



**Committee for Risk Assessment
RAC**

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of
octanoic acid

EC number: 204-677-5

CAS number: 124-07-2

CLH-O-0000002589-62-03/A2

**Adopted
6 June 2013**

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON OCTANOIC ACID

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

ECHA has compiled the comments received via the internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.

Substance name: octanoic acid

EC number: 204-677-5

CAS number: 124-07-2

Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	1
Comment received				
p. 6 Proposal for harmonised classification and labelling The Spanish CA agrees with the Austrian proposal to classify octanoic acid as: – Skin Corr. 1C, H314: Causes severe skin burns and eye damage according to Regulation EC 1272/2008 and as C; R34: Causes burns according to Directive 67/548/EC.				
Dossier Submitter's Response				
Thank you for your review.				
RAC's response				
Since the DS considered the findings borderline to corrosion they used the Toxtree QSAR evaluation of the three organic acids (which revealed that these substances were either irritating or corrosive to skin) and the in vitro rat skin corrosivity test on the basis of transcutaneous electrical resistance (TER), which indicated skin corrosion. RAC further concludes that classification as Eye Irrit. 2 H313 according to CLP (Xi; R36 according to DSD) for octanoic acid may be warranted. This is based on the evaluation of the Leoni and Riedel (2011) study. According to the OECD 403 test guideline, 0.1 ml of 70% octanoic acid has been applied for 24 hrs to 3 rabbits. The animals were observed over 72 hrs and at 6, 9, and 11 days after dosing. Conjunctival redness, chemosis and discharge were observed in all animals. In two animals, lesions of the iris and the cornea were observed. At the end of the prolonged observation period, no corneal lesions were seen in any of the animals. This more recent study does not confirm the results of the older non-guideline studies. However, the "Guidance on the application of the CLP Criteria" clearly states that when a substance is classified as skin corrosive, potential to cause serious damage to the eyes is implicit in that classification. Since octanoic acid is classified as skin corrosive, there is no need to proceed with classification for eye effects.				
Date	Country	Organisation	Type of Organisation	Comment number
26/07/2012	France		MSCA	2
Comment received				
FR agrees with the classification proposal.				
Dossier Submitter's Response				
Thank you for your review.				
RAC's response				
Noted, please see response to comment 1.				

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Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Germany		MSCA	3

Comment received

The German CA supports the proposed C&L.

Dossier Submitter's Response

Thank you for your review.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	4

Comment received

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM COMMENTS OCTANOIC C8_final_final.pdf** was submitted as a separate attachment. Attachment no. 1. Summary/conclusion and Overall conclusions were copied below.*
Summary/conclusion of C&L for octanoic acid proposed by RAC (CLH) and FAC (REACH dossier)

Table 1 Summary/conclusion of C&L for octanoic acid proposed by RAC (CLH) and FAC

Endpoint	FAC according CLP 1272/2008/EC	FAC according 67/548/EEC	RAC/CLH according CLP	RAC/CLH 67/548/EEC	Comments by FAC
Skin corrosion /irritation	GHS 05 "Danger" Cat 1C, H314 SCL: >70% Cat 1C; H314	C, Corrosive R34 SCL>70% C, R34	GHS 05 "Danger" Cat 1C H314	C, Corrosive, R34	Please add SCL setting: >70% corrosive on the basis of Nixon, 1981 [1]
Serious eye damage/ eye irritation	SCL: >70% Cat 1, H318 ≥1 - ≤70% Cat 2, H319	SCL: >70% Xi, R41 ≥1 - ≤70% Xi, R36	-	-	Classification is covered by H314 Please add SCL settings: >70% serious eye damage; ≥1 - ≤70% eye irritation on the basis of Leoni and Riedel, 2011 [2]
Aquatic chronic toxicity	No classification needed	No classification needed	Cat 3, H412	N, R51/53	FAC disagrees with CLH/RAC's CLP proposal: Refer to Section Environmental Hazards FAC disagrees with CLH/RAC's 67/548/EEC proposal: Refer to Section Environmental Hazards

Overall Conclusions

1. Companies of FAC ask Competent Authorities/RAC to include C&L proposals as listed in the table 2

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Table 2 C&L proposal by FAC

Endpoint	FAC according CLP 1272/2008/EC	FAC according 67/548/EEC
Skin corrosion /irritation	GHS 05 "Danger" Cat 1C; H314 SCL: >70% Cat 1C; H314	C, Corrosive, R34, SCL: >70% C, R34
Serious eye damage/eye irritation	Classification is covered by H314 SCL: >70% Cat 1, H318 ≥1 - ≤70% Cat.2, H319	Classification is covered by R34 SCL: >70% Xi, R41 ≥1 - ≤70% Xi, R36
Aquatic chronic toxicity	no classification needed based on new data provided by FAC	no classification needed based on new data provided by FAC

2. Companies of FAC ask Competent Authorities/RAC to postpone the decision as new results on the read across substance decanoic acid on toxicity to aquatic invertebrates will be available in Oct 2012.

