	0	not determined; default value used for modelling	0	not determined; default value used for modelling
Maximum occurrence [% of AR]	100 %	not determined; default value used for modelling	100 %	not determined; default value used for modelling

Method of calculation and type of study	FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 using all FOCUS groundwater scenarios	
$DT_{50\ soil}$	DT_{50} (d): 3	
Application rate	Crop:	Pome-, stone fruit
	Application rate:	26490 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	50
Application rate	Crop:	Berry bushes
	Application rate:	18630 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	60
Application rate	Crop:	Vegetables

	Application rate:	20400 g a.i./ha
	Number of applications:	3
	Interval (d):	5
	% plant interception:	10
Application rate	Crop:	Woody ornamentals
	Application rate:	70640 g a.i./ha
	Number of applications:	3
	Interval (d):	7
	% plant interception:	25
Application rate	Crop:	Ornamentals
	Application rate:	21190 g a.i./ha
	Number of applications:	4
	Interval (d):	5
	% plant interception:	10
Application rate	Crop:	Potatoes
	Application rate:	6620 g a.i./ha
	Number of applications:	4
	Interval (d):	7
	% plant interception:	15

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent triolein (representative compound for rape oil) (µg/L)	Metabolite (µg/L)
			oleic acid (representative compound for fatty acids)
FOCUS PEARL & FOCUS PELMO / all proposed uses	Châteaudun	< 0.001	< 0.001
	Hamburg		
	Jokioinen		
	Kremsmünster		
	Okehampton		
	Piacenza		
	Porto		
	Sevilla		
	Thiva		

2.9 EFFECTS ON NON-TARGET SPECIES

2.9.1 Summary of effects on birds and other terrestrial vertebrates

It is concluded that the risk to birds and other terrestrial vertebrates exposed to rape oil is low, considering the available information. The available information leads to the following assumptions why a low risk is expected to birds and other terrestrial vertebrates for formulated products containing rape oil:

1) fatty acids are naturally contributing to the feed of birds and other terrestrial vertebrates,

2) the mode of action of rape oil is mechanical rather than chemical,

3) secondary poisoning for birds and other terrestrial vertebrates eating contaminated food is unlikely to occur and

4) low rat acute toxicity is showed (LD50 > 1794.1 mg a.i./kg b.w).

Based on peer-reviewed literature data, there are no indications of adverse effects of rape oil on terrestrial vertebrate wildlife when used as a active substance in a plant protection product and used in such a purpose.

2.9.2 Summary of effects on aquatic organisms [section 11.5 of the CLH report]

2.9.2.1 Bioaccumulation [equivalent to section 11.4 of the CLH report template]

Table 31: Summary of relevant information on bioaccumulation

Method	Species	Results	Key or Supportive study	Remarks	Reference
QSAR: KOWWIN v1.66 Substance: Triolein (Glyceryl trioleate; CAS 122-32-7)	-	log P_{OW} of 23.3	Key study	Accuracy exact value is debatable, as the substance differs substantially from the training set (applicability domain is not defined). Sufficient to conclude that log P_{ow} is very high.	EPI Suite

2.9.2.1.1 Estimated bioaccumulation

Rape oil is a mixture of triglycerides of fatty acids. A log POW value of 23.3 was estimated for the main constituent Triolein (Glyceryl trioleate; CAS 122-32-7) using KOWWIN (v1.66). The applicability domain of KOWWIN is not explicitly defined, but three points are noted that can lower the accuracy of the estimate. Triolein meets two of these points, i.e. the molecular weight (MW) is 885.46 g/mol, which is outside the MW range of the training set compounds (MW 18.02-719.92 g/mol), and Triolein contains the -CH2- fragment 44 times, which exceeds the maximum for all training set compounds (max 18 times). Thus, while the accuracy is debatable, it is clear that it

will be a high value that greatly exceeds the cut-off value of log Kow ≥ 4. It is therefore, not considered appropriate to estimate a BCF value using this potentially inaccurate log Pow value.

Overall, the dossier submitter considers that rape oil has a low bioaccumulation potential. A weight of evidence approach is followed to justify this. Firstly, the very high log Kow value is an indication that uptake and distribution of the substances is hindered (log Kow >10 is indicated as threshold in the ITS on B-assessment in Reach R11, Figure R11-4). The second indication under EC 1107/2009 for bioconcentration is hydrolytic stability, that is to say there is less than 90% loss of the original substance over 24 hours via hydrolysis. In the fate section, however, it is stated that hydrolytic degradation is not a relevant pathway for rape oil, since rape oil is practically not soluble in water. Thirdly and most importantly, triglycerides of fatty acids are metabolized by fish and serve as an energy and fatty acid source. This is amongst others demonstrated by a literature study that fed salmons from an initial weight of 85 g to a final average weight of 280 g with fish meal-based diets supplemented with 100% rape oil (https://link.springer.com/article/10.1007/s11745-005-1434-9). Overall, it can be considered that Rape oil has a low bioaccumulation potential.

2.9.2.1.2 Measured partition coefficient and bioaccumulation test data

Neither the log K_{ow}, nor the BCF have been experimentally determined for rape oil.

2.9.2.2 Acute aquatic hazard

Studies with the active substance rape oil

The aquatic toxicity studies performed with rape oil were rejected during the Pesticide Peer Review Experts' Meeting 91 (PRAPeR 91) (23-27 April 2012) as being unreliable. From the summaries in the RAR, the DS concludes that these studies were mainly considered unreliable because the test substance could not be kept in solution without the presence of emulsifiers and/or solvents. The DS notes that during the preparation of this proposal only the RAR summaries were available, and not the underlying study reports.

Studies with formulated products

The conclusions in the RAR are based on aquatic toxicity studies carried out with the formulations NEU 1160 I (883 g/L rape oil), and NEU 1128 I (515 g/L fatty acids, potassium salt). To use these formulated products for classification purposes of rape oil it is necessary to take into account the aquatic toxicity of the other constituents. The composition of the formulated products is confidential, and has therefore been added to the confidential Annex. Without going into detail on the individual constituents of the formulations, the DS notes the following.

The formulated product NEU 1161 I contains rape oil as active substance (90% w/w), but also another active substance (1% w/w) for which two CAS numbers are reported. One of the CAS numbers has a harmonised classification as Aquatic Chronic 3 (H412). The other CAS number has no harmonized classifications, but has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, indicating high aquatic toxicity. The formulated product NEU 1161 I contains also substances serving as solvents, wetting agents, surfactants and/or emulsifiers. These substances have no harmonized classifications. Only for one of these additional substances (present at 3% w/w) does a substantial part of the notifiers self-classify for aquatic toxicity, i.e. Aquatic Chronic 3 (H412) (70% of the notifiers). These data show that the formulated product NEU 1161 I contains for 4%

w/w substances that are toxic to aquatic organisms. Therefore, aquatic toxicity data obtained for the formulated product NEU 116 I needs to be considered carefully, as it might not be possible to attribute the observed effects to rape oil.

The formulated product NEU 1128 I does not contain rape oil as active substance, but fatty acids potassium salts (51% w/w). This substance is not registered under REACH, and no classification and labelling data have been submitted to ECHA (substance is not listed in the C&L inventory). As noted by the RMS in the RAR it is unclear whether rape oil is part of this formulated product, and whether the fatty acids are one-on-one comparable with rape oil. The DS further notes that the remaining 49% w/w of the formulated product consists of substances serving as solvents, wetting agents, surfactants and/or emulsifiers. These substances have no harmonized classifications. One of these substances that is present in 4% w/w of the formulation has self-classifications as Aquatic Acute 1 (H400) (86% of the notifiers), and is self-classified by 36% of the notifiers for aquatic chronic toxicity, i.e. Aquatic Chronic 1 (H410) (12% of the notifiers), Aquatic Chronic 2 (18% of the notifiers) and Aquatic Chronic 3 (5.7% of the notifier). Considering that it cannot be determined if the composition of fatty acids potassium salts resembles rape oil, and taking into account that the formulation contains a constituent that is toxic to aquatic organisms, the studies conducted with the formulated product NEU 1128 I are not considered suitable for classification purposes.

Aquatic toxicity estimation

Aquatic toxicity of rape oil was not estimated by QSARs, as no experimental log K_{ow} was available for the main constituents. The accuracy of the KOWWIN estimated log Kow value of 23 is rather debatable (see also table 31) and should be considered as an indication of high lipophilicity rather than an exact value. The available data do not allow reliable aquatic toxicity estimations for rape oil.

Table 32: Summary of relevant information on acute aquatic toxicity

Method	Species	Test material	Results[1]	Key or Supportive study	Remarks	Reference
Short-term, fish, 96 h, semi static OECD 203 GLP	*Oncorhynchus mykiss*	Rape oil (purity not reported)	96 h LC_{50} > 249.4 mg/L (nominal)	Supportive	Rejected during PRAPeR 91 as being not reliable and not relevant (R3/C3) Considered reliable with restrictions for classification purposes (R2). LC50 greatly exceeds estimated water	Anonymous (2000) KCA 8.2.1/01

Method	Species	Test material	Results[1]	Key or Supportive study	Remarks	Reference
					solubility	
Short-term, fish, 96 h, semi static OECD 203 GLP	*Oncorhynchus mykiss*	Formulated product: NEU 1160 I Rape oil: 96.0% (w/w)	96 h LC_{50} > 192 mg/L (nominal, verified by analytical measurements)	Key study	Fully acceptable (R1/C1) LC50 greatly exceeds estimated water solubility	Anonymous (2016) KCP 10.2.1/01
Short-term aquatic invertebrate, 48 h, semi-static Directive 92/69/EEC, C.2, 1992 and OECD 202 GLP	*Daphnia magna*	Rape oil (purity not reported)	48 h EC_{50} > 4.5 mg/L (nominal)	-	Rejected during PRAPeR 91 as being not reliable and not relevant (R3/C3) Physical effects observed. Not suitable for classification purposes.	Heinze (2000) KCA 8.2.4.1/01
Short-term aquatic invertebrate, 48 h, static Directive 92/69/EEC, C.2, 1992 and OECD 202 GLP	*Daphnia magna*	Formulated product: NEU 1160 I Rape seed oil: > 90% (w/w)	48 h EC_{50} > 91 mg/L (measured)	Key study	Fully acceptable (R1/C1) EC50 greatly exceeds estimated water solubility	Hertl (2002) KCP 10.2.1/04
Chironomus sp., acute immobilisation test, static, 48 h OECD 235 GLP	*Chironomus riparius*	Formulated product: NEU 1128 I SL Potassium salts of fatty acids 51 % (nominal), 47.26 % (analysed)	48 h EC_{50} > 47.3 mg/L (nominal)	-	Limited reliability (R2/C1) EC50 greatly exceeds estimated water solubility. Not used for classification purposes	Dabrunz (2016) KCP 10.2.1/03
Algal growth inhibition, static, 72 h	*Desmodesmus subspicatus*	Rape oil (purity not reported)	72 h E_bC_{50} = 82.2 mg/L	-	Rejected during PRAPeR 91	Dengler and

Method	Species	Test material	Results[1]	Key or Supportive study	Remarks	Reference
OECD 201 GLP			72 h E_rC_{50} = 287.4 mg/L (nominal)		as being not reliable and not relevant (R3/C3) Reliability and usability for classification purposes can not be assessed (Ri=4)	Eberhardt (2000) KCP 8.2.6.1/01
Algal growth inhibition, static, 72 h OECD 201 GLP	*Desmodesmus subspicatus*	Formulated product: NEU 1160 I Rape oil, 96 % (w/w)	72 h E_yC_{50} = 13.4 mg/L 72 h E_rC_{50} = 39.0 mg/L (nominal)	Key study	Fully acceptable (R1/C1) in the RAR EC50 greatly exceeds estimated water solubility. Study can be used with restrictions for classification purposes (Ri=2).	Falk (2016) KCP 10.2.1/02

[1] With respect to classification purposes, it is noted that all available aquatic toxicity studies report nominal and/or measured concentration that greatly exceed the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsion rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. The effect concentrations are considered to be greater than the estimated water solubility when no effect is observed. In cases where an effect is observed at levels in excess of the water solubility, the effect concentrations for classification purposes are considered to be equal to or below the measured water solubility (as specified in Annex I.4.2 of the CLP guidance).

2.9.2.2.1 Acute (short-term) toxicity to fish

Anonymous (2000) performed a GLP-compliant 96-hour test with rape oil (purity 96% w/w) using rainbow trout (*Oncorhynchus mykiss*) according to OECD TG 2013 (KCA 8.2.1/01; RAR B.9.2.1). Seven concentrations were tested with the nominal test concentrations being 2.2, 4.8, 10.6, 23.4, 51.5, 113.4 and 249.4 mg/L. Control was included. The RAR reports limitedly on this study, as the study was rejected during PRAPeR 91 (23-27 April 2012). The following reasons were given for the rejection: "*active substance endpoints were presented as nominal concentrations and there was difficulty obtaining representative measured concentrations due to the low solubility of the substance. Therefore, the above study is not acceptable for use in risk assessment*".

For classification purposes, the DS notes that the summary contains the following relevant information: there were no mortalities, abnormalities or behavioural changes at and below a nominal concentration of 249.4 mg/L; only low concentrations of test substance could be determined shortly after preparation of the test medium indicating phase separation; no emulsifier or solvent vehicle was used for the toxicity testing to keep the dispersions stable over more than 5 min. In the initial evaluation (2008) the RMS commented that as no mortality occurred, no 96 h LC50 could be determined, but it could be estimated that the 96 h LC50 is above the maximum concentration in water with a probability of 99.9%. The DS notes that the study was initially considered reliable and that the results support the conclusion drawn from the test conducted with the formulation NEU 1160 I (Anonymous, 2016; KCP 10.2.1/01) that rape oil is not toxic to fish up to its maximum water solubility. Furthermore, this study shows that in the absence of solvents, wetting agents, surfactants and/or emulsifiers, aquatic exposure to rape oil is very limited as phase separation rapidly occurs. Considering all above, the DS concludes that despite the unavailability of the study report and the limited reporting in the RAR, the data form this study can be used as reliable with restrictions for classification purposes demonstrating that rape oil exerts no acute toxicity to fish up to its maximum water solubility.

Anonymous (2016) preformed a GLP-compliant 96-hour semi-static limit test with the formulation NEU 1160 I (rape seed oil: 96% w/w) using rainbow trout according to OECD TG 203. The nominal test concentration was 200 mg/L. The treatment and the control consisted each of 7 test organisms. Fish were not fed during the test. Biological assessments (mortality, toxicity symptoms, behaviour, length and weight of fish) were made after 0, 4, 24, 48, 72 and 96 hours. Physicochemical assessments (temperature, oxygen saturation, pH value) were made after 0, 24, 48, 72 and 96 hours. Samples were taken for both treatments at t = 0 h, t = 24 h, t = 48 h and t = 72 h from fresh solutions and at t = 24 h from the aged solution.

Analytical verification of test item concentrations in test solutions was done by analysing the content of Oleic acid in the samples. The samples were acidified with formic acid and extracted with n-hexane. After optional dilution with *tert*-butyl methyl ether (TBME), samples were derivatised with trimethyl sulphonium hydroxide (TMSH) for the methyl ester derivative of oleic acid, which was quantified by GC-MS. LOQ was 0.5 mg/L of test item. Temperature ranged 15.8 to 16.1 °C. Oxygen saturation ranged 82 to 96%. pH ranged 7.51 to 8.40. The measured content of NEU 1160 I in fresh test solutions was between 86 % and 113 % of nominal with a mean value of 103 % of nominal. The measured content of NEU 1160 I in the 24 h aged test solution was 97 % of nominal. Since the mean measured concentrations of NEU 1160 I were between 80 and 120 % of nominal concentrations, the biological endpoints were evaluated using nominal test item concentration. NEU 1160 I was found to cause no lethal nor sublethal effects in rainbow trout. Thus the 96-hour LC_{50} (96 h) was determined to be > 200 mg test item/L (nominal). The corresponding NOEC (mortality) (96 h) was 200 mg/L (nominal). . In the RAR, it was concluded by the RMS that the validity criteria were met (<1 dead fish in the control, >60% oxygen saturation, ≥82 % dissolved oxygen throughout the test) and that the analytical method was sufficiently validated. In the RAR it was, however, also stated that it is not clear how samples for chemical analysis were taken i.e. whether the water accommodated fraction was sampled or whether just the top layer of oil was sampled. The RMS requested in the RAR the notifier to clarify this. The notifier presented the following information: “100 mL samples were taken using a glass pipette from the middle of the water column in order to analyse only the dissolved fraction of the test item. When the pipette was pulled out of the water, it was directly enclosed in a paper towel to prevent dripping of liquid from the exterior part of the pipette into the analytical sample. This procedure ensured that no test item floating on the water surface

and which might have attached to the exterior part of the pipette during withdrawal was unintentionally transferred into the analytical sample. The samples were pipetted in 250 ml glass bottles without immersing the pipette into the sample. No stabiliser was used. Samples were stored deep frozen until they were transferred to the analytical laboratory." This information was considered sufficient. The RMS concluded that the LC50 of > 200 mg/L (192 mg a.i.) (nominal) and the NOEC of 200 mg/L (192 mg a.i.) (nominal) are fully acceptable (R1/C1).

Regarding classification purposes, the DS notes that the nominal and measured concentrations greatly exceeded the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Considering that the tested formulated product contains 9.0% w/w of solvents, wetting agents, surfactants and/or emulsifiers, it is likely that the tests were performed with an emulsion rather than a true solution. The truly dissolved fraction of rape oil is thus considered to be much lower. As no acute toxicity was recorded at levels in excess of the estimated water solubility, the DS considers the LC50 in fish for classification purposes to be greater than the estimated water solubility of 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L.

2.9.2.2.2 Acute (short-term) toxicity to aquatic invertebrates

Heintze (2000) preformed a GLP-compliant 48-hour semi-static daphnia immobilisation test with rape oil (purity not specified) according to OECD TG 202 (KCA 8.2.4.1/01). Eleven concentrations were tested with the nominal test concentrations being 0.2, 0.4, 0.8, 1.6, 3.2, 6.4, 12.8, 25.6, 51.2, 102.4 and 204.8 mg/L. Positive control was included. From the available summary in the RAR it cannot be concluded if a negative control (medium only) was included. The RAR reports limitedly on this study, as the study was rejected during PRAPeR 91 (23-27 April 2012). The following reasons were given for the rejection: "*effects seen in the Daphnia study using the active substance were caused by trapping at the surface, active substance endpoints were presented as nominal concentrations and there was difficulty obtaining representative measured concentrations due to the low solubility of the substance. The use of mean measured concentrations from the formulation study on Daphnia was proposed a suitable approach for aquatic invertebrates. Therefore, the above study is not acceptable for use in risk assessment*.".