3. Companies of FAC ask Competent Authorities/RAC to be further involved in the process of decisions on C&L for octanoic acid.

REFERENCES

ALL REFERENCES CAN BE MADE AVAILABLE TO THE AUTHORITIES ON REQUEST.

[1] Nixon, G. A. (1981). Rabbit skin irritation - (Closed Patch Test) RPAT (Modified). Unpublished report. Testing laboratory: Miami Valley Laboratories, The Procter & Gamble Company, Cincinnati, Ohio, USA. Report no.: YE-394-1. Owner company: The Procter & Gamble Company. Study number: 25975. Report date: 1981-10-06

[2] Leoni, A-L. and Riedel, W. (2011). Acute Eye Irritation/Corrosion with Octanoic Acid. Testing laboratory: BSL Bioservice, Planegg, Germany. Report no.: 112747. Owner company: FATAAC Ltd., Gloucestershire, England. Report date: 2011-10-21

[3] Richterich, K. and Mühlberg, B., (2004) Octanoic acid (Edenor C8 98-100) - Ultimate biodegradability in the closed bottle test. unpublished. Testing laboratory: Henkel KGaA, Düsseldorf, Germany. Report no.: R 0400786. Owner company: Emery Oleochemicals GmbH, Henkelstrasse 67, 40589 Düsseldorf, Germany. Report date: 2004-05-11.

[4] Sousa, J. V. (1982). Acute toxicity of TSIN S0586.01 to bluegill (*Lepomis macrochirus*). unpublished. Testing laboratory: EG&G, Biomomics, Aquatic Toxicology Laboratory, 790 Main Street, Wareham, Massachusetts. Report no.: BW-82-1-1093. Owner company: Procter & Gamble Eurocor NV/SA, Temselann 100, 1853 Strombeek-Bever, Belgium. Report date: 1982-01-15.

[5] NITE (1999a). *Daphnia magna*, acute toxicity test for decanoic acid. Testing laboratory: Sumika Technoservice Corporation, Takarazuka, Japan. Report no.: EDI98008. Owner company: Ministry of the Environment, Government of Japan. Report date: 1999-06-30.

[6] Tobor-Kaplon, M. A. (2010). Fresh water algal growth inhibition test with octanoic acid, CAS # 124-07-2. unpublished. Testing laboratory: NOTOX B. V., Hambakenwetering 7, 5231 DD 's-Hertogenbosch, The Netherlands. Report no.: 494353. Owner company: FATAAC Ltd.

[7] Wenzel, A. (2012) Freshwater Alga, Growth Inhibition Test. Testing laboratory: Fraunhofer-Institute for Molecular Biology and Applied Ecology (IME) Schmallenberg, Germany, EME-002/4-30/A, Owner company: Emery Oleochemicals GmbH, Germany

[8] van Egmond (1999) Bioconcentration, biotransformation, and chronic toxicity of sodium laurate to zebrafish (*Danio rerio*), *Envir. Tox. Chem.* 18 (3), 466-473, 1999

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[9] NITE (1999b). *Daphnia magna*, reproduction toxicity test for decanoic acid. Testing laboratory: Sumika Technoservice Corporation, Takarazuka, Japan. Report no.: EDR98008. Owner company: Ministry of the Environment, Government of Japan. Report date: 1999-08-27.

[10] Schlechtriem, C. (2012), *Daphnia magna*, Reproduction test (OECD 211) Semi-static exposure, Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Schmallenberg, Germany, EME-001/4-21/G, Owner company: Emery Oleochemicals GmbH, Germany

[11] SOPURA N.V. (2006) OCTANOIC ACID: READY BIODEGRADABILITY IN A MANOMETRIC RESPIROMETRY TEST; RCC LTD, Itingen, Switzerland; RCC Study Number: A86578, Unpublished

[12] SOPURA (2006) Octanoic Acid: Acute Toxicity to Zebra Fish (*Brachydanio Rerio*) in a 96-hour semi-static Test, RCC Ltd; Itingen, Switzerland RCC Study Number A86501