For classification purposes, the DS notes that the summary contains the following relevant information: the immobilisation was between 0% at 0.2 mg/L after 48 h of test duration and 100% at 204.8 mg/L. At concentrations of 0.8 mg/L and above, the daphnids were fixed to the surface by oil spots and oil films. After 24 h nearly all of them were re-mobilised by the exchange of the test medium but were fixed again to the surface. In the initial evaluation (2008) the RMS commented that the EC50 (48 h) was calculated to be 4.5 mg/L, the NOEC was determined to be 0.2 mg/L. The DS notes that since the excess of undissolved substance appears to have given rise to physical effects on the test organisms, i.e. trapping at the surface, the study cannot be used for classification purposes.

Hertl (2002) preformed a GLP-compliant 48-hour static daphnia immobilisation test with the formulation NEU 1160 I (rape seed oil: >90% w/w) according to OECD TG 202 (KCP 10.2.1/04). Study consisted of a range-finding test, and a definitive test at 5 concentrations. In the definitive test, a stock emulsion was prepared by intense stirring of 200 mg test item in 1 L test medium for 96 hours. Nominal test concentrations were the undiluted sock emulsion and dilutions of 1:2, 1:4, 1:8 and 1:16. Test media were prepared just before introduction of test organisms. A control (test medium) and a reference item (potassium dichromate) were included. In each treatment 20 daphnids (age 6-21h) were exposed to 50 mL test medium in 50-mL flasks. pH, dissolved oxygen levels and temperature

were determined at test start and end. Analytical measurement were conducted at test start and end by taking duplicate samples of the test media and analysing them immediately using the triglyceride GPO-PAP test kit. Immobilisation and any adverse reactions to exposure were recorded after 24 and 48 hours. pH ranged 7.7-7.9, dissolved oxygen 8.5-8.9 mg/L. The mean measured concentrations were 4.8, 7.3, 18.2, 38.4 and 101.4 mg/L . Only one daphnid was trapped after 24 hours at the surface of the test medium at the lowest test concentration. The following effect concentrations were reported: a 48h-EC_{50} of > 101 mg/L, i.e. 91 mg rape seed oil/L, and a 48h-NOEC of 101 mg/L, i.e. 91 mg rape seed oil/L. This study was evaluated in the RAR as fully acceptable without restrictions (R1/C1).

Regarding classification purposes, the DS notes that the nominal and measured concentrations greatly exceed the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsions rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. As no acute toxicity was recorded at levels in excess of the estimated water solubility, the EC50 in aquatic invertebrates for classification purposes is considered to be greater than the estimated water solubility of 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L.

Dabrunz (2016) preformed a GLP-compliant 48-hours static chironomid immobilisation limit test with the formulation NEU 1128 I SL (fatty acids potassium salts: 51% w/w) according to OECD TG 235 (KCP 10.2.1/03). The nominal test concentration was 100 mg/L. Control was included. Both treatments consisted of four replicates each containing 5 first instar larvae. Temperature, pH and oxygen concentration were measured after 0, 24 and 48 hours. Hardness of the test water was measured on the day of application. Analytical measurement were conducted at test start and end, and were based on the content of oleic acid as lead component of NEU 1128 I SL. The measured concentration was 99% at test start and 90% at test end. Effect concentrations were expressed as nominal. No immobilization was observed in the control nor the 100 mg/L treatment. The study reported a 48h-EC50 of >100 mg formulation/L, i.e. 47.26 mg rape oil/L (nominal), and a 48h-NOEC of 100 mg formulation/L, i.e. 47.26 mg rape oil/L (nominal),

The RMS noted in the RAR that it was not clear how samples for chemical analysis were taken i.e. whether the water accommodated fraction was sampled or whether just the top layer of oil was sampled. The RMS requested the notifier to clarify this. The notifier provided the following information: “50 mL samples were taken from the limit test concentration and control at test start and after 48 hours. The samples were directly transferred to the analytical laboratory without freezing. No stabiliser was used.” This information was considered sufficient. The RMS also noted that the test was performed with a different formulation (NEU 1128 I SL; 47.26 % m/m potassium salts of fatty acids) than the representative formulation (NEU 1160 I EC; 96% w/w rape oil (872.6 g/L). The RMS noted in the RAR that it is unclear whether rape oil was part of the tested formulation. Since it was unclear whether fatty acids are one-on-one comparable with rape oil, even when taking into account the physical mode of action, further justification was required for extrapolating from this formulation to NEU 1160 I. The notifier was asked to address this issue during the first draft of this RAR, but did not provide any new information. The study was assigned a limited reliability (R2/C1) in the RAR.

Regarding classification purposes, the DS notes that this study is not suitable for classification purposes. The active substance accounts only for 51% w/w of the formulated product, and above all, it is unclear to what extent

the substance fatty acids potassium salts resembles rape oil.

2.9.2.2.3 Acute (short-term) toxicity to algae or aquatic plants

Dengler and Eberhardt (2000) performed a GLP-compliant growth inhibition test with the unicellular freshwater green algae *Desmodesmus subspicatus* (previously known as *Scenedesmus subspicatus*) with rape oil (purity not reported) according to OECD TG 201 (KCA 8.2.6.1/01). The nominal test concentrations were 10, 18, 32.4, 58.3, 105 and 189 mg/L. Control was included. There is no information on replicates. The RAR reports that analytical measurements were performed at test start in three treatments and the control, and that additional sampling was performed after 24, 48 and 72 h. Actual concentrations are not reported in the RAR, only that no general tendency of the actual concentrations in comparison to the nominal concentrations could be observed. The RAR summary reports that inhibitory effects were observed from 32.4 to 189.0 mg/L after 72 h for the biomass integral, and from 58.3 to 189.0 mg/L for the growth rate. The reported growth rate inhibition was -0.7, 1.9, 4.4, 11.7, 22.6 and 37.2% for the 0, 10, 18, 32.4, 58.3, 105 and 189 mg/L treatments respectively. The RMS reported the following effect concentrations based on yield: E_bC50 of 82.2 mg/L, E_bC10 of 15.2 and a NOE_bC of 18.0 mg/L (nominal), and based on growth rate: E_rC50 of 287.4 mg/L, E_r10 of 53.0 and a NOE_rC of 32.4 mg/L (nominal), The RAR summary does not report if validity criteria were met. The RMS commented in the RAR that the study was rejected during PRAPeR 91 (23-27 April 2012). The following reasons were given for the rejection: "*active substance endpoints were presented as nominal concentrations and there was difficulty obtaining representative measured concentrations due to the low solubility of the substance. Therefore, the above study is not acceptable for use in risk assessment*".

For classification purposes, the DS notes that the study summary limitedly reports on study design and validity criteria. The reported data show that algae were affected in a dose dependant manner by rape oil. This is based on nominal test concentrations though, as the available summary does not report analytical measurements. The PRAPeR argumentation (see above) suggests that the actual concentrations were low (as would be expected). Unfortunately, the study report was unavailable to exclude that effects were caused by physical effects (e.g. oily layer), that test design was adequate and to verify if validity criteria were met. Based on the available data, the reliability and usability of the data for classification purposes could not be determined, even though the data suggest that rape oil is at least to some extent toxic to algae (Ri=4).

Falk (2016) performed a GLP-compliant growth inhibition test with the unicellular freshwater green algae *Desmodesmus subspicatus* with the formulation NEU 1160 I (rape seed oil: 96% w/w) according to OECD TG 201 (KCP 10.2.1/02). The nominal test concentrations were 6.25, 12.5, 25.0, 50.0 and 100 mg/L. Control (AAP medium) was included. Treatments had three replicates, control six replicates. Measurements of pH-value were performed at t = 0h and t = 72h. The temperature was measured at hours 0, 24, 48 and 72 and the light intensity at test start. The morphological appearance of the algal cells was observed microscopically at the end of the test. Analytical verification of test item concentrations in test solutions was done by analysing the content of Oleic acid in the samples at test start and end. Samples were acidified with formic acid and extracted with n-hexane. After optional dilution with tert-butyl methyl ether (TBME), samples were derivatised with trimethyl sulphonium hydroxide (TMSH) for the methyl ester derivative of oleic acid, which was quantified by GC-MS. LOQ was 0.5 mg/L of test item. pH ranged 7.02-7.95 and temperature 21.0-23.3 °C. Actual concentrations ranged 88-110% of nominal. NEU 1160 I was found to inhibit the growth of the freshwater green algae *Desmodesmus subspicatus* after 72 hours at all tested concentrations with the following effect values (nominal concentrations) being reported based on growth rate:

E_rC_{50} of 39 (9.02 – 102) mg a.i./L and E_rC_{10} of 10.7 (0.00132 – 23.3) mg a.i./L; and based on yield: E_yC_{50} of 13.4 (5.89 – 30.98) mg a.i. /L and E_yC_{10} of 2.65 (1.27-5.57) mg a.i. /L. As statistically significant effects were determined in all test item concentrations, the LOEC was determined as 6.0 mg a.i./L and the NOEC was <6.0 mg a.i./L. At test end the morphology of the algae cells was observed microscopically. It was reported that the cells were considered normal for the control and up to a test item concentration of 12.5 mg/L, while no cells were observed at 25.0 mg/L test item concentration and above. The RMS requested the notifier to clarify how samples for chemical analysis were taken i.e. whether the water accommodated fraction was sampled or whether just the top layer of oil was sampled. The notifier presented the following information: "100 mL samples were taken using a glass pipette from the middle of the water column in order to analyse only the dissolved fraction of the test item. When the pipette was pulled out of the water, it was directly enclosed in a paper towel to prevent dripping of liquid from the exterior part of the pipette into the analytical sample. This procedure ensured that no test item floating on the water surface and which might have attached to the exterior part of the pipette during withdrawal was unintentionally transferred into the analytical sample. The samples were pipetted in 250 ml glass bottles without immersing the pipette into the sample. No stabiliser was used. Samples were stored deep frozen until they were transferred to the analytical laboratory." This information is considered sufficient. Validity criteria were met (Biomass Cell numbers measured in the controls between 0 h and 72 hours, were found to increase by a factor of 45.3 for the control; mean growth rate of 1.273 d^{-1}; mean coefficient of variation for the section-by-section specific growth rates (hours 24 - 0, 48 - 24 and 72 - 48) in the control cultures was 27.3 %; coefficient of variation of average growth in replicate control cultures was 4.2 % for the control). In the RAR it was concluded that the conclusions are fully acceptable (R1/C1). Regarding classification purposes, it is noted that the nominal and measured concentrations greatly exceed the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsions rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. Since acute toxicity was observed in all test concentrations at levels in excess of the estimated water solubility, the algal effect concentrations (NOEC, E_rC10 and E_rC50) for classification purposes are considered to be equal or below the estimated water solubility of 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L. It is furthermore noted that the water surface was covered by an oil layer, consequently, it remains unclear if the observed effects are due to the dissolved substance or due to physical effects on the algae caused by the oil layer. While in the latter case, the study should be considered invalid for classification purposes, there are no indications that this was the case (based on the extended summary available in the RAR Vol.3 – B.9 (PPP) – NEU 1160 I, and the original study report). The DS notes that the formulation NEU 1160 I contains in addition to rape oil other substances that might have attributed to the observed effects, i.e. one substance has a harmonised classification as Aquatic Chronic 3 (H412), another substance has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, while the third substance is self-classified as Aquatic Chronic 3 (H412) (70% of the notifiers). It cannot be excluded that the observed effects are at least partly caused by these substances (for details see confidential annex). Study can be used for classification purposes, and is considered reliable with restrictions (Ri=2).

2.9.2.2.4 Acute (short-term) toxicity to algae or aquatic plants

No data

2.9.2.2.4.1 Acute (short-term) toxicity to other aquatic organisms

No data

2.9.2.3 Long-term aquatic hazard

There are no long-term aquatic toxicity studies available for fish and aquatic invertebrates with the active substance rape oil. Only for algae is a study available that has been rejected during PRAPeR 91 as being not reliable and not relevant. Long-term toxicity studies on aquatic organisms have been carried out the formulated product NEU 1160 I (883g/L rape oil). Please see the section on short-term aquatic hazard where the usability of data generated with the formulated product is discussed.

Table 33: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results[1]	Relevant study	Remarks	Reference
Long-term fish, semi-static, 35 d OECD 210 GLP	*Danio rerio*	NEU 1160 I Rape oil 96.0% (w/w)	35 d NOEC = 19.6 mg/L 35 d LOEC ≥ 19.6 mg/L (measured)	Key study	Fully acceptable (R1/C1) NOEC greatly exceeds estimated water solubility	Anonymous (2017) KCP 10.2.2/01
Long-term aquatic invertebrate, semi-static, 21 d OECD 211 GLP	*Daphnia magna*	NEU 1160 I 872.6 g/L Rape oil	21 d LOEC = 4.61 mg/L 21 d NOEC = 1.34 mg/L (measured)	Key study	Fully acceptable (R1/C1) NOEC greatly exceeds estimated water solubility. Study can be used with restrictions for	Peither (2017) KCP 10.2.2/02

Method	Species	Test material	Results[1]	Relevant study	Remarks	Reference
					classification purposes (Ri=2).	
Algal growth inhibition, static, 72 h OECD 201 GLP	*Desmodesmus subspicatus*	Rape oil (purity not reported)	72 h E_bC_{10} = 15.2 mg/L 72 h NOE_bC = 18.0 mg/L 72 h E_rC_{10} = 53.0 mg/L 72 h NOE_rC = 32.4 mg/L (nominal)	-	Rejected during PRAPeR 91 as being not reliable and not relevant (R3/C3) Reliability and usability for classification purposes can not be assessed (Ri=4)	Dengler and Eberhardt (2000) KCP 8.2.6.1/01
Algal growth inhibition, static, 72 h OECD 201 GLP	*Desmodesmus subspicatus*	NEU 1160 I Rape oil, 96 % (w/w)	72 h NOE_rC ≤6.0 mg/L 72 h E_rC10 = 10.7 mg/L 72 h NOE_yC ≤6.0 mg/L 72 h E_yC10 = 2.65 mg/L (nominal)	Key study	Fully acceptable (R1/C1) in the RAR NOEC greatly exceeds estimated water solubility. Study can be used with restrictions for classification purposes (Ri=2).	Falk (2016) KCP 10.2.1/02

[1] With respect to classification purposes, it is noted that all available aquatic toxicity studies report nominal and measured concentration that greatly exceed the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsion rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. The effect concentrations are considered to be greater than the estimated water solubility when no effect is observed. In cases where an effect is observed at levels in excess of the water solubility, the effect concentrations for classification purposes are considered to be equal to or below the measured water solubility (as specified in Annex I.4.2 of the CLP guidance).

2.9.2.3.1 Chronic toxicity to fish

Anonymous (2017) assessed the effects of NEU 1160 I EC (purity 96% w/w) on the early-life stages of Zebrafish *Danio rerio* according to OECD 210. The test was performed as a semi-static limit test with a duration of 35 days. The nominal limit test concentration was 40.0 mg/L and a control with untreated test medium. The analytical method was sufficiently validated and measured concentrations were not within 80% of nominal concentrations. Therefore, results are based on the mean measured concentration of oleic acid (51% of nominal). The NOEC and LOEC (35 days) is therefore, > 20.4 mg formulation/L or 19.6 mg a.i./L. In the RAR it was noted that it was not clear how samples for chemical analysis were taken i.e. whether the water accommodated fraction was sampled or whether just the top layer of oil was sampled. The RMS requested the notifier to clarify this. The notifier provided the following information which was considered sufficient: “100 mL samples were taken using a glass pipette from the middle of the water column in order to analyse only the dissolved fraction of the test item. When the pipette was pulled out of the water, it was directly enclosed in a paper towel to prevent dripping of liquid from the exterior part of the pipette into the analytical sample. This procedure ensured that no test item floating on the water surface and which might have attached to the exterior part of the pipette during withdrawal was unintentionally transferred into the analytical sample. The samples were pipetted in 250 ml glass bottles without immersing the pipette into the sample. No stabiliser was used. Samples were stored deep frozen until they were transferred to the analytical laboratory. This information was considered sufficient, and the results were assessed as fully acceptable R1/C1.
Regarding classification purposes, it should be noted that the nominal and measured concentration greatly exceeded the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8×10^{-7} to 2.5×10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsion rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. As no chronic toxicity was recorded at levels in excess of the estimated water solubility, the NOEC in fish for classification purposes is considered to be greater than the estimated water solubility of 8.8×10^{-7} to 2.5×10^{-20} mg/L.

2.9.2.3.2 Chronic toxicity to aquatic invertebrates

Peither (2017) assessed the effects of NEU 1160 I EC (purity 96% w/w) on survival, growth, and reproduction of *Daphnia magna* during an exposure period of three weeks according to OECD TG 211. For this purpose, the daphnids were exposed in a semi-static test to aqueous test media at 0.40, 1.25, 4.0, 12.5, and 40 mg/L. A control group was tested in parallel. The mortality, reproduction and body length of the daphnids at the different test concentrations were compared with the corresponding parameters in the control and symptoms of toxicity were recorded. Additionally, the test animals were observed for visible abnormalities. Analytical measurements were based on the sum of the three mean fatty acid constituents of the test substance, i.e. oleic acid, linoleic acid and linoleic acid, which cover 90 % of all fatty acids represented in the test item, and were conducted at the start and the end of the test medium renewal periods. The LOQ was 0.4 mg/L and the LOD 0.25 mg/L. The mean measured test item concentrations were calculated as time-weighed mean from the concentrations measured, and amounted to 0.35, 0.83, 1.4, 4.8 and 18.7 mg/L. At the two highest test concentrations of 4.8 and 18.7 mg /L (mean measured concentrations), clear symptoms of toxicity were observed, i.e. reduced swimming activity, discoloration and reduced growth. The LOEC and NOEC for mortality and reproduction were determined, with the NOEC for

mortality and reproduction being 1.4 mg test item/L (mean measured), corresponding to 1.34 mg a.i./L. The RMS concluded in the RAR that the validity criteria were fulfilled. The analytical method was considered sufficiently validated. As measured concentrations of the test item were not within 20% of the nominal concentrations, mean measured concentrations were used to calculated the endpoints. The RMS calculated geometric mean measured concentrations. However, as the applicant's calculations were more worst-case, these were used for risk assessment in the RAR. The 21 day EC_{50} for inhibition of reproduction was 6.2 mg formulation/L (5.95 mg a.i.), NOEC was 1.4 mg formulation/L (1.34 mg a.i.) and the LOEC was 4.8 mg formulation/L (4.61 mg a.i.). The results were considered reliable without restriction R1/C1.