[13] SOPURA (2006) First Amendment to Study Plan Octanoic Acid: Acute Toxicity to Zebra Fish (*Brachydanio rerio*) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501

[14] SOPURA (2006) DECANOIC ACID: ACUTE TOXICITY TO DAPHNIA MAGNA IN A 48-HOUR IMMOBILIZATION TEST; RCC Ltd, Itingen, Switzerland; RCC Study Number: A86488, Unpublished

[15] SOPURA (2008) DECANOIC ACID: TOXICITY TO SCENEDESMUS SUBSPICATUS IN A 72-HOUR ALGAL GROWTH INHIBITION TEST; RCC Ltd, Itingen, Switzerland, RCC Study Number: A86523 (inclusive A86534), Unpublished

[16] OECD Guideline 211 for Testing of Chemicals: *Daphnia magna* Reproduction Test, adopted 03 October 2008

End of attachment no. 1 Summary/conclusion and Overall conclusions.

Dossier Submitter's Response

Human Health: On the basis of the summary provided by the company manufacture we can agree to add SCL of 70% for skin and eye corrosion in the table 3 and 4. However this needs to be carefully reviewed by RAC since we do not have the original study reports. The Nixon 1981 data supporting the skin irritation SCL are available to the dossier submitter as IUCLID study summaries. In contrast the Leoni, A-L. and Riedel, W. (2011) data supporting the eye corrosion SCL are not available as study summary to the study submitter.

Environment: No new data are available to the submitter. We cannot comment on this.

Based on the available data for octanoic acid and read across to other medium chain fatty acids for those endpoints, for which no data for octanoic acid are available we are of the opinion that the proposed C&L should be changed to no classification, according to DSD and to Aquatic chronic 2, according to CLP (reference is made to comment number 16).

RAC's response

Environment:

The result from the REACH registration dossier is not consistent with the results obtained in daphnia and fish or with the trend observed in the algae tests carried out on the other substances of the group. If this test is not considered, toxicity appears to increase with hydrophobicity.

Furthermore, there are some deficiencies in the test from REACH registration, such as the inconsistency in dose-responsiveness at the lowest concentrations, the rapid loss of the test concentration and fact that the highest effect is observed at 24 hours. Therefore, taking into account that the reliability of this test cannot be fully confirmed and that this test is not consistent with the results of the other taxonomic groups, it should not be used for classification purposes.

In relation to the new algae test performed with octanoic acid, it is not totally clear if, at the end of the test, the concentration has been measured with algae present as required by the guideline or without algae. On the other hand, if the test has been performed according to the guideline, it is difficult to understand why it is possible to maintain the concentration for the duration of the test for

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octanoic acid, and not for nonanoic, decanoic and lauric acid. Therefore the reliability of this test cannot be confirmed, and it should not be used for classification purposes

Read-across from nonanoic and decanoic acid is appropriate, considering that it is a worst case scenario because the toxicity is higher when the hydrophobicity is also higher.

Taking into account the deficiencies of the test submitted under REACH registration and of the new test submitted by industry and the justified use of measured concentrations in the algae tests, the classification is as follows.
Aquatic Chronic 3, H412 under CLP.
N, R51/53 under DSD.

Regarding skin and eye irritation please see RAC response to comment 1

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	5
Comment received				
<i>ECHA comment: The document 20120806_FAC_COMMENTS_on_CLH_OCTANOIC_C8_final.pdf was submitted as a separate attachment and claimed confidential. Attachment no.4</i>				
Dossier Submitter's Response				
You are kindly asked to refer to our answer to comment number 4. Without further explanation we cannot accept that this document is confidential. It does not contain any information that is subject to data protection.				
RAC's response				
Noted.				
Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Importer	6
Comment received				
<i>ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final Omya Hamburg.pdf was submitted as a separate attachment and claimed confidential. Attachment no.5</i>				
Dossier Submitter's Response				
You are kindly asked to refer to our answer to comment number 4. Without further explanation we cannot accept that this document is confidential. It does not contain any information that is subject to data protection.				
RAC's response				
Noted.				
Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Netherlands	Wilmar Europe Trading BV	Company-Importer	7
Comment received				
<i>ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf was submitted as a separate attachment. Attachment no. 3. The document text is identical with attachment 1,2.</i>				
Dossier Submitter's Response				
You are kindly asked to refer to our answer to comment number 4.				
RAC's response				
Noted.				
Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Switzerland		Company-Downstream user	8
Comment received				