Regarding classification purposes, the DS notes that the nominal and measured concentrations greatly exceed the estimated water solubility of the main constituent of rape oil, i.e. Triolein (Glyceryl trioleate; CAS 122-32-7 ; 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L; the estimated water solubility of Triolein is referred to in this case, as the water solubility of rape oil was not determined experimentally). Therefore, it is likely that the tests were performed with emulsions rather than true solutions, and the truly dissolved fraction of rape oil is considered to be much lower. This is supported by the study report where it is noted that duplicate samples were taken from the middle of the water column of the test vessels of the actual test including suspended test item only, not including test item which had separated to the water surface. The extended summary available in RAR Vol.3 – B.9 (PPP) – NEU 1160 I reports that: "*The test media with the higher test concentrations nominal 12.5 and 40 mg/L were homogeneous emulsions at the start of the renewal periods, but separation occurred during the renewal periods and a part of the test item was found at the test medium surface. The test media with lower test concentrations appeared to be clear solutions*.". There are no remarks made in the extended summary nor the study report regarding a physical effect of the overlaying oil layer on the daphnids. Considering all above, the NOEC in aquatic invertebrates for classification purposes is considered to be equal or below the estimated water solubility of 8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L. The DS notes that the formulation NEU 1160 I contains in addition to rape oil other substances that might have attributed to the observed effects, i.e. one substance has a harmonised classification as Aquatic Chronic 3 (H412), another substance has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, while the third substance is self-classified as Aquatic Chronic 3 (H412) (70% of the notifiers). It cannot be excluded that the observed effects are at least partly caused by these substances (for details see confidential annex). Study can be used for classification purposes, but is considered reliable with restrictions (Ri=2).

2.9.2.3.3 Chronic toxicity to algae or aquatic plants

See Section 2.9.2.2.3

2.9.2.3.4 Chronic toxicity to other aquatic organisms

No data

2.9.2.4 Comparison with the CLP criteria

2.9.2.4.1 Acute aquatic hazard

Table 34: Summary of information on acute aquatic toxicity relevant for classification

Method	Species	Test material	Results	Remarks	Reference
Short-term, fish, 96 h, semi static	*Oncorhynchus mykiss*	Formulated product: NEU 1160 I	LC_{50} >8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L	LC_{50} expressed as greater than the estimated water solubility	Anonymous (2016) KCP 10.2.1/01
Short-term aquatic invertebrate, 48 h, static	*Daphnia magna*	Formulated product: NEU 1160 I	EC_{50} >8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L	EC_{50} expressed as greater than the estimated water solubility	Hertl (2002) KCP 10.2.1/04
Algal growth inhibition, static, 72 h	*Desmodesmus subspicatus*	Formulated product: NEU 1160 I	E_rC_{50} ≤8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L	EC_{50} expressed as equal or below the estimated water solubility. Effects could (at least to some extent) be attributed to other constituent of the formulated product. .	Falk (2016) KCP 10.2.1/02

The short-term aquatic toxicity studies with rape oil were rejected during the PRAPeR 91 meeting mainly because the test substance could not be kept in solution without the presence of emulsifiers and/or solvents. During the PRAPeR meeting it was concluded that formulation endpoints (containing high levels of rape oil, but also emulsifiers, solvent, surfactants and/or wetting agents) can be used for risk assessment and for classification and labelling. The DS notes that the reports of the rape oil studies were not available for classification purposes, and that the limited reporting in the RAR did not allow to conclude on the reliability and usability of these data for classification purposes. The DS also notes that using studies with the formulated product NEU 1160 I adds to the uncertainty as there are other substances present in the formulated product that could exert aquatic toxicity, i.e.: one substance has a harmonised classification as Aquatic Chronic 3 (H412), another substance has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, while the third substance is self-classified as Aquatic Chronic 3 (H412) (70% of the notifiers) (for details see confidential annex). The fish and aquatic invertebrate studies showed no acute effects upon exposure to the formulated product NEU 1160 I. Acute effects were only reported for the algae *Desmodesmus subspicatus*, with the E_rC50 amounting to 39.0 mg/L. This value is based on nominal concentrations and greatly exceeds the estimated water solubility of the main component of rape oil. As an acute effect was observed in algae, the E_rC50 should be considered as equal or below the estimated water solubility, i.e. ≤8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L. In accordance with table 4.1.0(a) of the CLP guidance and

considering that the lowest acute effect concentration is far below 1 mg/L, rape seed oil should consequently be classified as Acute Aquatic 1 with an M-factor of at least 10.000.000. This is considered overly worst-case when considering the uncertainties associated with the available algal growth inhibition study, i.e. the observed effects on algal growth could at least partially be caused by one or more of the other substances in the formulated product NE 1160 I, and cannot with certainty be attributed to rape oil only. Therefore, taking all available information into account the DS proposes no acute classification for rape oil.

2.9.2.4.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Table 35: Summary of information on long-term aquatic toxicity relevant for classification

Method	Species	Test material	Results	Remarks	Reference
Long-term fish, semi-static, 35 d	*Danio rerio*	Formulated product: NEU 1160 I	NOEC >8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L	NOEC expressed as greater than the estimated water solubility	Anonymous (2017) KCP 10.2.2/01
Long-term aquatic invertebrate, semi-static, 21 d	*Daphnia magna*	Formulated product: NEU 1160 I	NOEC ≤8.8 x 10^{-7} to 2.5 x 10^{-20} mg/L	NOEC expressed as equal or below the estimated water solubility.	Peither (2017) KCP 10.2.2/02
Algal growth inhibition, static, 72 h	*Desmodesmus subspicatus*	Formulated product: NEU 1160 I	NOEC ≤8.8 x 10^{-7} to 2.5 x 10^{-20} mg./L	NOEC expressed as equal or below the estimated water solubility.	Falk (2016) KCP 10.2.1/02

In the fate section it is concluded that rape oil is readily biodegradable, and thus rape oil is considered rapidly degradable for classification purposes.

Rape oil is very hydrophobic. For the main constituent Triolein (Glyceryl trioleate; CAS 122-32-7) a log K_{ow} of 23.3 is estimated, which greatly exceeds the trigger of log K_{ow} > 4. However, the estimated log K_{ow} also strongly points to hindrance of uptake and distribution of the substance in fish (generally considered to occur when log K_{ow} exceeds 10). Furthermore, rape oil, is an edible oil that is expected to be rapidly metabolized by fish. Overall, rape oil is considered to have a low bioaccumulation potential.

There are no long-term aquatic toxicity studies for rape oil with fish and aquatic invertebrates. The available algal growth inhibition study was rejected during the PRAPeR 91 meeting, mainly because the test substance could not be kept in solution without the presence of emulsifiers and/or solvents. During the PRAPeR meeting it was concluded that formulation endpoints (containing high levels of rape oil, but also emulsifiers, solvent, surfactants

and/or wetting agents) can be used for risk assessment and for classification and labelling. The DS notes that in the rape oil study an effect was observed on algae, but also that the study report of the respective algal growth inhibition test was not available for classification purposes, and that the limited reporting in the RAR did not allow to conclude on the reliability and usability of the data for classification purposes. The DS also notes that using studies with the formulated product NEU 1160 I adds to the uncertainty as there are other substances present in the formulated product that could exert aquatic toxicity, i.e.: one substance has a harmonised classification as Aquatic Chronic 3 (H412), another substance has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, while the third substance is self-classified as Aquatic Chronic 3 (H412) (70% of the notifiers) (for details see confidential annex).

Adequate chronic toxicity data for the formulated product NEU 1160 I were available for fish, aquatic invertebrates and algae. The reported effect concentrations greatly exceed the estimated water solubility of the main component of rape oil, probably due to the emulsifier, solvent, surfactant and/or wetting agent in the product. In fish no effects were observed, and the NOEC can be expressed as above the estimated water solubility of 8.8×10^{-7} to 2.5×10^{-20} mg/L. As chronic effects were observed in aquatic invertebrates and algae, their respective NOECs should be considered as equal or below the estimated water solubility, i.e. $\leq 8.8 \times 10^{-7}$ to 2.5×10^{-20} mg/L. In accordance with table 4.1.0(b)(ii) of the CLP guidance and considering that the lowest chronic effect concentrations are far below 0.01 mg/L, rape oil should consequently be classified as Chronic Aquatic 1 with an M-factor of at least 1.000.000. This appears overly worst-case when considering the uncertainties associated with the available daphnia reproduction study and algal growth inhibition study, i.e. the observed effects on algal growth could at least partially be caused by one or more of the other substances in the formulated product NE 1160 I, and cannot with certainty be attributed to rape oil only. While the reliability and usability of the algal growth inhibition study with rape oil could not be determined, the DS does note that algae were effected in that study. Considering all uncertainties discussed above, itis proposed to apply a safety net classification as aquatic chronic category 4.

2.9.2.5 Conclusion on classification and labelling for environmental hazards

On the basis of the above information on chronic toxicity, bioaccumulation and rapid degradability, the following classification and labelling of rape oil is proposed:

Aquatic Chronic 4, H410 (May cause long lasting harmful effects to aquatic life); as toxic effects at concentrations below trigger values for classification cannot be excluded.

2.9.3 Summary of effects on arthropods

2.9.3.1 Summary of effects on bees

Toxicity studies on bees have been carried out with the formulation NEU 1160 I and formulation NEU 1128 I. A summary of the available toxicity endpoints for Rape oil is presented in the following table.

Species	Test, Substance	Available endpoints	Reference
LABORATORY STUDIES (Product: NEU 1160 I, ai: Rape oil)			
Apis mellifera	contact + oral 24+48 h, laboratory, NEU 1160 I EC Rape oil 96%	Oral, 24h+48h, measured: LD_{50} > 2572.0 µg ai/bee $NOED_o \geq$ 2572.0 µg ai/bee Contact, 24h+48h, nominal: LD_{50} > 650.0 µg ai/bee $NOED_c \geq$ 650.0 µg ai/bee	**KCP 10.3.1.1.1/01** Ehmke 2016a
Apis mellifera	Chronic toxicity oral, 10 days, laboratory, NEU 1160 I EC Rape oil 96%	10-d LD_{50} = 1421.02 µg ai/bee/day 10-d LC_{50} = 53250.02 mg ai/kg feeding solution 10-d NOEC = 37500.0 mg ai/kg feeding solution 10-d NOED = 1010.3 µg ai/bee/day	**KCP 10.3.1.2** Ehmke 2016b
Apis mellifera	Chronic larval toxicity 8 days, laboratory NEU 1160 I EC Rape oil 96%, repeated exposure	Calculated values: 8-d LD_{50} > 1040 µg ai/larva 8-d LC_{50} > 6750 mg ai/kg diet 8-d LD_{20} > 760 µg ai/ larva 8-d LC_{20} > 4587 mg ai/ kg diet 8-d LD_{10} > 403 µg ai/ larva 8-d LC_{10} > 2614 mg ai/ kg diet 8-d NOEC = 844 mg ai/kg diet 8-d NOED = 130 µg ai/larva Remark RMS: These study endpoints are valid with the annotation that they only cover effects on larvae, but not effects on pupation and pupa emergence. Therefore the risk assessment for effects on bee brood is only indicative.	**KCP 10.3.1.3** Vergé 2017
SEMI-FIELD TESTS (Product: NEU 1128 I, ai: potassium salts of fatty acids)			

Species	Test, Substance	Available endpoints	Reference
Apis mellifera	semi-field test : confinement in tunnels	- Two treatments (treatment interval 13 days) with NEU 1128 I (47.26% potassium salt of fatty acids) at 19.3 kg a.s./ha (40 L product/ha) in Phacelia tanacetifolia crop, exposure of honeybees in tunnels for 10 days starting 3 days before the second treatment and lasting up to 7 days after the second treatment, thereafter relocation of honey bee to a remote area with no main flowering, bee attractive crops - No adverse effects on bee mortality, foraging activity and behaviour, ~~however~~ results for ~~colony strength and~~ brood development ~~are considered to be inconclusive~~ were discussed in the Expert Meeting (TC 67 Nov 21), and the study was considered acceptable for this particular case in a weight of evidence approach.	**KCP 10.3.1.5** Tänzler 2017
FIELD TESTS			

Discussion on KCP 10.3.1.3 (Vergé 2017):

The study was conducted in compliance with the OECD Draft Guidance Document on Honey bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure (Version dated 20 July 2015), except for the fact that the test duration was 8 days instead of 22 days, hence effects on the pupation stage (day 8-15) and on pupa emergence were not determined. A justification was not provided in the report. Since at the time the study was conducted the guideline was still in a draft stage (which is now finalized as an unclassified OECD 239 test guideline), and since there is no official evaluation framework yet where the study endpoints are used, the study is not rejected because of the study duration of 8 days, but the notation of the study endpoints should always be accompanied by the study duration and a note that they only cover effects on larvae, but not effects on pupation and pupa emergence. Therefore the risk assessment for effects on bee brood is only indicative.

Further, the report stated that during the mortality assessment on D7 other observations such as deviating larval sizes were made in the three highest test item groups. No other information concerning this observation was provided in the report (such as the magnitude of the deviating larval sizes, and the

number of larvae affected). Based on this finding, the reported NOEC (for mortality) of 1690 mg a.i./kg diet was not acceptable, and RMS set the NOEC at the highest level without any adverse effects, which is 844 mg a.i./kg diet, equivalent to of 130 µg a.i./larva.

Discussion on KCP 10.3.1.5 (Tänzler 2017) :

The results for colony strength and brood development of the tunnel test with NEU 1128 I were considered inconclusive because of the following reasons:

- No statistically significant differences of the colony strength between the test item-treated colonies and the control colonies occurred on any of the assessment dates. However, seven days after DA0 (DA7), all honey bee colonies were relocated from their respective tunnels and placed in an area with no main flowering, bee attractive crops (distance between tunnels and remote area: *ca.* 7 km). The report did not provide any further details on this remote area and it could not be verified that no bee attractive crops were present within a radius of 3 km from the test hives, which would have forced the bees to use up all contaminated food in the colonies (nectar and pollen stores in the control remained at the same level between day 7 and 21, as judged from the results in Table 10.3.1.5-3 (Vol. 3, CP, B.9.5.1)).

- The methods followed in this study are considered to be insufficiently accurate to reliably measure effects on brood development, due to e.g. large differences between initial values between treatments (in this test for example on day 0 the mean area covered with eggs was 3 times higher in T than in C) and because of large variation between hives (e.g. on day 0 the SD for area covered with larvae in T was 4.4 for a mean value of 4.0).

To determine with more precision effects on brood development, the design outlined in OECD Guidance Document 75 on the honeybee (Apis mellifera L) brood test under semi-field conditions is preferred, where initial conditions for all treatments are made equal by marking for each treatment and the control at the start of exposure at least 100 cells with eggs and by following the development of the brood in these 100 cells during the course of time, followed by the calculation of parameters such as brood termination rate, brood index and brood compensation rate and statistical analysis on these parameters.

Both issues were further discussed in the RAR (Vol.3 CP B.9.5.1.4) during the commenting round, after which the RMS concluded that the results on colony strength are acceptable, but the results on bee brood development remained inconclusive.

Expert meeting TC 67 Novemver 2021 :

During the expert meeting, the bee semi-field study was discussed. It was concluded that the results of the semi-field (tunnel) study (Tänzler, V., 2017) could be used to assess the effect of rape oil on honey

bee brood for this particular case, using a weight of evidence approach. See the risk assessment in Vol.3 CP B.9.6.1 or section 2.9.9.3.1 in this Volume 1 for more details.

2.9.3.2 Summary of effects on non-target arthropods other than bees

Toxicity studies on non-target arthropods other than bees have been carried out with the formulation NEU 1160 I. A summary of the available toxicity endpoints for Rape oil is presented in the following table.

Table 2.9.3.2-1 Toxicity of Rape oil to non-target arthropods

Species	Test item Test rate Test substrate	Effect	Parameter	Endpoint	Reference
Laboratory tests					
--	--	--	--		--
Extended laboratory tests					
Typhlodromus pyri	NEU 1160 I 0.33, 1.0, 3.3, 10, 30 L product /ha Treatment applied to excised apple leaves	0, 0, 0, 16, 29	% Corrected mortality	7d LR50 > 30 L product/ha	**KCP 10.3.2.2/05** Taruza 2002
		-22, -4, 21, 72(sign), 63 (sign)	% Reduction in fecundity relative to control[1]	Effects <50% up to 3.3 L/ha	
Aphidius rhopalosiphi	NEU 1160 I 1, 10, 30, 60, 100 L product /ha Sprayed barley seedlings	0, 0, 7, 25, 50	% Corrected mortality	48 h LR_{50} = 100 L product /ha	**KCP 10.3.2.2/06** Fussell 2002
		-, 22, 6, 56 (sign), -	% Reduction in fecundity relative to control[1]	Effects <50% up to 30 L/ha	
Coccinella septempunctata	NEU 1160 I EC 10, 18, 30, 44, 60 L product /ha	7.9, 4.8, 5.6, -4.1, 7.9	% Corrected mortality		**KCP 10.3.2.2/03** Duffner 2016b

Species	Test item Test rate Test substrate	Effect	Parameter	Endpoint	Reference
Laboratory tests					
--	--	--	--		--
	Foliage collected from treated apple tree plants (*Malus domestica*) at the 2-leaf growth stage,	(control: 35.3), 30.7, 39.9, 42.0, 28.3, 34.9	Mean fertile eggs/female/day		
		(control: 98.6), 96.8, 97.2, 97.0, 97.3, 98.1	Hatching rate		
Chrysoperla carnea	NEU 1160 I EC 10, 18, 30, 44, 60 L product /ha Foliage collected from treated apple tree plants (*Malus domestica*) at the 2-leaf growth stage,	16.7, 24.1 (sign), 13.3, 16.7, 16.7	% Corrected mortality		**KCP 10.3.2.2/01** Duffner 2016a
		(control: 33.9), 27.5, 21.4, 27.9, 22.3, 40.9	Eggs/female/day		
		(control: 95.8), 95.2, 97.4, 94.5. 81.5, 90.4	Hatching rate		
Aged residue tests					
Typhlodromus pyri	NEU 1160 I 30 L product /ha Foliage collected from treated whole apple trees (in Germany).	0 DAT: 96.3 7 DAT: 39.1 14 DAT: 12.5 21 DAT: 3.4	% Corrected mortality		**KCP 10.3.2.2/04** Rathke 2016
		0 DAT: 100 (sign) 7 DAT: 70.3 (sign) 14 DAT: 31.3 (sign) 21 DAT: 29.3 (sign)	% Reduction in fecundity relative to control[1]		

[1] A negative value indicates an increase in reproduction, relative to the control

Another study with Chrysoperla was submitted (KCP 10.3.2.2/02, Gossman (2016), but considered as supporting information only due to the use of a different formulation (NEU 1128 I, ai: potassium salts of fatty acids) and overdosing of the reference item.