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Please refer to the attached document.
<i>ECHA comment: The document FAC Comments on CLH of octanoic acid - 04.08.12.pdf was submitted as a separate attachment. Attachment no. 4. The document text is identical with attachment 1,2,3.</i>
Dossier Submitter's Response
You are kindly asked to refer to our answer to comment number 4.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS

Skin hazard

Date	Country	Organisation	Type of Organisation	Comment number				
19/07/2012	Spain		MSCA	9				
Comment received								
<p>p. 26 Summary and discussion of corrosion/irritation</p> <p>The Spanish CA supports the proposed classification of octanoic acid as Skin Corr. 1C, H314: Causes severe skin burns and eye damage according to Regulation EC 1272/2008 and as C; R34: Causes burns according to Directive 67/548/EC.</p> <p>This classification is mainly based on the result of the TER corrosivity test with a resulting value <5 KOhm/disc (Whittle, 1994), indicative of skin corrosion. It also supports this classification the signs of corrosion observed in the skin irritation tests in rabbits submitted in the Chemical Safety Report (under REACH) of the octanoic acid (Nixon, 1981 and Weterings, 1984).</p> <p>Moreover, signs of corrosion were observed in the skin irritation study in rabbit with nonanoic acid (Otterdijk, 2001c). As it has been mentioned in the Draft Assessment Report of July 2007, and in other papers (HERA, Fatty Acid Salts; Human Health Assessment, June 2002), the length of the hydrophobic chain influences in the corrosion of the free fatty acids. Shorter hydrophobic chains increase corrosive effects. Consequently, observed corrosion signs with nonanoic acid are indicative that the octanoic acid is potentially corrosive. Besides, in the DAR (2007), was established a cut off value of 9-carbon length to distinguish between corrosivity and irritation in free fatty acids (free fatty acids with $C \leq 9$ are corrosive).</p>								
Dossier Submitter's Response								
OK, thank you for your review, we agree with regard to the octanoic acid classification proposal.								
RAC's response								
Please see response to comment 1.								
Date	Country	Organisation	Type of Organisation	Comment number				
26/07/2012	France		MSCA	10				
Comment received								
<p>SKIN IRRITATION</p> <p>Since the studies of Nixon (1981), Weterings (1984) and Whittle (1994) reported in the CSR, are considered as key studies to classify octanoic acid as corrosive R34, please summarize them in section 4.4.1 (Skin irritation) and report their reference details in section 7 (References).</p>								
Dossier Submitter's Response								
Ok, the data are available as IUCLID study summaries please see below:								
Table 12c: Summary of data with C8 fatty acid from IUCLID study summaries from Emery Oleochemicals GmbH								
Species, Number	Method	Conc.	Dose	Exp. time	Result	Revers. yes/no	Conclusion	Reference

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Rabbit, 6 animals	Dermal irritation test with Octanoic acid; occlusive exposure observation up to 48h GLP	0, 30, 50, 60, 70% in PEG + 100%	0.8 ml/ 2 cm ²	3 h	Average score 24, 48 hours in 6 animals / max score in individual animals 100%: erythema: ≥ 3.3 / 4; edema = 3.2 / 4 30%-70%: erythema = 0; edema = 0	100%: not fully reversible within 48h in 5/6 animals 30-70%: max score 1 after 2h, fully reversible till 24h	100%: skin corrosive 70%: SCL	Nixon 1981, unpublished, Miami Valley Laboratories study number 25975
Rabbit, 3 animals	dermal irritation test with Octanoic acid semi-occlusive exposure observation up to 14d OECD TG No. 404 GLP	100%	0.5 ml	4 h	Average score 24, 48, 72 hours in 3 animals / max score in individual animals Erythema = 3 / 4; edema = 1.8 / 4	Full thickness necrosis at reading time point 48h in all animals Not fully reversible within 14 days	Skin corrosive	Weterings 1984, NOTOX, Netherlands, report no NOTOX 0039/91
Rat skin in vitro	Transcutaneous electrical resistance test as described in Oliver, Pemberton & Rhodes (1986 & 1988; Toxicol In Vitro. 1988; 2(1):7-17. An in vitro model for identifying skin-corrosive chemicals. I. Initial validation.) Similar to OECD TG No 430, but no measurement of dye binding	100%	150ul/skin disc	24 h	TER mean/disc = 3.6 kOhm	TER < 5 kOhm; the test substance did display properties characteristic of those substances which may be corrosive to animal skin in vivo.	Skin corrosive	Whittle 1994, Environmental Safety Laboratory Unilever Research, England, study no XE930513

The original studies are not available to the study submitter.