2.9.4 Summary of effects on non-target soil meso- and macrofauna

Toxicity studies on earthworms and other soil non-target macro-organisms have been carried out with the following formulations: NEU 1160 I (883g/L Rape oil), NEU 1161 I (825 g/L Rape oil), CEL 32601 (777 g/L Rape oil) and NEU 1128 I (515 g/L Fatty acids, potassium salt).

A summary of the available toxicity endpoints for Rape oil is presented in the following table.

Table 2.9.4-1 Toxicity of Rape oil to non-target soil meso- and macrofauna

Test substance	Species	Test type		Reference
			mg a.i./kg soil dw	
NEU 1161 I (90% Rape oil and 2% Pyrethrins)	*Eisenia fetida*	Acute toxicity (14 d) artificial soil (10% peat)	LC_{50} > 900	KCP 10.4.1.1/03 Wachter 1998a
NEU 1160 I (96% Rape oil)	*Eisenia fetida*	reproduction (56 d) artificial soil (5% peat)	$NOEC_{repr}$ = 3550 EC_{10} = 1063.5 EC_{20} = 2321.7 EC_{50} = 10338	KCP 10.4.1.1/01 Lührs 2016 [1)]
NEU 1128 I (Fatty acids, potassium salt, 515 g/L)	*Eisenia fetida*	reproduction (56 d) artificial soil (5% peat)	$NOEC_{repr}$ = 1683	KCP 10.4.1.1/02 Ganßmann 2013
CEL 32601 (Rape oil analysed 769 g/L, 84 % w/w)	*Folsomia candida*	reproduction (28 d) artificial soil (5% peat)	$NOEC_{repr} \geq 192$	KCP 10.4.2.1/01 Straube 2018
CEL 32601 (Rape oil analysed 769 g/L, 84 % w/w)	*Hypoaspis aculeifer*	reproduction (14 d) artificial soil (5% peat)	$NOEC_{repr}$ = 788	KCP 10.4.2.1/02 Straube 2017 [2)]

[1] Endpoints uncorrected for soil organic matter content. For Tier 1 risk assessment, the endpoint should be corrected by a factor 2, according to the agreement in EFSA Pesticides peer review meeting on recurring issues (2015 :EN-924).

For earthworms, the leading endpoint for risk assessment is the EC10-value from the study with the representative formulation NEU 1160 I.

Ad 1):
The applicant used the NOEC for mortality of 14200 mg a.i./kg soil dw, however since effects on reproduction are more critical these should be used for risk assessment.

The study author commented as follows on the EC10 value: 'The EC_{10} was determined to be 1107.9 mg test item/kg soil (1063.5 mg a.i./kg soil) and the EC_{20} was determined to be 2418.4 mg test item/kg soil dry weight (2321.7 mg a.i./kg soil dry weight). The reproduction values at the six lowest concentrations were slightly reduced but there was no concentration related response. Although the determination of the EC values was possible, they should be used with caution, since these values contradict the actual observations at the corresponding concentration range and no dose-response relationship was observed.'

The comment from the study author on the EC-values is noted. However, according to Appendix E from the EFSA 'Technical report on the Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology', the test design is suitable for allowing ECx calculation. Looking further at Appendix F from this technical report, two criteria can be checked for assessing the reliability of the EC-values, which were checked by RMS for the EC10-value:
- width of the confidence interval around the median value: a high width of the interval is noted
- the certainty of the level of protection offered by the median ECx (using Table F2 from the technical report): based on the median EC10 being > lower limit EC20 and > lower limit EC50, the protection level is classified as medium.

In conclusion, RMS considers that the EC10-value for *E. fetida* can be used for risk assessment, but the considerations above will be taken into account for the final conclusion on the risk.

Ad 2) :
According to OECD 226, eight treatment concentrations in a geometric series should be used to allow for a combined determination of both NOEC and ECx-values. Since only five concentrations were tested, according to Appendix E of the EFSA 'Technical report on the Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology' the test guideline is not optimised for the derivation of ECX concentrations, but the design could still provide reliable EC10 estimations. However, when justifiable reasons hamper the estimation of ECx-values, such as e.g. a clear lack of dose-response, it is acceptable that ECx-values are not provided.

RMS agrees that there is no dose-response for mortality, but for reproduction this is less clear, i.e. based on the two highest concentrations. However, considering the results, i.e. 7% adverse effects at the concentration of the NOEC-value, it is not expected that the EC10-value will deviate much from the NOEC. Therefore, the NOEC-value is accepted as endpoint for the risk assessment.

2.9.5 Summary of effects on soil nitrogen transformation

A summary of the available endpoints for Rape oil is presented in the following table.

Table 2.9.5-1 Toxicity of Rape oil to soil micro-organisms

Test Substance	Parameter	Test result	remarks	Reference
NEU 1160 I (872.6 g/L Rape oil)	Nitrogen transformation rate	< 25% effect at day 70 at 220 mg product/kg d.w. soil (211 mg a.i./kg d.w. soil)		KCP 10.5/01 Häuser 2016
NEU 1161 I (4.59 g/L Pyrethrins and 825.3 g/L Rape oil)	Nitrogen transformation (deviation of NH4+, NO3- and NO2- N contents (mg/100 g soil dw) from the control)	< 25% effect at day 28 at 12 and 120 L/ha (9.9 and 99 g a.s./ha)	Supportive information, due to the different testguideline, and since no nitrate formation rates were given	KCP 10.5/02 Wachter 1998b

2.9.6 Summary of effects on terrestrial non-target higher plants

Toxicity studies on terrestrial non-target plants have been carried out with the following formulation: NEU 1161 I (825.3 g/L rape oil, 4.59 g/L pyrethrins).

A summary of the available toxicity endpoints for Rape oil is presented in the following table.

Table 2.9.6-1 Toxicity of Rape oil to non-target soil meso- and macrofauna

Test type (number of species)	Species	Test substance	Most sensitive species	Endpoint	Reference
Vegetative vigour (n=6, 21 days)	*Raphanus sativus, Cucumis sativus, Vicia faba, Lycopersicon esculentum, Allium cepa, Avena sativa*	NEU 1161 I (825.3 g/L Rape oil, 4.59 g/L Pyrethrins)	-	NOEC > 30 L test substance/ha, corr. to 24.76 kg a.s./ha LOEC > 30 L test substance/ha, corr. to 24.76 kg a.s./ha	KCP 10.6.2/01 Spatz 2001

Since this formulation is comparable with NEU 1160 I (883 g/L Rape oil) and it is not expected that the absence of pyrethrins will enhance the toxicity of the formulation to non-target plants, the endpoints can be used for the risk assessment for NEU 1160 I.

2.9.7 Summary of effects on other terrestrial organisms (flora and fauna)

2.9.8 Summary of effects on biological methods for sewage treatment

2.9.9 Summary of product exposure and risk assessment

2.9.9.1 Risk assessment for birds and other terrestrial vertebrates

For terrestrial vertebrate wildlife no risk assesssment with endpoints is done due to the lack of endpoints. Based on peer-reviewed literature data, there are no indications of adverse effects of rape oil on terrestrial vertebrate wildlife when used as a active substance in a plant protection product and used in such a purpose.

2.9.9.2 Risk assessment for aquatic organisms

In Vol.3CP, section B.9.4, a risk assessment based on the EFSA Aquatic Guidance (EFSA Journal 2013;11(7):3290) is presented. The notifier provided a risk assessment for the active substance using endpoints from studies submitted for the DAR for rape oil. All studies with aquatic organisms exposed to the active substance were rejected during PRAPeR 91 (23-27 April 2012) because of the following reasons: active substance endpoints were presented as nominal concentrations and there was difficulty obtaining representative measured concentrations due to the low solubility of the substance. Therefore, the risk assessment provided by the applicant was not acceptable. In the same PRAPer it was also considered that more studies using the formulation would have been beneficial and could have been used in the risk assessment. For the current renewal, the applicant has submitted formulation studies for fish, daphnids and algae and therefore, the risk assessment using the formulation studies is considered sufficient to address the risk posed by the active substance.

The applicant also submitted two literature studies with *Hyalella Azteca and Culex quinquefasciatus.* Both these studies can be used as supporting information and suggest that the active substance does not lead to any long-term toxicity. However, the applicant also submitted a US EPA review discussed under **KCA 8.2.4.2/02**, which raised some issues concerning toxic effects of rape oil. The RMS analysed the underlying information and considering the scope of application of rape oil according to the current GAP and the fact that the PEC values calculated are overestimations, considered the risk to be acceptable.

Expert meeting TC65 (fate and behaviour0 and TC 67 (ecotoxicology) (November 2021).
During the fate expert meeting on the active substance (TC 65), it was decided by the experts that Step 3 and further are not appropriate for fatty acids with a high K_{OC} when simultaneously using an emulsifier. Instead, an approach was suggested with Step 2, with a drift-only (no drainage, no run-off) scenario, where mitigation measures are manually introduced in Step 2. This approach was preferred as Step 2 does not consider instantaneous partitioning to the sediment, but rather after 24 hours when the run-off and drainage values are added. Based on these PECsw-values, including risk mitigation by buffer zones, an acceptable risk was demonstrated for all intended uses.

Greenhouse uses :
As the PECsw-value calculated for the greenhouse uses is below the most critical RAC of 134 µg a.i./L, the risk from the proposed greenhouse uses is acceptable.

Conclusion aquatic risk assessment:
The risk for aquatic organisms is acceptable for all proposed uses, provided that risk mitigation measures are applied (buffer zones) as indicated in the tables in Vol.3 CP B.9.4.

2.9.9.3 Risk assessment for non-target arthropods

2.9.9.3.1 Risk assessment for bees

In Vol.3CP, section B.9.6.1, a Tier I risk assessment based on the EFSA (2013) Guidance is presented. However, due to the fact that the EFSA guidance document has not been noted in Europe yet, it is not possible to derive a conclusion on the risk to bees based on this document. Therefore also the risk assessment based on the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) is presented, including a higher tier assessment and conclusion on the risk.

Risk assessment based on EFSA (2013) Bee guidance document – screening step and first tier

The screening step for contact exposure indicated an acceptable risk for all intended uses, but for oral exposure a first tier risk assessment was necessary for all uses for chronic exposure to adults and bee larvae.

The first tier risk assessment showed that for all uses except potatoes, for several scenarios in the first tier according to the EFSA bee guidance (2013), a further risk assessment is necessary for oral exposure to nectar and pollen for adults (chronic) and larvae.

Due to the fact that the EFSA guidance document has not been noted in Europe yet, it is not possible to derive a conclusion on the risk to bees based on this document.

Risk assessment based on Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002)

Table 2.9.9.3.1-1: Hazard quotients for bees – oral exposure to rape oil

Use	**Oral LD_{50} [µg a.s./bee]**	**Max. application rate [g a.s./ha]**	**Hazard quotient HQ**	**Trigger**	***A-priori* acceptable risk for adult bees**
Woody ornamentals	>2572	70640	< 27	50	yes
Pome and stone fruit	> 2572	26490	< 10	50	yes

The HQfor oral exposure is below the validated trigger value of 50, indicating a low acute risk for all intended uses.

Table 2.9.9.3.1-1: Hazard quotients for bees – contact exposure to rape oil

Use	**Contact LD_{50} [µg a.s./bee]**	**Max. application rate [g a.s./ha]**	**Hazard quotient HQ**	**Trigger**	***A-priori* acceptable risk for adult bees**
Woody ornamentals	> 650	70640	<**109**	50	no
Pome and stone fruit	> 650	26460	<41	50	yes

The HQ for contact exposure is below the validated trigger value of 50 for the use in pome and stone fruit, indicating a low acute risk for this use and all other uses except for woody ornamentals. For the use in woody ornamentals an acute risk cannot be excluded.

Chonic adult and larvae toxicity:

Chronic oral toxicity tests with adult bees and larval laboratory tests are available. Based on these endpoints, there is no indication that the chronic toxicity to adults is higher than the acute toxicity. However, for larvae a higher toxicity than to adults cannot be excluded, with the note that effects on pupation and pupa emergence are not covered in this study. Therefore the risk assessment for effects on bee brood is only indicative.

Thus, based on the above, a higher tier risk assessment is required to address :
- the tier 1 risk for the use in woody ornamentals
- the risk for larvae for all intended uses

Higher tier

A tunnel test with the formulation NEU 1128 I (47.26% potassium salt of fatty acids) was submitted, in which no adverse effects on bee mortality, foraging activity and behaviour were observed after two treatments of 19.3 kg a.s./ha (interval 13 days) in Phacelia crop.

Expert meeting TC67 November 2021
During the expert meeting, the bee semi-field study (Tänzler, V., 2017 ; KCP 10.3.1.5) was discussed. It was concluded that the results of the semi-field (tunnel) study could be used to assess the effect of rape oil on honey bee brood for this particular case, using a weight of evidence approach.

Based on the following considerations :

- The bees were directly exposed while foraging at a high density on a small crop area, which is highly attractive.
- In the study no effects after the application (DA0-DA2) were observed. Only on day DA3 there was a significant difference in mortality, which was judged as not biologically relevant and was likely caused by high variability between test hives and did not correspond to the flight activity measured on this day (here no differences between control and treatment).
- Due to the known mode of action of the active substance rape oil, an immediate effect on all acute parameters (mortality, flight activity) would have been expected without time delay.
- Due to the mode of action of the active substance rape oil, an effect on pupation and emergence seems to be very unlikely

- No statistically significant differences of the colony strength between the test item-treated colonies and the control colonies occurred on any of the assessment dates, and it was noted that colony strenghth is linked directly to adverse effects on larvae and pupation.
- Exposure of bee brood in the hive is expected to be low, i.e. it is considered unlikely that bees would transport rapeoil into the hive (i.e. adhered to their body, or to the pollen) in such amounts that would cause a risk of suffocation of the bee brood.

It was concluded during the meeting that the results from the semi-field study could be used to cover the risk for the intended uses up to an application rate of 26.49 kg a.s./ha (covering also the multiple uses, due to the expected direct mode of action). However, extrapolation of the study results to the use rate of 70 kg a.s./ha (woody ornamentals) was considered not acceptable.

Based on the above, the risk to bees is considered acceptable for all proposed uses, except for the non-professional glasshouse use in woody ornamentals, due to the high application rate. For the professional use in permanent glasshouses in woody ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level).

2.9.9.3.2 Risk assessment for non-target arthropods other than bees

The exposure and risk to non-target arthropods was assessed using the approach recommended in the published ESCORT 2 document (Candolfi et al. 2001)[7] and the EC Guidance Document on Terrestrial Ecotoxicology [8].

In-field risk assessment

The MAF is a generic multiple application factor, which is used to take into account the potential build-up of applied substances between applications based on the application interval, DT_{50} value and number of applications. The applicant used calculated MAF-values, based on a statement (Kodrik (2019)) in which a dissipation half-life from plants of 2.40 days was estimated based on a log-linear model (Model III) that is described in Fantke *et al*. (2014). Fantke et al. (2014) present data to show a realistic half-life under field conditions, based on calculations with a regression model using substance properties. The

[7] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) 'Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods' From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.
[8] EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

applicant used the model developed in Fantke et al., along with some parameter estimates taken from the EFSA Journal regarding rape oil. The foliar dissipation half-life derived with the model is 2.40 days. According to RMS, parameter estimates used are correct or can be considered to be conservative. The Fantke et al. 2014 regression model has been applied correctly, and the half-life of 2.40 days can be used for risk assessment and is considered acceptable for refinement of the MAF-values, since it is based on dissipation processes that will not change the texture of the oil. The DT50 of 2.40 days is used below in the refined MAF-values, which were calculated based on Appendix III from the ESCORT 2 guidance document, using the ratio between DT50 and spray interval.

Table 9.6.1-1 PER after application of NEU 1160 I in-field

Crop	Maximum application rate		Number of applications	Minimum application interval [days]	T1/2:spray interval	MAF[1]	PER In-field	
	L/ha						L/ha	
Pome / Stone fruit	30.0		3	7	1 :3	1.2	36	
Berry bushes	21.1		3	7	1 :3	1.2	25.3	
Vegetables	23.1		3	5	1 :2	1.3	30.0	
Ornamentals	24.0		4	5	1 :2	1.3	31.2	
Woody ornamentals	80		3	7	1 :3	1.2	96	
Potatoes	7.5		4	7	1:3	1.2	9	

[1]Based on foliar DisT50 of 2.40 days and ratio between DT50 and spray interval, using Appendix III in ESCORT 2 guidance document

Typhlodromus pyri

In an extended laboratory test with *T. pyri* (KCP 10.3.2.2/05) effects on reproduction were < 50% at test rates up to 3.3 L/ha. From table 9.6.1-1 above it is therefore clear that an in-field risk can not be excluded for all uses. This is not surprising, taking into account the target organism of the product (spider mites).

In an aged residue test at 30 L/ha (KCP 10.3.2.2/04) the fresh (DAT 0) residues showed 96.3% mortality and 100% reduction of reproduction. It is noted that these effects are more severe than the effects at 30 L/ha in the extended laboratory study (KCP 10.3.2.2/05).

The aged residue study showed that at 30 L/ha effects on mortality were <50% 7 days after treatment and effects on reproduction were <50% 14 days after treatment. This means that an acceptable in-field risk for *T. pyri* is shown for the use in berry bushes, vegetables and potatoes. Also for the use in ornamentals except woody ornamentals, the risk is considered acceptable, taking into account that the dose rate is only slightly above the acceptable rate of 30 L/ha. F or the other uses, i.e. pome and stone fruit and woody ornamentals, the PERin-field is higher than the test rate from the aged residue test and a risk cannot be excluded.

According to the applicant it cannot be concluded that *T. pyri* is the most sensitive species, because the tested rate (30 L/ha) was too low to derive a fixed endpoint (LR50 >30 L/ha). However, this does not take into account the effects on reproduction, for which also an endpoint should be derived, since it concerns extended laboratory studies used in a Tier II assessment. In the aged residue test, DAT 0 residues at 30 L/ha resulted in 100% reduction of on reproduction. In the extended laboratory test, effects on reproduction were < 50% at test rates up to 3.3 L/ha only ; above this test rate effects on reproduction were > 50%.
The applicant also states that since rape oil has a physical mode of action, there is no reason why the endpoint for *T. pyri* should be substantially lower. However, the results from the vailable studies clearly show differences in sensitivity between the tested species, with the most sensitive results for T. *pyri.* Although the mode of action is mechanical rather than toxical, there seems to be a logic in the smallest species being the most vulnerable. Therefore, for the risk assessment RMS maintains that *T. pyri* is considered the most sensitive species.