RAC's response

Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	11

Comment received

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM COMMENTS OCTANOIC C8_final_final.pdf** was submitted as a separate attachment. Attachment no. 1. Skin irritation/corrosion were copied below.*

Skin irritation/corrosion

Conclusion FAC:

The FAC agrees with the classification and labelling for the undiluted octanoic acid that is proposed in the CLH dossier, Page 6.

Additionally, a specific concentration limit (SCL) of 70% for skin corrosiveness and for serious eye damage and a SCL of .1 - .70% for eye irritation are proposed, respectively based on a modified rabbit skin irritation closed patch test [1] and an acute eye irritation / corrosion test according to OECD 405 [2]:

Endpoint summary: Rabbit skin irritation closed patch test RPAT (modified) [1]

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The level of primary skin irritation of octanoic acid was examined in a GLP study (rabbit skin irritation closed patch test RPAT (modified)) on rabbits under occluded conditions [1]. 0.8 mL of octanoic acid at concentrations of 30%, 50%, 60%, 70% in PEG200/H₂O and 100% was applied to the clipped skin of 6 New Zealand White rabbits under occlusive conditions for 3 hours. All animals were examined for signs of erythema and oedema, and the responses were scored at 0.5, 1, 2, 24 and 48 hours after patch removal.

Under the conditions of this test, octanoic acid did not produce skin reactions at concentrations of 0, 50 and 60%, since no signs of erythema and oedema were observed. At 30 and 70 %, the test substance produced very slight erythema (score 1) only on 2 of 6 and 3 of 6 sites, which subsided within 2 and 24 hours, respectively. Erythema reaction produced by the undiluted test substance exceeded the scoring scale on 4 of 6 sites while one animal showed a severe (grade 4) reaction. Moderate to severe edema developed on 5 of 6 test sites. There were no dermal reactions produced by the undiluted material on one test site.

Thus, the mean scores for 24 – 48 hour readings were both 0 for erythema and edema after application of 30%, 50%, 60%, 70% octanoic acid, respectively, the scores were 3.3 for erythema and 3.2 for edema for 100% octanoic acid, respectively.

FAC conclusion/ proposal for C&L skin irritation / corrosion

Based on this data a SCL of >70% for skin corrosion can be assigned and is therefore proposed for octanoic acid. At a concentration of ≤70%, a non-classification is warranted for skin corrosion/irritation. It is assumed that between 70% and 100% there is a region where a classification as skin irritant is probably applicable, but the data base is not solid enough to support this. Accordingly following a worst case approach, classification as corrosive >70% to 100% is proposed.

End of Skin hazard, attachment no. 1

Dossier Submitter's Response

We agree to add SCL of 70% for corrosion in the table 3 and 4.

RAC's response

Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	12

Comment received

see confidential attachment

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM COMMENTS OCTANOIC C8_final_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no.6*

Dossier Submitter's Response

Without further explanation we cannot accept that this document is confidential. It does not contain any information that is subject to data protection.

RAC's response

Please see response to comment 1.

Eye hazard

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	13

Comment received

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attachment. Attachment no. 1. serious eye damage / eye irritation were copied below.

Endpoint summary: Acute eye irritation/corrosion with octanoic acid (OECD 405, GLP) [2]

The eye irritation potential by octanoic acid at a concentration of 70% was examined in a GLP study according to OECD guideline 405. 0.1 mL of 70% octanoic acid in vaseline was instilled into one eye each of 3 female New Zealand White rabbits [2]. The untreated left eye of each animal served as control. After 24 h the eyes were rinsed. The eye reactions were examined 24, 48 and 72 h after application and every 24 h thereafter for up to 11 days. Under the conditions of the test, a single ocular application produced irritant effects in the rabbits, which were fully reversible within 6-11 days. The mean scores for corneal opacity, iris, conjunctival redness and chemosis were 0.78, 0.66, 1.6 and 1 respectively. Since, in 2 out of 3 tested animals lesions of the iris with a score equal to 1 were induced, the test item has to be considered as eye irritant at a concentration of 70%.

FAC conclusion/ proposal for C&L serious eye damage / eye irritation

A SCL of >70% for serious eye damage is proposed for octanoic acid.
At a concentration of $\geq 1 - \leq 70\%$ octanoic acid has to be classified as eye irritant.

End of serious eye damage / eye irritation from attachment no. 1

Dossier Submitter's Response

On the basis of the information sent by FAC we agree to add SCL of 70% for eye corrosion in the table 3 and 4. However we do not have the study or a study summary available for the Leoni, A-L. and Riedel, W. (2011) study, which is the critical one for this proposal.

RAC's response

Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	14

Comment received

see confidential attachment

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no.6*

Dossier Submitter's Response

Without further explanation we cannot accept that this document is confidential. It does not contain any information that is subject to data protection.

RAC's response

Please see response to comment 1.

Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
26/07/2012	France		MSCA	15

Comment received

FR agrees with the general conclusion dealing with the environmental classification of the substance.

Dossier Submitter's Response

Thank you for your agreement. Reference is made to our new C&L proposal in comment number 16.

RAC's response

RAC agrees with the original classification proposal because the result from the REACH registration dossier is not consistent with the results obtained in daphnia and fish or with the trend observed in

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the algae tests carried out on the other substances in the group. When this test is not considered, toxicity appears to increase with hydrophobicity. Furthermore, there are some deficiencies in the test from REACH registration, such as the inconsistency in dose-responsiveness at the lowest concentrations, the rapid loss of the test concentration and the fact that the highest effect is observed at 24 hours. Therefore, taking into account that the reliability of this test cannot fully be confirmed and that this test is not consistent with the results of the other taxonomic groups, it should not be used for classification purposes.

A read-across from nonanoic and decanoic acid is appropriate, considering that it is a worst case scenario, because the toxicity increases with increasing hydrophobicity, therefore the classification is as follows:

**Aquatic Chronic 3, H412 under CLP.
N, R51/53 under DSD**

Date	Country	Organisation	Type of Organisation	Comment number
02/08/2012	United Kingdom		MSCA	16

Comment received

Under REACH, octanoic acid (C₈H₁₆O₂) is considered as part of a category approach with analogues such as heptanoic acid (C₇H₁₄O₂), nonanoic acid (C₉H₁₈O₂) and decanoic acid (C₁₀H₂₀O₂). A consolidated set of all available ecotoxicity data would be useful to understand the read-across, its validation and classification. At present not all relevant data is included in the dossier and it appears some analogue data is potentially conflicting.

We think the TWA based NOEC from the 2010 algal study (read-across from decanoic acid) is valid and should be used for the classification. We feel a NOEC considering all measured data is representative of exposure concentrations.

The chronic toxicity to Daphnia study read-across from decanoic acid (C₁₀) reports a 21d NOEC of 0.2 mg/l based on nominal data. However, given the losses observed we think, if possible, some attempt to provide a result based on measured data should be considered.

In addition, chronic toxicity to Daphnia studies using heptanoic acid (C₇) and nonanoic acid (C₉) are available in the nonanoic acid REACH registration and classification proposal. We feel these data from close analogues should also be considered for the classification of octanoic acid (C₈).

Dossier Submitter's Response

The intention of the submitter of the CLH-report on octanoic acid is to initiate a harmonised C&L for octanoic acid, which is important under the biocides regime.

In order to enable read across with other medium chain fatty acids we now provide a summary of all available acute and chronic eco-toxicity data for all three trophic levels from CARs on octanoic, nonanoic and decanoic acid and CSRs on nonanoic and octanoic acid.

1) Summary of acute toxicity data for all three trophic levels available from CARs on octanoic, nonanoic and decanoic acid and CSRs on nonanoic and octanoic acid:

fish LC₅₀ (96h):

nonanoic acid (C 9): > 7.2 mg/L (CLH report on nonanoic acid, no effects at the highest conc. tested, mean measured, *Leuciscus idus*);

104 mg/L (CSR on nonanoic acid, mean measured, *Pimephales promelas*)

octanoic acid (C 8): 68 mg/L (CLH report on octanoic acid, nominal confirmed, *Brachydanio rerio*); **22 mg/L and 39.9 mg/L** (CSR on octanoic acid, both nominal and *Lepomis macrochirus*)

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crustacean EC₅₀ (48h):

decanoic acid (C 10): 16 mg/L (CLH report on decanoic acid, nominal confirmed, *Daphnia magna*); **21 mg/L** (CSR on octanoic acid, mean measured, *Daphnia magna*)

nonanoic acid (C 9): 23.63 mg/L (CLH report on nonanoic acid, mean measured, *Daphnia magna*); **96 mg/L** (CSR on nonanoic acid, nominal, *Daphnia magna*)

heptanoic acid (C 7): 859.6 mg/L (CSR on nonanoic acid, arithmetic mean, *Daphnia magna*)

algae E_rC₅₀ (72h):

decanoic acid (C 10): 2 mg/L (CLH report on decanoic acid, mean measured, *Scenedesmus subspicatus*)

nonanoic acid (C 9): 103.4 mg/L (CLH report on nonanoic acid, nominal, *Scenedesmus subspicatus*);

octanoic acid (C 8): 31 mg/L (CSR on octanoic acid, measured TWA, *Pseudokirchnerella subcapitata*)

heptanoic acid (C 7): 60 mg/L (CSR on nonanoic acid, *Pseudokirchnerella subcapitata*)