A. rhopalosiphi
An extend laboratory showed that the LR50 was 100 L/ha. In the same study, effects on reproduction were <50% at test rates up to 30 L/ha. At 60 L/ha, 56% reduction of reproduction was found.
Therefore, it can be concluded that the in-field risk for *A. rhopalosiphi* is acceptable for the use in berry bushes, vegetables and potatoes. Also for the use in ornamentals except woody ornamentals, the risk is considered acceptable, taking into account that the dose rate is only slightly above the acceptable rate of 30 L/ha. F or the other uses, i.e. pome and stone fruit and woody ornamentals, the PERin-field is higher than the test rate from the aged residue test and a risk cannot be excluded.

Coccinella septempunctata
For *C. septempunctata* no effects >50% were found at test rates up to 60 L/ha. This means that the in-field risk for *C. septempunctata* is acceptable for all uses except the use in woody ornamentals.

Chrysoperla carnea

For *C. carnea* no effects >50% were found at test rates up to 60 L/ha. This means that the in-field risk for *C. septempunctata* is acceptable for all uses except the use in woody ornamentals.

Discussion:

It is noted that rape oil has a physical mode of action, i.e. the insects are killed because an oil film is formed on their body, which prevents them from breathing. The available studies are performed with exposure to dried residues. The tested exposure scenarios therefore reflect introduction of species after the product has dried, which is relevant for organisms hiding under leaves or entering from off-field areas. The studies do not cover the direct effect of the application, i.e. when arthropods are oversprayed or come in contact with the wet oil spray, but in fact can be considered in a way, in light of the specific mode of action of rape oil, as 'aged residue' studies (i.e. with an ageing time of 1-2 hrs). For the in-field risk assessment, this is acceptable.

Conclusion in-field risk

Based on the above, it is concluded that the in-field risk is acceptable for application rates up to 30 L/ha. Thus, an acceptable in-feld risk is demonstrated for the use in berry bushes, vegetables and potatoes. Also for the use in ornamentals except woody ornamentals, the risk is considered acceptable, taking into account that the dose rate is only slightly above the acceptable rate of 30 L/ha.

For the other uses, i.e. pome and stone fruit and woody ornamentals, the PERin-field is higher than the test rate from the aged residue test and a risk cannot be excluded. Exception to this is the professional use in permanent glasshouses in woody ornamentals: for this use the risk can be adressed with appropriate warning sentences for NTA used in IPM. However, the exact sentences are to be determined at member state level.

Off-field risk assessment

Table 2.99.6.1-2 Predicted off-field environmental rates (PER) after application of NEU 1160 I for Tier 2 risk assessment

Use	PER $_{\text{in-field}}$ [L product/ha]	Drift scenario	Drift rate [%]	VDF	CF	Off-field exposure [L product/ha]
Pome / Stone fruit	36.0	Fruit crops, early	23.96	-	5	43.1
				10		4.3

		(3 m)				
Berry bushes	25.3	Small fruits, height >50cm (3 m)	6.90	-	5	8.7
				10		0.87
Vegetables	30.0	Vegetables, height >50cm (3 m)	6.90	-	5	10.4
				10		1.0
Ornamentals	31.2	Ornamentals height >50cm (3 m)	6.71	-	5	10.5
				10		1.1
Woody ornamentals	96.0		6.71	-		32.2
				10		3.2
Potatoes	9	Field crops (1 m)	1.85	-	5	0.83
				10		0.08

Discussion and risk assessment :

For the off-field risk assessment, only endpoints based on fresh residues are acceptable. As discussed in the in-field risk assessment, *T. pyri* is the most sensitive species and is driving the risk assessment. In a 3D aged residue test (KCP 10.3.2.2/04) with *T. pyri* at 30 L/ha the fresh (DAT 0) residues showed 96.3% mortality and 100% reduction of reproduction. Since there is no explanation as to why the mortality effects at 30 L/ha in the 2D extended laboratory test (KCP 10.3.2.2/05) are less severe (29% mortality at 30 L/ha, ER50 <10 L/ha), the result of the 3D study is considered leading for the risk assessment.

Based on the 3D aged residue study, an off-field risk cannot be excluded for any of the uses, since it is unknown at which exposure rates effects of the fresh residues would be <50% . In addition, there is the discussion on the physical mode of action of rape oil (see in-field risk assessment), and the resulting uncertainty in the relevance of the exposure scenario in the available studies.

Based on the above, it is concluded that an acceptable off-field risk cannot be demonstrated for any of the uses.

To adress the risk, RMS suggests to applicant to perform a single species field study with *T. pyri*, covering the predicted exposure rates for both in- and off-field. It is noted that the off-field risk is also

not acceptable for one of the other species for some of the uses (*A. rhopalosiphi* in pome and stone fruit and woody ornamentals) . For a chemical active substance with a toxic mode of action, a single species in-field field study would not have been sufficient, but instead a full community off-field field study would be required. However, RMS considers that taking into account the physical mode of action, the differences in community composition and species sensitivity between in-field and off-field fauna is less relevant for rape oil and a field study with the most sensitive species, covering the exposure routes of direct overspray and exposure to undried residues, is sufficient.

Conclusion off-field risk assessment :
An acceptable off-field risk cannot be demonstrated for any of the uses, with the exception of the professional uses in permanent glasshouses, for which no off-field risk assessment is performed. This concerns the professional uses in permanent glasshouses in berry bushes, vegetables and ornamentals (inlcuding woody ornamentals).

Overall conclusion non-target arthropods
An acceptable in-field risk was demonstrated for the use in berry bushes, vegetables, ornamentals (except woody ornamentals) and potatoes.
For the uses in pome and stone fruit and woody ornamentals an in-field risk cannot be excluded. Exception to this is the professional use in permanent glasshouses in woody ornamentals: for this use the risk can be adressed with appropriate warning sentences for NTA used in IPM. However, the exact sentences are to be determined at member state level.

The off-field risk was not acceptable for any of the uses, with the exception of the professional uses in permanent glasshouses, for which no off-field risk assessment is performed. This concerns the professional uses in permanent glasshouses in berry bushes, vegetables and ornamentals (inlcuding woody ornamentals).

To address the risk (in-field and off-field), RMS suggests to applicant to perform a single species field study with *T. pyri*, covering the predicted exposure rates for both in- and off-field.

2.9.9.4 Risk assessment for non-target soil meso- and macrofauna

The risk assessment for earthworms and other soil non-target meso- and macro-organisms has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).
Further details on the risk assessment can be found in Vol. 3, CP section B.9.8.

A summary of the effects on non-target arthropods is presented in Vol. 1, section 2.9.4.

In the tables below, TER-values were calculated with and without the correction factor of 2 for soil organic matter, since in the EFSA Pesticides peer review meeting on recurring issues (2015 :EN-924) it was acknowledged that a correction factor of 2 may not be totally appropriate for studies in which the organic matter percentage was lowered (i.e. <10%), and that in these cases a smaller factor could be more appropriate (no further quantification given). However, in the absence of any better data, it was agreed that the factor of 2 should be applied.

All studies were performed with 5% organic matter.

Table 2.9.9.4-1 Toxicity exposure ratios for earthworms exposed to rape oil

Use	Test substance	Test species	Endpoint [mg a.i./kg soil]	Max. initial PEC_{soil} [mg a.i./kg]	TER	TER_{corr}	Trigger
Pome-, stone fruit	NEU 1160 I (96% Rape oil)	*Eisenia fetida*	EC10 = 1063.5	21.860	49	25	5
Berry bushes				12.299	86	43	
Vegetables				34.619	31	16	
Woody ornamentals				87.438	12	6	
Ornamentals				36.755	29	15	
Potatoes				9.345	114	57	

The table above shows that all TER-values meet the trigger of 5 for all uses.

Table 2.9.9.4-2a Tier 1Toxicity exposure ratios for other soil mesofauna exposed to rape oil

Use	Test substance	Test species	Endpoint [mg a.i./kg soil]	Max. initial PEC_{soil} [mg a.i./kg]	~~TER~~	TER_{corr}	Trigger
Pome-, stone fruit	CEL 32601 (Rape oil analysed 769 g/L)	*Folsomia candida*	$NOEC_{repr}$ ≥ 192	21.860	~~8.8~~	**4.4**	5
Berry bushes				12.299	~~16~~	8.0	
Vegetables				34.619	~~5.5~~	**2.8**	
Woody ornamentals				87.438	~~**2.2**~~	**1.1**	
Ornamentals				36.755	~~5.2~~	**2.6**	
Potatoes				9.345	~~21~~	10	
Pome-, stone fruit	CEL 32601 (Rape oil analysed 769 g/L)	*Hypoaspis aculeifer*	$NOEC_{repr}$ = 788	21.860	~~36~~	18	5
Berry bushes				12.299	~~64~~	32	
Vegetables				34.619	~~23~~	12	
Woody ornamentals				87.438	~~9.0~~	**4.5**	
Ornamentals				36.755	~~21~~	11	
Potatoes				9.345	~~84~~	42	

~~The table above shows that for soil mites (*H. aculeifer*) all TER values meet the trigger of 5 for all uses.~~ During the expert meeting on rapeoil (TC 67 November 2021), the use of the correction factor of 2 for soil organic matter content was discussed and it was agreed that in a weight of evidence approach, taking into account the fact that no effects occurred in the study with *Folsomia candida*, the risk for Folsomia could be further refined by lowering the correction factor of 2 for soil organic matter to 1.

Table 2.9.9.4-2a Tier 2 Toxicity exposure ratios for other soil mesofauna exposed to rape oil

Use	Test substance	Test species	Endpoint [mg a.i./kg soil]	Max. initial PEC_{soil} [mg a.i./kg]	TER	Trigger
Pome-, stone fruit	CEL 32601 (Rape oil analysed 769 g/L)	*Folsomia candida*	$NOEC_{repr}$ ≥ 192	21.860	8.8	5
Berry bushes				12.299	16	
Vegetables				34.619	5.5	
Woody ornamentals				87.438	**2.2**	
Ornamentals				36.755	5.2	
Potatoes				9.345	21	

For springtails (*F. candida*), an acceptable risk is demonstrated for the use in berry bushes and potatoes. For the uses in pome and stone fruit, vegetables and ornamentals, the risk is acceptable when no correction factor is used. Taking into account that in the study no effects were found on mortality or reproduction (see Straube (2016) ; study KCP 10.4.2.1/01), and taking into account the remarks on the correction factor as stated above, RMS considers that the risk is acceptable for these uses as well. For the use in woody ornamentals, the high application rate leads to lower TER-values and a risk cannot be excluded. Although no effects were found in the study, based on the mechanical mode of action (a thin oil film is blocking the body pores or spiracles) the higher application rate may lead to unacceptable adverse effects.

For soil mites (*H. aculeifer*) all TER-values meet the trigger of 5 for all uses, except for the use in woody ornamentals. Since statistically significant effects on reproduction were found in the study, the line of reasoning as followed for springtails does not apply.

In conclusion :
The risk to earthworms and other soil non-target meso- and macro-organisms is acceptable for the uses in berry bushes, potatoes, pome and stone fruit, vegetables and ornamentals. For the use in woody ornamentals, based on the TER-values for *Folsomia candida* and *Hypoaspis aculeifer*, a risk for soil organisms cannot be excluded due to the high application rate. Exception to this is the professional use in permanent glasshouses in woody ornamentals, for which exposure of soil organisms is considered not relevant by several Member States due to the regular sterilisation of the glasshouse soil.

2.9.9.5 Risk assessment for soil nitrogen transformation

The risk assessment for soil nitrogen transformation has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).

The highest PECsoil was estimated for the multiple application use in woody ornamentals, and amounts 87.438 mg a.s./kg soil.

The results of the available study from Hauser (2016) (KCP 10.5/01) demonstrate effects < 25% on soil nitrogen transformation after 70 days at a rate of 220 mg product/kg soil, which is equivalent to 211 mg ai product/kg soil.

Therefore, the risk to soil microbial processes from the proposed uses of NEU 1160 I is considered to be acceptable for all intended uses.

In addition to the above, it is noted that rape oil is ubiquitous in soil and readily biodegradable by micro organisms (study KCP 10.5/03). Additionally, fatty acids are essential components in the life cycle of microorganisms. This further supports the conclusion that rape oil poses no risk to micro-organisms when used according to GAP and will pose an acceptable risk to soil microbial organisms.

2.9.9.6 Risk assessment for non-target terrestrial plants

The risk assessment for non-target terrestrial plants has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).

See table 2.9.9.6-1 for TER calculation for the two worst case uses.

Table 2.9.9.6-1 Overview of exposure concentrations and TERs for non-target plants

Use	Substance	Application rate [kg a.s. /ha]	MAF	Drift% (off-field)	Exposure (kg kg a.s./ha)	ER_{50} [kg a.s./ha]	TER	Trigger value
Fruit trees		26.49	-*	23.96	6.35	> 24.76	> 3.9	5
Woody ornamentals		70.64	-*	6.90	4.87	> 24.76	> 5.1	

* as agreed in the pesticides peer review meeting on recurring issues in ecotoxicology (2015)

For fruit trees, the TER-value is below the trigger of 5, however since no effects were observed in the test and the used endpoint is actually a NOER-value, the risk is considered acceptable. For woody ornamentals, the ratio between EC_{50} and the exposure concentration is > 5 and the risk is acceptable.

Based on the above, NEU 1161 I (825.3 g/L Rape oil and 4.59 g/L pyrethrins) poses no unacceptable risk to terrestrial non-target plants following the proposed uses. Since this formulation is comparable with NEU 1160 I (883 g/L Rape oil) and it is not expected that the absence of pyrethrins will enhance the toxicity of the formulation to non-target plants, the risk for non-target terrestrial plants is considered acceptable for all intended uses.

2.10 PROPOSED HARMONISED CLASSIFICATION AND LABELLING ACCORDING TO THE CLP CRITERIA *[SECTIONS 1-6 OF THE CLH REPORT]*

2.10.1 Identity of the substance [section 1 of the CLH report]

2.10.1.1 Name and other identifiers of the substance

Table 36: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	Rape oil
Other names (usual name, trade name, abbreviation)	-
ISO common name (if available and appropriate)	Rape oil / LEAR / Canola oil[1]
EC number (if available and appropriate) **EC name (if available and appropriate)**	232-299-0 (Rape oil) 296-916-5 (Rape oil - low erucic acid)
CAS number (if available)	8002-13-9 (Rape oil) 93165-31-2 (Rape oil - low erucic acid)
Other identity code (if available)	-
Molecular formula	Not possible as it is a mixture of triglycerides of fatty acids.
Structural formula	
SMILES notation (if available)	
Molecular weight or molecular weight range	
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Not applicable.
Description of the manufacturing process and identity of the source (for UVCB substances only)	Not applicable.
Degree of purity (%) (if relevant for the entry in Annex VI)	The purity complies with the European Pharmacopeia 7.0 and Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 and ph. Eur. 5, 2005. Active substance is not a single compound but a mixture of triglycerides of fatty acids and the mode of action is mechanical rather than chemical: 100% of technical active substance is considered as active substance. The specifications is based on the composition as fatty acids and some physical and chemical parameters.

[1] Rapeversus Canola (see also definition according to CODEX-STAN 210): Canadian breeders successfully lowered the erucic acid content from as high as 40% (Polish rapeseed) and 23.5% (Argentine rapeseed) down to just 2%, and in 1986 the trademark "Canola" was altered to apply only to canola oil with less than 2% erucic acid. The word “canola” was derived from “Canadian oil, low acid” in 1978. On the European market, it is better known as LEAR oil (for Low Erucic Acid Rapeseed). Thus, although low in erucic acid the manufacturer named its product “Rape oil”. Codex Standard for named vegetable oils, CODEX-STAN 210 (Amended 2003, 2005).

2.10.1.2 Composition of the substance

Table 37: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
Rape oil	100%		

Table 38: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling
Erucic acid	Max. 2 % w/w			

Table 39: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
None	-	-	-	-	-

Table 40: Test substances (non-confidential information)

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)	Other information	The study(ies) in which the test substance is used
None	-	-	-	-

2.10.2 Proposed harmonized classification and labelling

2.10.2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 41: Proposed harmonised classification and labelling according to the CLP criteria

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry											
Dossier submitters proposal		Rape oil	232-299-0	8002-13-9	**Aquatic Chronic 4**	H413	-	H413	-		
Resulting Annex VI entry if agreed by RAC and COM		Rape oil	232-299-0	8002-13-9	**Aquatic Chronic 4**	H413	-	H413	-		

2.10.2.2 Additional hazard statements / labelling

Table 42: Reason for not proposing harmonised classification and status under CLH public consultation

Hazard class	Reason for no classification	Within the scope of CLH public consultation
Explosives	Data conclusive but not sufficient for classification.	Yes
Flammable gases (including chemically unstable gases)	Not applicable	No
Oxidising gases	Not applicable	No
Gases under pressure	Not applicable	No
Flammable liquids	Data conclusive but not sufficient for classification.	Yes
Flammable solids	Not applicable	No
Self-reactive substances	Data conclusive but not sufficient for classification.	Yes
Pyrophoric liquids	Data conclusive but not sufficient for classification.	Yes
Pyrophoric solids	Not applicable	No
Self-heating substances	Data conclusive but not sufficient for classification.	Yes
Substances which in contact with water emit flammable gases	Data conclusive but not sufficient for classification.	Yes
Oxidising liquids	Data conclusive but not sufficient for classification.	Yes
Oxidising solids	Not applicable	No

Hazard class	Reason for no classification	Within the scope of CLH public consultation
Organic peroxides	Data conclusive but not sufficient for classification.	Yes
Corrosive to metals	Data conclusive but not sufficient for classification.	Yes
Acute toxicity via oral route	Data conclusive but not sufficient for classification.	Yes
Acute toxicity via dermal route	Data conclusive but not sufficient for classification.	Yes
Acute toxicity via inhalation route	Data conclusive but not sufficient for classification.	Yes
Skin corrosion/irritation	Data conclusive but not sufficient for classification.	Yes
Serious eye damage/eye irritation	Data conclusive but not sufficient for classification.	Yes
Respiratory sensitisation	Data lacking.	No
Skin sensitisation	Data conclusive but not sufficient for classification.	Yes
Germ cell mutagenicity	Data conclusive but not sufficient for classification.	Yes
Carcinogenicity	Data conclusive but not sufficient for classification.	Yes
Reproductive toxicity	Data conclusive but not sufficient for classification.	Yes
Specific target organ toxicity-single exposure	Data conclusive but not sufficient for classification.	Yes
Specific target organ toxicity-repeated exposure	Data conclusive but not sufficient for classification.	Yes
Aspiration hazard	Data conclusive but not sufficient for classification.	Yes
Hazardous to the aquatic environment	Harmonised classification proposed**.**	Yes
Hazardous to the ozone layer	Not assessed in this report.	No

2.10.3 History of the previous classification and labelling

Rape oil has not previously been assessed for harmonised classification by RAC or TC C&L.
Rape oil is not registered under REACH (July 2017).
According to the data presented in the DAR (2007), Rape oil has no classification.
The conclusions on the peer review of pesticide risk assessment of rape oil was published as an EFSA scientific report (2013;11(1):3058). The classification was unchanged. The DAR can be requested via: http://dar.efsa.europa.eu/dar-web/provision. EFSAs peer review is available via the EFSA website (http://www.efsa.europa.eu/en/efsajournal/pub/3058).