2) Summary of chronic toxicity data for all three trophic levels available from CARs on octanoic, nonanoic and decanoic acid and CSRs on nonanoic and octanoic acid:

fish NOEC (28d):

sodium laurate (C 12): based on growth rate: 6.4 mg/L, based on mortality 2 mg/L (CSR on octanoic acid, nominal, flow through, *Danio rerio*)

nonanoic acid (C 9): ≥19.2 mg/L (CLH report on nonanoic acid, no effects at the highest conc. tested, nominal confirmed, flow through, based on mortality and non-lethal effects, *Oncorhynchus mykiss*)

crustacean NOEC (21d):

decanoic acid (C 10): 0.2 mg/L (CSR on octanoic acid, nominal, semi static, based on reproduction, *Daphnia magna*)

nonanoic acid (C 9): 9.93 mg/L (CLH report on nonanoic acid, mean measured, based on reproduction and mortality, *Daphnia magna*);

heptanoic acid (C 7): 18 mg/L (CSR on nonanoic acid, based on reproduction, static, *Daphnia magna*);

algae NOEC (72 h):

decanoic acid (C 10): 0.57 mg/L was recalculated with **0.25 mg/L** (CLH report on decanoic acid, mean measured, *Scenedesmus subspicatus*); (reference is made to comment number 22)

nonanoic acid: (C 9) 0.57 mg/L (CLH report on nonanoic acid, mean measured, *Scenedesmus subspicatus*); **3.48 mg/L** (mean measured, *Anabaena flos-aquae*) and **9.6 mg/L** (nominal, *Lemna gibba*) both presented in the CLH report on nonanoic acid);

octanoic acid (C 8): 0.07 mg/L (CSR on octanoic acid, meas. TWA, *Pseudokirchnerella subcapitata*). In contrast to our argumentation in the CLH-report we now agree with UK and are meanwhile of the opinion, that this value is valid, since recalculation as geometric mean from the measured concentration at the beginning of the test and from half of the limit of quantification (LOQ =0.008 mg/L) at all other measuring points, gives approximately the same value. The low LOQ also explains the low effect value compared to chronic algae results for the other fatty acids.

heptanoic acid (C 7): 29 mg/L (CSR on nonanoic acid; static, *Pseudokirchnerella subcapitata*)

According to the comments from FAC a new chronic daphnia study with decanoic acid is in progress and should be completed in October 2012 (ref. to comment number 18).

If the chronic daphnia NOEC (21d) values from nonanoic and heptanoic acid are additionally taken into account, then the value from nonanoic acid (9.93 mg/L) would probably be the most appropriate for octanoic acid, considering that toxicity increases with chain length and in order to have a worst case approach.

Conclusion:

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<p>Based on all available data for octanoic acid and read across to other medium chain fatty acids for those endpoints, for which no data for octanoic acid are available we are of the opinion that the proposed C&L should be changed to no classification, according to DSD (since all acute values are >10 mg/L, new E_rC₅₀ of 31 mg/L) and to Aquatic chronic 2, according to CLP (algae NOE_rC of 0.07 mg/L).</p>				
<p>RAC's response</p>				
<p>The RAC agrees with the original classification because the result from the REACH registration dossier is not consistent with the results obtained in daphnia and fish or with the trend observed in the algae tests carried out on the other substances in the group. When this test is not considered it appears that toxicity increases with hydrophobicity.</p> <p>Furthermore, there are some deficiencies in the test from REACH registration, such as the inconsistency in dose-responsiveness at the lowest concentrations, the rapid loss of the test concentration and the fact that the highest effect is observed at 24 hours. So taking into account that the reliability of this test cannot fully be confirmed and that this test is not consistent with the results of the other taxonomic groups, it should not be used for classification purposes. A read-across from nonanoic and decanoic acid is appropriate considering that it is a worst case scenario, because the toxicity is higher when the hydrophobicity is also higher, therefore the classification is as follows: Aquatic Chronic 3, H412 under CLP. N, R51/53 under DSD.</p>				
Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Belgium		MSCA	17
<p>Comment received</p> <p>Based on the results of the aquatic toxicity test (most sensitive species : algae with 72hEC₅₀=1.67mg/l, 72hNOErC=0.47 mg/l) the fact that the substance is readily degradable (84% degradation within 28d), it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic Chronic 3, H412.</p> <p>Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, LC₅₀ between 1 en 10 mg/l, log Kow>3, octanoic acid should be classified as N, R51/53.</p> <p>In conclusion: we support the proposed classification for the environment by the Austrian MSCA.</p>				
<p>Dossier Submitter's Response</p> <p>Thank you for your support. Reference is made to comment number 16.</p>				
<p>RAC's response</p> <p>See comments number 15 and 16.</p>				
Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	18
<p>Comment received</p> <p>ENVIRONMENTAL HAZARDS</p> <p>CLH proposal:</p> <p>Aquatic chronic toxicity category 3; H412 = Harmful to aquatic life with long lasting effects According to the CLH dossier octanoic acid CAS 124-07-2, is proposed to be classified as Aquatic Chronic 3 (N, R51/53).</p> <p>FAC proposal: No classification due to new data</p>				