2.10.4 Identified uses

The field of uses is described in 1.4

2.10.5 Data sources

Within the context of Regulation EC 1107/2009, a dossier was received by RMS the Netherlands from applicant Task Force Rape oil (W. Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH). This CLH report has been prepared based on the data on Rape oil that was submitted and evaluated in the DAR (2007).

2.11 RELEVANCE OF METABOLITES IN GROUNDWATER

2.11.1 STEP 1: Exclusion of degradation products of no concern

Oleic acid was selected as a model fatty acid in risk assessment calculation, because it constitutes between one-half and two-thirds of the fatty acids in typical Rape oil. PEC groundwater calculations were performed for a triglyceride consisting of glycerine and oleic acid (referred to as Triolein) being degraded

to the respective fatty acid, oleic acid. Triolein is a simple or monoacid because it contains only one type of fatty acid, in this case oleic acid.

Overall, the PEC_{GW} values for Triolein and Oleic acid are all well below the regulatory threshold level for groundwater (concentrations < 0.1 µg/L) for all crop/application scenarios, for each time point calculated.

2.11.2 STEP 2: Quantification of potential groundwater contamination

Not applicable.

2.11.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not applicable.

2.11.3.1 STEP 3, Stage 1: screening for biological activity

Not applicable.

2.11.3.2 STEP 3, Stage 2: screening for genotoxicity

Not applicable.

2.11.3.3 STEP 3, Stage 3: screening for toxicity

Not applicable.

2.11.4 STEP 4: Exposure assessment – threshold of concern approach

Not applicable.

2.11.5 STEP 5: Refined risk assessment

Not applicable.

2.11.6 Overall conclusion

None of the triglyceride, Triolein or oleic acid, as soil degradation product exceed the threshold level in groundwater calculations for any of the intended uses.

2.12 CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT

2.12.1 Identity and physical chemical properties

Not applicable. The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.12.2 Methods of analysis

Not applicable. The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.12.3 Mammalian toxicity

The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.12.4 Operator, Worker, Bystander and Resident exposure

The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.12.5 Residues and Consumer risk assessment

Not applicable. The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.12.6 Environmental fate

Not relevant.

2.12.7 Ecotoxicology

Not applicable. The main component is not of concern and does not have optically resolvable isomers; therefore, no isomeric forms exist which have to be considered for risk assessment.

2.13 RESIDUE DEFINITIONS

2.13.1 Definition of residues for exposure/risk assessment

Food of plant origin: No residue definition proposed

Food of animal origin: No residue definition proposed

Soil: saturated and multi-unsaturated triglycerides of long-chain fatty acids and long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers).

Groundwater: saturated and multi-unsaturated triglycerides of long-chain fatty acids and long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers).

Surface water: saturated and multi-unsaturated triglycerides of long-chain fatty acids and long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers).

Sediment: saturated and multi-unsaturated triglycerides of long-chain fatty acids and long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers).

Air: saturated and multi-unsaturated triglycerides of long-chain fatty acids.

2.13.2 Definition of residues for monitoring

Food of plant origin: No residue definition proposed

Food of animal origin: No residue definition proposed

Soil: No residue definition proposed

Groundwater: No residue definition proposed

Surface water: No residue definition proposed

Sediment: No residue definition proposed

Air: No residue definition proposed

2.14 ED ASSESSMENT FOR OTHER NON-TARGET VERTEBRATES

RMS ecotoxicology note: The applicant presented the ED assessment in a different format, going through the available data and presenting some data from the public literature rather than focussing on the ED modes of action assessed under ECHA/EFSA, 2018. The following text and conclusions are those of the RMS ecotoxicology unless otherwise indicated.

The applicant performed a literature search however, no studies on the T or EAS adversity of rapeoil were found.

The applicant focused on the endocrine disruption of the fatty acids since the rapeoil is a mixture of fatty acids. Fatty oils are important in the growth and development of animals. The two major groups of fatty acids are the n-6 polyunsaturated acids (PUFA) (e.g. linoleic acid) which are obtained from fats and oils and the n-3 PUFA (e.g. alpha-linolenic acid) which are obtained from fish and seafood products[9].

The rapeoil is produced from rapeseeds with a low level of erucic acid. Rapeoil is indeed a source of saturated fatty acids (i.e. myristic, palmitic, stearic, behenic, lignoceric), monounsaturated fatty (i.e. palmitoleic, oleic, erucic acids) and polyunsaturated fatty acids (linoleic, linolenic and arachidonic acid).

The applicant refers to the EFSA Scientific Opinion on the re-evaluation of fatty acids (E 570) as a food additive. EFSA Journal 2017;15(5):4785. According to the information provided in this document, "*Caprylic acid, capric acid, lauric acid, myristic acid, palmitic acid and oleic acid are included in the European Union Register of feed additives (Regulation (EC) No 1831/2003).[…] The European Food Safety Authority (EFSA) also peer reviewed the initial risk assessments carried out by the competent authority of the rapporteur Member State Ireland, for the pesticide active substance fatty acids C7–C18 (approved under Regulation (EC) No 1107/2009 as Fatty acids C7–C20) (EFSA, 2013). It was concluded that exposure to fatty acids derived from the use as plant protection products would be considered of low toxicological concern and no reference values would be needed if the different groups of fatty acids could be considered of food grade quality"*.

The use of fatty acids in feed is as a tool to counter pathogens and reduce the use of antibiotics in the meat industry. Saturated medium chain fatty acids, 6-12 carbon long chains (n.b. caproic, caprylic, capric and lauric acid), have been demonstrated to improve animal health and food digestibility in pigs[10]. The EFSA CEF panel concluded in 2015[11] that the fatty acids, C16-C18 is safe for the consumers when used in food contact materials. As the applicant mentioned the EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA) decided not to set any Dietary Reference Values (DRVs) for fats[12].

[9] Meyer BJ, et al. Dietary intakes and food sources of omega-6 and omega-3 polyunsaturated fatty acids. Lipids. 2003;38(4):391-398

[10] Baltić B, Starčević M, Đorđević J, Mrdović B, Marković R. Importance of medium chain fatty acids in animal nutrition. IOP Conf Ser Earth Environ Sci. 2017;85:012048

[11] EFSA Journal 2015;13(2):4021 : Scientific Opinion on the safety assessment of the substance fatty acids, C16–18 saturated, hexaesters with dipentaerythritol for use in food contact materials

[12] EFSA Journal 2010; 8(3):1461 Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol

No studies investigating the toxicity of rapeoil to birds and mammals are available, as these were not considered relevant in the EU review. It was concluded in the EFSA Journal (2013)[13] that the risk to birds exposed to rape oil is low, considering the available information, such as the fact that fatty acids (degradation products of triglycerides) are routinely used in feed commodities, that the mode of action to target organisms is mechanical rather than chemical, and the available toxicological endpoint for mammals (LD_{50} > 1794.1 mg a.s./kg b.w.).
Considering the information available in the EFSA Journal (2013), the use of fatty acids in the meat industry to improve the immune system of animals, and taking into account that fatty oils are important in growth and development, the RMS is of opinion that no endocrine disruption in birds and mammals is expected from exposure to rapeoil.

No information is available on the effects of rapeoil on amphibians and reptiles, however, fats in the diet of amphibians and reptiles are a source of fatty acids[14] . According to Browne RK. (2009)[15] the proportion of fatty acids in the amphibian diet is very important: "*Insects range from less than 10% to more than 30% fats on a fresh weight basis, and are relatively high in the essential C18 fatty acids, oleic acid (18: 1), linoleic acid (18:2) and linolenic acid (18:3) (DeFoliart, 1991). The Coleoptera (beetles and weevils) are generally particularly high in C 18:2 while the Lepidoptera (butterflies and moths) are particularly high in C 18:3 (Fast, 1970). The essential fatty acids, provide precursors for the hormone-like compounds needed for localized metabolic regulation in many tissues, to regulate cellular lipid metabolism, are required for growth (Dadd 1983), and regulate the fluidity of the membranes in thermo-conforming organisms (Stanley and Samuelson et al 1988). Vertebrate metabolic studies show that vertebrates are poor at metabolising new forms of fatty acids and so they should be provided in diet"*.

For reptiles, linoleic acid is the primary essential fatty acid with requirement of 1% of the diet. According to Wallach JD and Hoff GL (1982)[16] "*If the diet becomes deficient in this EFA, a rapid decline in cellular integrity occurs. This is manifested clinically by the skin becoming flaky, inelastic, and prone to recurrent infections and also to fluid loss through the skin, which in turn leads to polydipsia*".

Considering that fatty acids are essential diet requirement in the diet of amphibians and reptiles, it is not expected that rapeoil will have endocrine disruptive properties in these organisms.

One acceptable formulation NEU 1160 I EC toxicity study on the early-life stages of Zebrafish *Danio rerio* is available. The test was performed as a semi-static limit test with a duration of 35 days. The nominal limit test concentration was 40.0 mg/L NEU 1160 I EC and a control with untreated test medium. The formulation was administered three times per week, no sublethal effects or behavioral abnormalities related to toxicity of the test item were observed.

Fish, just like other vertebrates, require fatty acids for normal growth and development, including reproduction[17].
Taken together, in the absence of mortality and sublethal effects in the ELS study and the general knowledge on the fish nutrition, rapeoil is not expected to have endocrine disruptive properties in fish.

The RMS concludes that the rapeoil does not have endocrine disruptive properties that may cause adverse effects on non-target organisms.

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[13] European food safety authority (2013): Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/rape oil; EFSA Journal 2013; 11(1): 3058
[14] Reptile and Amphibian Nutrition | Veterian Key
[15] Browne RK. 2009. Amphibian diet and nutrition. AArk Science and Research, Microsoft Word - Amphibian diet and nutrition.docx (amphibianark.org)
[16] Wallach JD, Hoff, GL. Metabolic and Nutritional Diseases of Reptiles. In *Hoff GL, Davis JW (eds), Noninfectiopus Diseases of Wildlife,* pp. 155-167. Ames, IA. The Iowa State University Press, 1982

[17] Sargent J et al. 1999 Recent developments in the essential fatty acids nutrition of fish, Aquaculture, Vol. 177 (1-4), pg 191-199

RMS human toxicology note: Fatty acids are known signaling molecules which can interfere in the hormonal balance and in the lipid metabolism via binding to the PPAR receptors. To assess the possible effects on humans various literature studies have been evaluated. None of these studies showed a severe weight gain or loss in the tested animals as proposed by the mode of action. Furthermore, there were no studies that specifically investigated endocrine mechanisms therefore the knowledge on rape oil as part of mammalian food consumption was taken into account. From this it can be concluded that any disruptive effect on the endocrine system would already have been observed on an epidemiological level and would undoubtably have triggered further investigations.

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of fatty acids (E 570) when used as a food additive (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4785). The opinion is summarised below:

The food additive includes caprylic- (C8), capric- (C10), lauric- (C12), myristic- (C14), palmitic- (C16), stearic- (C18) andoleic acid (C18:1), present alone or in combination. In 1991, the Scientific Committee on Food (SCF) established a group acceptable daily intake (ADI) ‘not specified’ for the fatty acids (myristic, stearic, palmitic and oleic acid). The fatty acids (E 570) are absorbed in the same way as the free fatty acids from the regular diet. They show low acute toxicity. The available studies on subchronic toxicity were limited but there was no evidence for toxic effects at doses up to 10% in the diet (equivalent to 9,000 mg lauric acid/kg body weight (bw) per day). The Panel considered that the fatty acids (E 570) did not raise a concern for genotoxicity. Data on chronic toxicity, reproductive toxicity and developmental toxicity were too limited to reach a conclusion on these endpoints. The Panel noted that the contribution of fatty acids (E 570) represented on average only 1% of the overall exposure to saturated fatty acids from all dietary sources (food additive and regular diet). Based on the approach described in the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 and taking into account the considerations mentioned above, the Panel concluded that the food additive fatty acids (E 570) was of no safety concern at the reported uses and use levels.

According to the RMS in the light of the above findings and based on the nature of the substance, its intrinsic properties, natural occurrence and widespread traditional use as feed- and foodstuff as well as the absence of any evidence of adversity, the RMS concludes that Rape oil is not to be regarded as endocrine disruptive substance.

During the Pesticide Peer Review TC64 (15-19 November 2021) all available information on rape oil was taken into account by the experts for the weight of evidence approach on endocrine disruption. All the experts agreed with the RMS that based on the accepted low toxicity of rape oil to mammals, the natural occurrence of the substance, the widespread traditional use as feed- and food-stuff and lack of known adverse effects the ED assessment can be waived. Furthermore, the experts indicate that although rape oil is acting on the lipid metabolism, the overall weight of evidence indicates that this has no consequences on the thyroid hormone system. All experts agreed that it is highly unlikely that rape oil will meet the endocrine disruption criteria based on its intrinsic properties and available evidence.

Level 3

Rape oil

3 PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1 BACKGROUND TO THE PROPOSED DECISION

3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1 Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	x		~~Open.~~ ~~A risk to bees, non-target arthropods and aquatic organisms cannot be excluded for all intended uses.~~
3.1.1.2 Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	X		
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			*Not applicable*

3.1.1.3 Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.		X	
3.1.1.4 Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		Reference values are not necessary for rape oil. TDI for erucic acid is high. The maximum level of 2% erucic acid is no longer set out in the specification.
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;	X		Rape oil is a food commodity and fatty acids are naturally present in the plants. Additionally, toxicological reference values (ADI, ARfD) are not considered necessary. No MRLs are proposed. Therefore, a quantitative consumer risk assessment is considered as not required and rape oil can be considered as a candidate for Annex IV of Regulation (EC) No 396/2005.

	(e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.			
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		Products containing rape oil as active ingredient have been authorized at memberstate level for > 10 years. Representative products are authorized as insecticide/acaricide in ornamental and edible
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content	X		Technical Rape oil is 100% pure, consisting of a mixture of fatty acids and triglycerides. The maximum level of 2% erucic acid is no longer set out in the specification.

	of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.			
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	X		NO FAO specification available.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted		X	NO FAO specification available.
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		No post-registration analytical monitoring methods required.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		

Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		Reference values are not necessary.
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation. Therefore no genotoxic potential is expected being supported by scientific opinions from different EFSA panels.
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**		X	Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation. Therefore no carcinogenic potential is expected being supported by scientific opinions from different EFSA panels.

ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not applicable
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation. Therefore no reproduction potential is expected being supported by scientific opinions from different EFSA panels.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or			Not applicable.

	synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β -oxidation. Fatty acids are known signaling molecules which can interfere in the hormonal balance and in the lipid metabolism via binding to the PPAR receptors. no EATS mediated effects are expected. Therefore no endocrine disrupting potential is expected.
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	Fat, oils and fatty acids are essential components of our daily food. Rape oil is metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via β-oxidation. Fatty acids are known signaling molecules which can interfere in the hormonal balance and in the lipid metabolism via binding to the PPAR receptors. no EATS mediated effects are expected. Therefore no endocrine disrupting potential is expected.
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used			Not applicable.

	in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	Rape oil is readily biodegradable.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	Rape oil is readily biodegradable. The chronic aquatic NOEC for marine of freshwater organisms is > 0.01 mg/L,
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	Rape oil is readily biodegradable.
Ecotoxicology				
		Yes	No	

	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.		X	For terrestrial vertebrate wildlife no risk assessment with endpoints is done due to the lack of endpoints. Based on peer-reviewed literature data, there are no indications of adverse effects of rape oil on terrestrial vertebrate wildlife when used as a active substance in a plant protection product and used in such a purpose. The risk to aquatic organisms is acceptable for all intended uses, provided risk mitigation measures are applied (buffer zones).~~, provided that the applicant addresses the following issues:~~ ~~- For the aquatic study with NEU 1128 I SL (KCP 10.2.1/03 ; S16-00257), the test was performed with a different formulation (NEU 1128 I SL; 47.26 % m/m potassium salts of fatty acids) than the representative formulation for the RAR (NEU 1160 I EC; 96% w/w rape oil (872.6 g/L). The notifier is requested to clarify how the active substance in this formulation is equivalent to the one in the representative formulation.~~ ~~A risk to bees cannot be excluded for all uses, except the professional uses in permanent glasshouses. This could be addressed as follows :~~ ~~- Further information to adress the issues highlighted for the tunnel test results on colony strength and brood development (see section B.9.5.1.4 and Vol. 1, section 2.9.3.1), or a new larvae toxicity test in which measurements of effects on pupation and pupa emergence are included, or a well sustained waiver on why effects on bee brood development are not considered relevant.~~

				~~- A well justified argumentation on the suitability of the tunnel test to cover for the dose rates of the intended uses.~~ ~~- Justification for extrapolating the results from the tunnel test with formulation NEU 1128 I to the representative formulation NEU 1160 I.~~ ~~- For the professional uses in permanent glasshouses in berry bushes, vegetables, woody ornamentals and ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level).~~ ~~- In addition to the above, to accept the results from the chronic adult toxicity test, chemical analysis should be performed to confirm the nominal dose levels. If the measured concentrations are <80% of nominal, recalculation of endpoints based on measured concentrations is required.~~ The risk to bees is considered acceptable for all proposed uses, except for the non-professional glasshouse use in woody ornamentals, due to the high application rate. For the professional use in permanent glasshouses in woody ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level). For non-target arthropods an acceptable in-feld risk was demonstrated for the use in berry bushes, vegetables, ornamentals (except woody ornamentals) and potatoes.

				For the uses in pome and stone fruit and woody ornamentals an in-field risk cannot be excluded. Exception to this is the professional use in permanent glasshouses in woody ornamentals: for this use the risk can be adressed with appropriate warning sentences for NTA used in IPM. However, the exact sentences are to be determined at member state level. The off-field risk was not acceptable for any of the uses, with the exception of the professional uses in permanent glasshouses, for which no off-field risk assessment is performed. This concerns the professional uses in permanent glasshouses in berry bushes, vegetables and ornamentals (inlcuding woody ornamentals). To adress the risk (in-field and off-field), RMS suggests to applicant to perform a single species field study with *T. pyri*, covering the predicted exposure rates for both in- and off-field. The risk to earthworms and other soil non-target meso- and macro-organisms is acceptable for the uses in berry bushes, potatoes, pome and stone fruit, vegetables and ornamentals. For the use in woody ornamentals, based on the TER-values for *Folsomia candida* and *Hypoaspis aculeifer*, a risk for soil organisms cannot be excluded due to the high application rate. Exception to this is the professional use in permanent glasshouses in woody ornamentals, for which exposure of soil organisms is considered not relevant by several Members States due to the regular sterilisation of the glasshouse soil. The risk to soil microbial processes from the proposed uses of NEU 1160 I is considered to be acceptable for all intended uses.

				The risk for non-target terrestrial plants is considered acceptable for all intended uses.
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	The RMS concludes that the rapeoil does not have endocrine disruptive properties that may cause adverse effects on non-target organisms, please refer to the section 2.14 above.
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.			Not applicable
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.		X	The risk to bees is considered acceptable for all proposed uses, except for the non-professional glasshouse use in woody ornamentals, due to the high application rate. For the professional use in permanent glasshouses in woody ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level). ~~A risk to bees cannot be excluded for all uses, except the professional uses in permanent glasshouses. This could be addressed as follows :~~ ~~- Further information to adress the issues highlighted for the tunnel test results on colony strength and brood development (see section~~

				~~B.9.5.1.4 and Vol. 1, section 2.9.3.1), or a new larvae toxicity test in which measurements of effects on pupation and pupa emergence are included, or a well sustained waiver on why effects on bee brood development are not considered relevant.~~ ~~- A well justified argumentation on the suitability of the tunnel test to cover for the dose rates of the intended uses.~~ ~~- Justification for extrapolating the results from the tunnel test with formulation NEU 1128 I to the representative formulation NEU 1160 I.~~ ~~- For the professional uses in permanent glasshouses in berry bushes, vegetables, woody ornamentals and ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level).~~ ~~- In addition to the above, to accept the results from the chronic adult toxicity test, chemical analysis should be performed to confirm the nominal dose levels. If the measured concentrations are <80% of nominal, recalculation of endpoints based on measured concentrations is required~~.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		No residue definition is proposed, not required. Rape oil is proposed to be included in Annex IV of the Regulation 396/2005.
Fate and behaviour concerning groundwater				
		Yes	No	

	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		Due to the rapid degradation and high adsorption of rape oil and potential metabolites all predicted concentrations in groundwater are < 0.001 µg/L.

3.1.2 Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	

3.1.3 Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** If the active substance is not a micro-organism, in particular it is considered that: (a) the substance **should NOT be classified or proposed for classification** in accordance to Regulation (EC) No 1272/2008 as any of the following: — carcinogenic category 1A, 1B or 2, — mutagenic category 1A, 1B or 2, — toxic to reproduction category 1A, 1B or 2, — skin sensitiser category 1, — serious damage to eye category 1, — respiratory sensitiser category 1, — acute toxicity category 1, 2 or 3, — specific Target Organ Toxicant, category 1 or 2, — toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests,	X		No classification proposed.

	— explosive, — skin corrosive, category 1A, 1B or 1C; (b) it has **not been identified as priority substance under Directive 2000/60/EC**; (c) it is **not deemed to be an endocrine disruptor** in accordance to Annex II of Regulation (EC) No 1107/2009; (d) it **has no neurotoxic or immunotoxic effects**; (e) it **is not persistent** (half-life in soil is more than 60 days) or its **bio-concentration factor is lower than 100**. (f) it is a **semiochemical** and verifies points (a) to (d). Paragraph (e) doesn't apply to naturally occurring active substances. If the active substance is a micro-organism, in particular it is considered that at strain level the micro-organism has not demonstrated multiple resistance to anti-microbials used in human or veterinary medicine. If the active substance is a baculovirus, in particular it has not demonstrated adverse effects on non-target insects.			

3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
3.1.4.1 Identity of the active substance or formulation				
-	-	-	-	-
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
Active substance: ~~B.2.4/05, UV/Vis, IR and MS spectra for the relevant impurity Erucic acid. *Erucic acid at a maximum of 2% is considered an relevant impurity in Rape oil however this value is open for discussion (see Volume 4).*~~	-			
Formulation NEU 1160 I: B.2.4/02 (KCP 2.4/001), The temperature at which the pH was determined (initial and after storage)	-			

was not provided, as is required according to CIPAC MT 75.3.				
Formulation NEU 1160 I: B.2.7/01 (KCP 2.7/01) and B.2.7/03 (KCP 2.7/03), No final storage stability can be stated for the formulation NEU 1160I, additional data should be provided to support an 2 year shelf-life, also as no acceptable accelerated storage stability data is available.	-			
3.1.4.3 Data on uses and efficacy				
No data gap.				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
No data gap.				
3.1.4.5 Methods of analysis				
Active substance : B.5.1.2 (KCA 4.1.2/01), provide the final signed study report by C. Jansen (Validation of an analytical method for the determination of Rape oil	-			

and fatty acids in soil and aerobic soil degradation of Rape oil) and GLP status.				
3.1.4.6 Toxicology and metabolism				
None ~~Applicant could you please address medical surveillance on manufacturing plant personnel and monitoring by e,g. submitting a statement that no adverse effects were observed in the manufacturing plant.~~ ~~Applicant could you please address medical surveillance on manufacturing plant personnel and monitoring by e,g. submitting a statement that no adverse effects were observed in the manufacturing plant.~~				
~~Applicant please submit the study performed by Marzin (1999).~~				
~~Applicant please submit the composition of NEU 1161 I and give detailed information about the co-formulants (C&L) to address the bridging possibilities.~~				

3.1.4.7 Residue data				
None				
3.1.4.8 Environmental fate and behaviour				
None				
3.1.4.9 Ecotoxicology				
~~A risk to bees cannot be excluded for all uses, except the professional uses in permanent glasshouses. This could be addressed as follows :~~ ~~- Further information to adress the issues highlighted for the tunnel test results on colony strength and brood development (see section B.9.5.1.4 and Vol. 1, section 2.9.3.1), or a new larvae toxicity test in which measurements of effects on pupation and~~				

~~pupa emergence are included, or a well sustained waiver on why effects on bee brood development are not considered relevant.~~ ~~- A well justified argumentation on the suitability of the tunnel test to cover for the dose rates of the intended uses.~~ ~~- For the professional uses in permanent glasshouses in berry bushes, vegetables, woody ornamentals and ornamentals the risk can be adressed with restriction sentences on the label (i.e. Spe8, to be further specified at member state level).~~ ~~- Justification for extrapolating the results from the tunnel test with formulation NEU 1128 I to the representative formulation NEU 1160 I.~~ ~~- In addition to the above, to accept the results from the chronic adult toxicity test, chemical analysis should be performed to confirm the nominal dose levels. If the measured concentrations are <80% of nominal, recalculation of endpoints based on measured concentrations is required.~~				

To address the identified risks for non-target arthropods (in-field and off-field), RMS suggests to applicant to perform a single species field study with *T. pyri*, covering the predicted exposure rates for both in- and off-field.				

3.1.5 Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
~~For the aquatic study with NEU 1128 I SL (KCP 10.2.1/03 ; S16 00257), the test was performed with a different formulation (NEU 1128 I SL; 47.26 % m/m potassium salts of fatty acids) than the representative formulation for the RAR (NEU 1160 I EC; 96% w/w rape oil (872.6 g/L). The notifier is requested to clarify how the active substance in this formulation is equivalent to the one in the representative formulation.~~	~~Relevant for all uses.~~
~~Bees:~~ ~~KCP 10.3.1.2 / Ehmke 2016b: These study endpoints are valid provided that chemical analysis is performed and confirms the nominal dose levels. If the measured concentrations are <80% of nominal, recalculation of endpoints based on measured concentrations is required.~~ ~~See Vol. 3 CP, section B.9.5.1.2 for further details.~~	~~Relevant for all uses.~~
RMS to confirm whether the batches used in the ecotoxicological toxicity studies are compliant with the technical specification of the a.s. in line with the Commission guidance (European Commission, 2012).	Relevant for all uses.

3.1.6 Critical areas of concern

An issue is listed as a critical area of concern:

(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including

non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
~~Risk assessment for honeybees~~	~~Relevant for all uses.~~
~~Risk assessment for non-target arthropods~~	~~Relevant for all uses.~~

3.1.7 Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)
All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		All uses (X^1)	Use "B" (X^1)
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X	
	Assessment not finalised	X	
Risk to aquatic organisms	Risk identified		
	Assessment not finalised	~~X~~	
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8 Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
~~Volume 4, C.1.2.3. (a) Analytical profile of batches, maximum value of the relevant impurity Erucic acid~~	~~*The applicant has indicated that it does not agree with the view of EFSA considering Erucic Acid as relevant impurity (EFSA Journal 2013;11(1):3058, page 22). Based on the content <0.05 % w.w LOQ (or even <0.005 % w/w LOD) in the new 5 batch analysis this may be justified. However the evaluation of the assignment of relevance for this compound should be done within the toxicological and ecotoxicological sections of the dossier. In the view of the RMS, based on the 5 batch data, the following three options are open to be further discussed before finalization:*~~ ~~*1) keep the level at <2%, or*~~ ~~*2) lower its content to <0.05% or*~~ ~~*3) conclude that this impurity is non relevant anymore and should therefore be removed from the reference specification (as <0.1%).*~~ ~~*The RMS has chosen, until now, to keep the level at <2%, as no indication is provided, based on toxicological, ecotoxicological and environment reasoning, to change this. However this view is open for discussion.*~~
Risk to bees	

3.1.9 Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS

3.2 PROPOSED DECISION

It is still inconclusive whether Rape oil can be renewed under Regulation (EC) No 1107/2009. Additional information or mitigation measures are needed to reduce the risk to bees and aquatic organisms.

3.3 RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPROVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1 Particular conditions proposed to be taken into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)
	[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]

3.4 APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

Guidances in place at the moment of submission of the application for renewal.

3.5 REFERENCE LIST

List [in the conventional format] any references specifically cited in Volume 1 (i.e references to underpinning documents such as PPR-Panel Opinions, EFSA conclusions, national documents etc.).

Section identity, physical chemical and analytical methods

Section data on application and efficacy

Section toxicology

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 5.1.1/01	Asadi, F.; Shahriari, A.; Chahardah -Cheric, M.	2010	Effect of long-term optional ingestion of canola oil, grape seed oil, corn oil and yogurt butter on serum, muscle and liver cholesterol status in rats Food and chemical toxicology 48:8-9, pp. 2454-2457 2010 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.1.1/02	Pieszka, M.; Tombarkiewicz, B.;	2013	Effect of bioactive substances	Y	N	n.a.	--	Not EU peer reviewed

	Roman, A.; Migdal, W.; Niedziolka, J.		found in Rape seed, raspberry and strawberry seed oils on blood lipid profile and selected parameters of oxidative status in rats Environmental toxicology and pharmacology 36:3, pp. 1055-1062 2013 GLP: no, published					
KCA 5.1.1/03	Berroukche, A.; Hachem, K.; Benabdesslem, Y.; Siouda, W.; Aoued, S. R.	2015	Study of nutritional effects of Rape seed and sunflower oils on ponderal and biochemical parameters in Wistar rats American journal of biochemistry 5:5, pp. 85-91 2015 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.1.1/04	Ohara, N.; Naito, Y.; Kasama, K.; Shindo, T.; Yoshida, H.; Nagata, T.; Okuyama, H.	2009	Similar changes in clinical and pathological parameters in Wistar Kyoto rats after a 13-week dietary intake of canola oil or a fatty acid composition-based interesterified canola oil mimic Food and chemical toxicology 47:1, pp. 157–162 2009 GLP: no,	Y	N	n.a.	--	Not EU peer reviewed

			published					
KCA 5.1.1/05	Monteiro, J. P.; Pereira, C. V.; Silva, A. M.; Maciel, E.; Baldeiras, I.; Peixoto, F.; Domingues, M. R.; Jurado, A. S.; Oliveira, P. J.	2013	Rape seed oil-rich diet alters hepatic mitochondrial membrane lipid composition and disrupts bioenergetics Archives of toxicology 87:12, pp. 2151–2163 2013 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.1.1/06	Ohara, N.; Naito, Y.; Nagata, T.; Tachibana, S.; Okimoto, M.; Okuyama, H.	2008	Dietary intake of Rape seed oil as the sole fat nutrient in Wistar rats--lack of increase in plasma lipids and renal lesions The journal of toxicological sciences 33:5, pp. 641–645 2008 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.1.1/07	Scalerandi, M. V.; Gonzalez, M. A.; Sain, J.; Farina, A. C.; Bernal, C. A.	2014	Effect of conjugated linoleic acid mixtures and different edible oils in body composition and lipid regulation in mice Nutricion hospitalaria 29:3, pp. 591-601 2014 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.1.1/08	WHO/FAO	1994	Aspects of fat digestion and metabolism. In: Fats and oils in human nutrition. Report of a	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

			joint expert consultation FAO Food and nutrition paper 57, pp. 17-25 1994 GLP: no, published					
KCA 5.1.1/09	Kramer, J.K.G., Sauer, F.D.	1983a	Results obtained with feeding low erucic acid Rape seed oils and other vegetable oils to rats and other species. High and low erucic acid Rape seed oils. Production, usage, chemistry, and toxicological examination. (J. K. G. Kramer, F.D. Sauer and W.J. Pigden, eds.). Academic Press, Toronto, Canada, pp. 413–474 1983 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.1.1/10	Kramer, J.K.G., Sauer, F.D.	1983b	Cardiac lipid changes in rats, pigs and monkeys fed high fat diets High and low erucic acid Rape seed oils. Production, usage, chemistry, and toxicological examination. (J. K. G. Kramer, F.D. Sauer and W.J. Pigden, eds.). Academic Press, Toronto, Canada, pp. 475–513 1983 GLP: no,	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

			published					
KCA 5.2.1	Anonymous	2005	Opinion of the scientific panel on dietetic products, nutrition and allergies on a request from the commission related to Rape seed oil high in unsaponifiable matter as a novel food ingredient The EFSA Journal, 304, pp. 1-11 2005 GLP: no, published	N	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.1/01	Kramer, J.K.G., Sauer, F.D., Wolynetz, M.S., Farnworth, E.R., Johnston, K.M.	1992	Effects of dietary saturated fat on erucic acid induced myocardial lipidosis in rats Lipids 27, pp. 619–623 1992 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.1/02	Zhang, L., Tan, Y., Ouyang, Y., Wang, R.	1991	Effects of high erucic acid Rape seed oil on fatty acid oxidation in rat liver Biomedical and environmental sciences 4, pp. 262–267. 1991 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.1/03	Badawy, I.H., Atta, B., Ahmed, W.M.	1994	Biochemical and toxicological studies on the effect of high and low erucic acid Rape seed oil on rats	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

			Die Nahrung 38, pp. 402–411 1994 GLP: no, published					
KCA 5.3.1/04	Vogtmann, H., Christian, R., Hardin, R.T., Clandinin, D.R	1975	The effects of high and low erucic acid Rape seed oils in diets for rats J. Vit. Nutr. Res., 45 (2), pp. 221-229 1975 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.2/01	Watkins, T.R., Lenz, P.H., Sideritis, R., Struck, M., Bierenbaum, M.L.	1995	Dietary mustard, rape seed oils and selenium exert distinct effects on serum Se, lipids, peroxidation products and platelet aggregability J. Am. Coll. Nutr. 14, pp. 176–183. 1995 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.2/02	Kramer, J.K.G., Farnworth, E.R., Johnston, K.M., Wolynetz, M.S., Modler, H.W., Sauer, F.D.	1990	Myocardial changes in newborn piglets fed sow milk or milk replacer diets containing different levels of erucic acid Lipids 25 (11), pp. 729–737 1990 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.3.2/03	Cullen, C., Singh, A., Shahidi, E.	1996	Ultrastructure of liver from piglets fed Tower Rape seed oil Histol. Histopathol. 11 (1), pp. 27–33 1996 GLP: no,	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

			published					
KCA 5.3.2/04	Aherne, F.X., Bowland, J.P., Christian, R.G., Hardin, R.T.	1976	Performance of myocardial and blood seral changes in pigs fed diets containing high or low erucic acid Rape seed oils Can. J. Anim. Sci. 56, pp. 275–284 1976 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.4.1/01	Lewinska, A.; Zebrowski, J.; Duda, M.; Gorka, A.; Wnuk, M.	2015	Fatty acid profile and biological activities of linseed and Rape seed oils Molecules 20:12, pp. 22872-22880 2015 GLP: no, published	N	N	n.a.	--	Not EU peer reviewed
KCA 5.4.1/02	Oliveira, N. de M. S.; Resende, M. R.; Morales, A. D.; Umbuzeiro , G. de ragao; Boriollo, M. F. G.	2016	In vitro mutagenicity assay (Ames test) and phytochemical characterizatio n of seeds oil of Helianthus annuus Linné (sunflower) Toxicology reports 3, pp. 733-739 2016 GLP: no, published	N	N	n.a.	--	Not EU peer reviewed
KCA 5.4.1/03	Chen, H.; Yang, M.; Ye, S.	1992	A study on genotoxicity of cooking fumes from Rape seed oil Biomed Environ Sci 1992, 5(3), pp. 229-35 1992 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

KCA 5.5/01	Ion, G.; Akinsete, J. A.; Hardman, W. E.	2010	Maternal consumption of canola oil suppressed mammary gland tumorigenesis in C3(1) TAg mice offspring Biochemistry and microbiology 10:81 2010 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.5/02	He, X. Q.; Duan, J.-L.; Zhou, J.; Song, Z.-Y.; Cichello, S. A.	2015	Effects of two traditional chinese cooking oils, canola and pork, on pH and cholic acid content of faeces and colon tumorigenesis in Kunming mice Asian pacific journal of cancer prevention 16:15, pp. 6225–6229 2015 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.5/03	He, X.-Q.; Cichello, S. A.; Duan, J.-L.; Zhou, J.	2014	Canola oil influence on azoxymethane-induced colon carcinogenesis, hypertriglyceridemia and hyperglycemia in Kunming mice Asian pacific journal of cancer prevention 15:6, pp. 2477–2483 2014 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed

KCA 5.5/04	Bhatia, E.; Doddivenaka, C.; Zhang, X.; Bommareddy, A.; Krishnan, P.; Matthees, D. P.; Dwivedi, C.	2011	Chemopreventive effects of dietary canola oil on colon cancer development Nutrition and cancer 63:2, pp. 242-247 2011 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.5/05	Hardman, W. E.	2007	Dietary canola oil suppressed growth of implanted MDA-MB 231 human breast tumors in nude mice Nutrition and cancer 57:2, pp. 177-183 2007 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.5/06	Mabasa, L.; Cho, K.; Walters, M. W.; Bae, S.; Park, C. S.	2013	Maternal dietary canola oil suppresses growth of mammary carcinogenesis in female rat offspring Nutrition and cancer 65 (5), pp. 695-701 2013 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.5/07	Engfeldt, B., Brunius, E	1975	Morphological effects of Rape seed oil in rats: II. Long-term studies Acta Med. Scand. Suppl. 585, pp. 27-40 1975 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed
KCA 5.5/08	Duthie, I.F., Barlow, S.M., Ashby, R., Tesh, J.M., Whitney,	1988	Feeding of partially hydrogenated fish oils to rats in comparison with partially hydrogenated	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

	J.C., Saunders, A., Chapman, E., Norum, K.R., Svaar, H., Opstvedt, J.		soybean oil and refined Rape seed oil: A combined chronic oral toxicity and carcinogenicity study with in-utero phase Acta Med. Scand. Suppl. 726, pp. 1-89 1988 GLP: no, published					
KCA 5.5/09	Suzuki, H., Yamazaki, M., Arai, S., Nagao, A., Terao, J.	1991	Effect of lard, palm and Rape seed oil life conservation in aged mice Mechanism of ageing and development, 60, pp. 267-274 GLP: no, published	Y	N	n.a.	--	DAR 2008
KCA 5.5/10	Yamashiro, S., Clandinin, M.T.	1980	Myocardial ultrastructure of rats fed high and low erucid acid rape seed oils Experimental and molecular pathology, 33, pp. 55-64 GLP: no published	Y	N	n.a.	--	DAR 2008
KCA 5.6.1/01	Duthie, I.F., Barlow, S.M., Ashby, R., Tesh, J.M., Whitney, J.C., Saunders, A., Chapman, E., Norum, K.R., Svaar, H., Opstvedt, J.	1988	Feeding of partially hydrogenated fish oils to rats in comparison with partially hydrogenated soybean oil and refined Rape seed oil: A combined chronic oral toxicity and carcinogenicity study with in-utero phase Acta Med. Scand. Suppl. 726, pp. 1-89	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

			1988 GLP: no, published					
KCA 5.6.1/02	Reyes, H., Ribalta, J., Hernández, I., Arrese, M., Pak, N., Wells, M., Kirsch, R. E	1995	Is dietary erucic acid hepatotoxic in pregnancy? An experimental study in rats and hamsters Hepatology 21 (5), pp. 1373 1379 1995 GLP: no, published	Y	N	n.a.	--	DAR 2008
KCA 5.8.2/01	Kabiri Rad, M.; Neamati, A.; Boskabady, M.H.; Mahdavi-Shahri, N.; Mahmoudabady, M.	2013	The preventive effect of Brassica napus L. oil on pathophysiological changes of respiratory system in experimental asthmatic rat Avicenna journal of phytomedicine 3:1, pp. 56–63 2013 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.8.2/02	Ion, G.; Fazio, K.; Akinsete, J. A.; Hardman, W. E.	2011	Effects of canola and corn oil mimetic on Jurkat cells Lipids in health and disease 10:90 2011 GLP: no, published	N	N	n.a.	--	Not EU peer reviewed
KCA 5.9.2/01	Kruse, M.; Loeffelholz, C. von; Hoffmann, D.; Pohlmann, A.; Seltmann, A. C.; Osterhoff, M.; Horneman	2015	Dietary Rape seed/canola-oil supplementation reduces serum lipids and liver enzymes and alters postprandial inflammatory responses in adipose tissue	Y	N	n.a.	--	Not EU peer reviewed

	n, S.; Pivovarova, O.; Rohn, S.; Jahreis, G.; Pfeiffer, A. F. H.		compared to olive-oil supplementation in obese men Molecular nutrition & food research 59:3, pp. 507-519 2015 GLP: no, published					
KCA 5.9.2/02	Gillingham, L. G.; Gustafson, J. A.; Han, S.-Y.; Jassal, D. S.; Jones, P. J.H.	2011	High-oleic Rape seed (canola) and flaxseed oils modulate serum lipids and inflammatory biomarkers in hypercholesterolaemic subjects The british journal of nutrition 105:3, pp. 417-427 2011 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.9.2/03	Senanayake, V. K.; Pu, S.; Jenkins, D. A.; Lamarche, B.; Kris-Etherton, P. M.; West, S. G.; Fleming, J. A.; Liu, X.; McCrea, C. E.; Jones, P. J.	2014	Plasma fatty acid changes following consumption of dietary oils containing n-3, n-6, and n-9 fatty acids at different proportions: preliminary findings of the Canola Oil Multicenter Intervention Trial (COMIT) Trials 15:136 2014 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.9.2/04	Gelpi, E.; de la Paz, M.P.; Terracini, B.; Abaitua, I.; de la	2002	The Spanish toxic oil syndrome 20 years after its onset: a multidisciplinary review of	Y	N	n.a.	--	Not EU peer reviewed

	Camara, A.G.; Kilbourne, E.M.; Lahoz, C.; Nemery, B.; Philen, R.M.; Soldevilla, L.; Tarkowski, S.		scientific knowledge Environ. Health Perspect. 110 (5), pp. 457-464 2002 GLP: no, published					
KCA 5.9.3/01	Fonseca, E.	2009	Skin manifestations of toxic syndrome due to denatured Rape seed oil Actas dermosifiliograf. 100:10, pp. 857-860 2009 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.9.3/02	WHO/FAO	1994	Aspects of fat digestion and metabolism. In: Fats and oils in human nutrition. Report of a joint expert consultation FAO Food and nutrition paper 57, pp.17-25 1994 GLP: no, published	Y	N	n.a.	--	Not EU peer reviewed
KCA 5.9.4/01	Aguinaga, M. L. G.; Paz, M. P.; Cabo, E. E.; Cano, M. del M. P.; Alvarez, C. S.; Saro, B. B.; Borda, I. A.; Sanchez, R. G.; Hernandez, F. J. B.	2008	High prevalence of cardiovascular risk in patients with toxic oil syndrome: a comparative study using the general Spanish population European journal of internal medicine 19:1, pp. 32-39 2008 GLP: no,	Y	N	n.a.	--	Not EU peer reviewed

			published					
KCA 5.9.7/01	WHO/FAO	1994	Aspects of fat digestion and metabolism. In: Fats and oils in human nutrition. Report of a joint expert consultation FAO Food and nutrition paper 57, pp.17-25 1994 GLP: no, published	Y	N	n.a.	--	Spain 2010 (technical equivalence) Not EU peer reviewed

Data Point	**Author(s)**	**Year**	**Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previous evaluation**
KCP 7.1.1/01		1996a	Assessment of acute oral toxicity with NEU 1161 I in the rat Report No.: 170764 GLP, unpublished	Y	N	--	NEU	Submitted for product approval and in DAR 2007
KCP 7.1.2/01		1996b	Assessment of acute dermal toxicity with NEU 1161 I in the rat Report No.: 170775 GLP, unpublished	Y	N	--	NEU	Submitted for product approval and in DAR 2007
KCP 7.1.3/01		1996	Acute inhalation toxicity – NEU 1161 I Report No.: 96 5041 804 GLP, unpublished	Y	N	--	NEU	Submitted for product approval and in DAR 2007
KCP 7.1.4/01		1997	Primary skin irritation/corrosion study with NEU 1161 I in the rabbit (4-hour semi-	Y	N	--	NEU	Submitted for product approval and in DAR 2007

			occlusive application) Report No.: 205739 GLP, unpublished					
KCP 7.1.5/01		1996c	Acute eye irritation/corrosion study with NEU 1161 I in the rabbit Report No.: 170797 GLP, unpublished	Y	N	--	NEU	Submitted for product approval and in DAR 2007
KCP 7.1.6/01		2002	Assessment of contact hypersensitivity to NEU 1160 I in the albino guinea pig (maximisation-test) Report No.: 356052 GLP, unpublished	Y	N	--	NEU	Submitted for product approval and in DAR 2007

Section residue and consumer risk assessment

Section fate and behavior in environment

Data Point	**Author(s)**	**Year**	**Title Company Report No. Source (where different from company) GLP or GEP status Published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previous evaluation**
KCA 7.2.2.1/01	Beran, E.	2008	Experience with evaluating biodegradabilit	N	N	n.a.	--	N.A.

			y of lubricating base oils Tribology international 41 (12), pp. 1212–1218 2008 GLP: no, published					
KCA 7.2.2.1/ 02	Vauhkonen , V.; Lauhanen, R.; Ventelä, S.; Suojaranta, J.; Pasila, A.; Kuokkanen , T.; Prokkola, H.; Syväjärvi, S.	2011	The phytotoxic effects and biodegradabilit y of stored rape seed oil Agricultural and food science 20, pp.131-142 2011 GLP: no, published	N	N	n.a.	--	N.A.
KCA 7.2.2.1/ 03	Feil, N.	2008	Ready biodegradabilit y of rape seed oil, refined in a manometric respirometry test. IBACON Project 39151163, 2008-06-24 GLP: yes, unpublished	N	Y	2010 Spain (technical equivalence)	SCO	Not EU reviewed, 2010 Spain (technical equivalence)
KCA 7.2.2.1/ 07	Fabig, W., Hund, K.,	1989	Biotic degradation of rape seed oils.	N	N	n.a.	--	Not EU reviewed, 2010 Spain

	Gross, K.-J.		Fat Sci. Technol. 91 (9), pp. 357-360 1989 GLP: no, published					(technical equivalence)
KCP 10.5/03	Brunswik-Titze, A.	2017	NEU 1160 I EC: Assessment of the ready Biodegradability with the Manometric Respirometry Test according to OECD 301 F (July 1992) Hydrotox Labor für Ökotoxikologie und Gewässerschutz GmbH, Germany Report No.: 1129 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU approval

Section residue and consumer risk assessment

Section fate and behavior in environment

Data Point	Author(s)	Year	Title Company Report No.	Vertebrate study Y/N	Data protection claimed	Justification if data	Owner	Previous evaluation

			Source (where different from company) GLP or GEP status Published or not		**Y/N**	**protection is claimed**		
KCA 7.2.2.1/ 01	Beran, E.	2008	Experience with evaluating biodegradabilit y of lubricating base oils Tribology international 41 (12), pp. 1212–1218 2008 GLP: no, published	N	N	n.a.	--	N.A.
KCA 7.2.2.1/ 02	Vauhkonen , V.; Lauhanen, R.; Ventelä, S.; Suojaranta, J.; Pasila, A.; Kuokkanen , T.; Prokkola, H.; Syväjärvi, S.	2011	The phytotoxic effects and biodegradabilit y of stored rape seed oil Agricultural and food science 20, pp.131-142 2011 GLP: no, published	N	N	n.a.	--	N.A.
KCA 7.2.2.1/ 03	Feil, N.	2008	Ready biodegradabilit y of rape seed oil, refined in a manometric respirometry	N	Y	2010 Spain (technical equivalence)	SCO	Not EU reviewed, 2010 Spain (technical equivalence)

			test. IBACON Project 39151163, 2008-06-24 GLP: yes, unpublished					
KCA 7.2.2.1/ 07	Fabig, W., Hund, K., Gross, K.-J.	1989	Biotic degradation of rape seed oils. Fat Sci. Technol. 91 (9), pp. 357-360 1989 GLP: no, published	N	N	n.a.	--	Not EU reviewed, 2010 Spain (technical equivalence)
KCP 10.5/03	Brunswik-Titze, A.	2017	NEU 1160 I EC: Assessment of the ready Biodegradability with the Manometric Respirometry Test according to OECD 301 F (July 1992) Hydrotox Labor für Ökotoxikologie und Gewässerschutz GmbH, Germany Report No.: 1129 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU approval

Section ecotoxicology

Data point	Author(s)	Year	Title Source (where different from company) Company Report No. GLP or GEP status (where relevant), Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 10.1.2.1	[redacted]	1996 a	Assessment of acute oral toxicity with NEU 1161 I in the rat [redacted] Report No.: 170764 GLP: yes unpublished	Y	N	-	NEU	DAR 2008
KCP 10.2.1/01	[redacted]	2016	Toxicity to the Rainbow Trout *Oncorhynchus mykiss* under Laboratory Conditions (Acute Toxicity Test – Semi-Static) [redacted] Report No.: S16-00482 GLP: yes unpublished	Y	Y	New study	NEU	No, new study for EU renewal

KCP 10.2.1/02	Falk, S.	2016	Toxicity to the Single Cell Green Alga *Desmodesmus subspicatus* Chodat under Laboratory Conditions Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-00481 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.2.1/03	Dabrunz, A.	2016	NEU 1128 I SL: Toxicity to the Larvae of Chironomus riparius under Laboratory Conditions (Acute Immobilisation Test – Static) Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-00257 GLP: yes unpublished	Y	Y	New study	NEU	No, new study for EU renewal
KCP 10.2.1/04	Hertl, J.	2002	Acute Toxicity of Neu 1160 I to *Daphnia magna* in a 48-hour Immobilization Test Institut fur Biologische Analytik und Consulting IBACON GmbH, Germany Report No.: 12742220 GLP: yes unpublished	N	N	-	NEU	DAR 2008

KCP 10.2.2/01	[redacted]	2017	Toxicity Test on Early-life Stages of Zebrafish *Danio rerio* [redacted] Report No.: S16-00483 GLP: yes unpublished	Y	Y	New study	NEU	No, new study for EU renewal
KCP 10.2.2/02	Peither, A.	2017	NEU 1160 I EC - Effect on Survival, Growth and Reproduction of *Daphnia magna* in a Semi-Static Test over Three Weeks Innovative Environmental Services (IES) Ltd, Switzerland Report No.: 20160265 Report date: 2017-04-21 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.1.1.1	Ehmke A.	2016a	NEU 1160 I EC: Effects (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory Ibacon GmbH, Germany Report No.: 111671035 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal

KCP 10.3.1.1.2	Ehmke A.	2016a	NEU 1160 I EC: Effects (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory Ibacon GmbH, Germany Report No.: 111671035 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.1.2	Ehmke A., Knebel N.	2016b	NEU 1160 I EC: Chronic Oral Toxicity Test on the Honey Bee (*Apis mellifera* L.) in the Laboratory Ibacon GmbH, Germany Report No.: 111671136 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.1.3	Vergé, E	2017	NEU 1160 I EC - Honey Bee (*Apis mellifera* L.) Larval Toxicity Test (Repeated Exposure) Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-04781 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal

KCP 10.3.1.5	Tänzler, V.	2017	NEU 1128 I: Toxicity Testing on Honey Bees (*Apis mellifera* L.) under Semi-Field Conditions – Tunnel Test Ibacon GmbH, Germany Report No.: 111121037 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.2	Kodrik, L.S.	2019	NEU 1160 I: Supplement: Risk assessment for other non-target arthropods DHD-Consulting Gmbh Sponsor: Task Force Rape seed Oil	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.2.2/01	Duffner A.	2016a	NEU 1160 I EC: Toxicity to the Green Lacewing *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) after Exposure to Freshly Applied Spray Deposits under Extended Laboratory Conditions Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-04041 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal

KCP 10.3.2.2/02	Goßmann, A.	2016	NEU 1128 I SL: Effects on the Lacewing *Chrysoperla carnea*, Extended Laboratory Study- Dose Response Test Ibacon GmbH, Germany Report No.: 111121047 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.2.2/03	Duffner A.	2016b	NEU 1160 I EC: Toxicity to the Ladybird *Coccinella septempunctata* (Coleoptera, Coccinellidae) after Exposure to Freshly Applied Spray Deposits under Extended Laboratory Conditions Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-04042 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.3.2.2/04	Rathke A. K.	2016	NEU 1160 I: Aged Residue Test on Typhlodromus pyri (Acari: Phytoseiidae), Exposed to Apple Leaves Noack Laboratorien GmbH, Germany Report No.: 15128NM/IRD16964 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal

KCP 10.3.2.2/05	Taruza, S.	2002	A rate-response extended laboratory test to determine the effects of Neu 1160 I on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae) Mambo-Tox Ltd. Biomedical Sciences Building Bassett Crescent East Southampton SO 16 7PX, U.K. Report No.: NEU-02-3 GLP: yes unpublished	N	N	--	NEU	DAR 2008
KCP 10.3.2.2/06	Fussell, S.	2002	A rate-response extended laboratory test to determine the effects of NEU 1160 I on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) Mambo-Tox Ltd. Biomedical Sciences Building Bassett Crescent East Southampton SO 16 7PX, U.K. Report No.: NEU-02-2 GLP: yes unpublished	N	N	--	NEU	DAR 2008
KCP 10.4.1.1/01	Lührs, U.	2016	NEU 1160 I: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5% Peat Ibacon GmbH, Germany Report No.: 111671022 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal

KCP 10.4.1.1/02	Ganßmann, M.	2013	Effects of NEU 1128 I on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5% Peat Ibacon GmbH, Germany Report No.: 83842022 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.4.1.1/03	Wachter, S.	1998a	Acute toxicity of NEU 1161 I on earthworms *Eisenia foetida* using an artificial soil test GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Germany Report No.: 98028/01-NLEf GLP: yes unpublished	N	N	--	NEU	DAR 2008
KCP 10.4.2.1/01	Straube, D.	2018	CEL 32601: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Ibacon GmbH, Germany Report No.: 122161016 GLP: yes unpublished	N	Y	New study	TFRSO NEU / EGC	No, new study for EU renewal

KCP 10.4.2.1/02	Straube, D.	2017	CEL 32601: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Ibacon GmbH, Germany Report No.: 122161089 GLP: yes unpublished	N	Y	New study	TFR SO NE U / EG C	No, new study for EU renewal
KCP 10.5/01	Häuser, R.	2016	NEU 1160 I: Effects on the Activity of Soil Microflora under Laboratory Conditions (Nitrogen Transformation) Eurofins Agroscience Services EcoChem GmbH/ Eurofins Agroscience Services Ecotox GmbH, Germany Report No.: S16-00215 GLP: yes unpublished	N	Y	New study	NE U	No, new study for EU renewal
KCP 10.5/02	Wachter, S.	1998 b	Assessment of the side effects of NEU 1161 I on the activity of the soil microflora GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Germany Report No.: 98028/01-ABMF GLP: yes unpublished	N	N	--	NE U	DAR 2008

KCP 10.5/03	Brunswik -Titze, A.	2017	NEU 1160 I EC: Assessment of the ready Biodegradability with the Manometric Respirometry Test according to OECD 301 F (July 1992) Hydrotox Labor für Ökotoxikologie und Gewässerschutz GmbH, Germany Report No.: 1129 GLP: yes unpublished	N	Y	New study	NEU	No, new study for EU renewal
KCP 10.6.2/01	Spatz, B.	2001	Effects of NEU 1161 I on terrestrial (non-target) plants: Vegetative Vigour Test Institut für Biologische Analytik und Consulting IBACON GmbH, Germany Report No.: 11841087 GLP: yes unpublished	N	N	--	NEU	DAR 2008