Summary of relevant data for the environmental hazard classification of octanoic acid

Endpoint	Fatty Acid Consortium	CLH
Biodegradation	readily [3]	readily [11]
Bioaccumulation	BCF 288 L/kg (RA Na-laurate): no bioaccumulation according to data and expert statement	log Kow 3.03; BCF 75 (calculated with EPI suite and formula 74 of TGD)
Acute aquatic toxicity		
fish (LC50)	22 mg/L [4]	68 mg/L [12,13]
daphnia (EC50)	RA from decanoic acid 20 mg/L [5]	RA from decanoic acid 13.4 mg/L [14]
algae (EC50)	Current data in CSR 2010: 31 mg/L [6] <u>New data</u> in the update CSR (in progress): 43.7 mg/L [7]	RA from decanoic acid 1.67 mg/L [15]
Chronic aquatic toxicity		
fish (NOEC)	2 mg/L (Na-laurate) [8]	no data
daphnia (NOEC):	Current data in CSR 2010: RA from decanoic acid: 0.2 mg/L [9] <u>New data</u> in the update CSR (in progress) : No effect observed up to the highest test concentration (2 mg/L nominal, 0.6 mg/L TWA measured) (RA from decanoic acid, reproduction) [10]	no data
algae (NOEC)	Current data in CSR 2010: 0.07 mg/L [6] <u>New data</u> in the update CSR (in progress): 17.5 mg/L [7]	RA from decanoic acid 0.47 mg/L [15]

DSD classification

General rule for R51/53

Acute toxicity (Algae or fish or daphnia) EC/LC50: 1 – 10 mg/L
AND
not readily biodegradable OR log Pow \geq 3 (unless experimental BCF \leq 100)

CLH Proposal: N, R51/53

The CLH dossier proposes a classification as N, R51/53, based on the lowest short-term value of 1.67 mg/L in combination with bioaccumulation potential that is derived from a calculated log Kow of 3.03.

Quote of justification (CLH Page 65):

“Justification: Octanoic acid is readily biodegradable. The log Pow is given with 3.05 (REACH dossier) –3.03 (CAR). A calculated BCF_{fish} =75 (CAR) and measured BCF values from 234 - 249 (REACH dossier) are available. All available L(E)C50 values are between 10 and 100 mg/L. The only exception is the lowest ErC50 algae with 1.67 mg/L (CAR). The ErC50 algae with 1.67 mg/L in combination with a log Pow of 3.03 – 3.05 and measured BCF values of >100 lead to a classification with N, R51/53 and S61.”

FAC proposal: no classification

The Fatty Acids Consortium considers the assessment of bioaccumulation potential based solely on the calculated log Kow inappropriate for fatty acids, which occur naturally in all aquatic

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organisms and are ubiquitously present in the aquatic environment, where they are readily biodegraded by microorganisms. The log Kow is a physico-chemical parameter, describing the partitioning of a substance between water and an organic phase. It is a good parameter for estimation of bioaccumulation where uptake and distribution are passive that means driven by physico-chemical processes of dissolution in different media. In case where specific up-take and distribution mechanisms and a regulated metabolism are in place in the respective organism, it is not applicable for such an estimate. Short- and medium chain fatty acids (C1 - C12) are absorbed via intestine capillaries into the blood stream. In the body, fatty acids are rapidly metabolised by various routes to provide energy, stored as lipids in adipose tissue and used as precursors for signalling molecules and for the phospholipids of the cell membranes. Relevant literature is discussed in detail in the REACH registration dossier for octanoic acid. Furthermore, the CLH dossier demonstrated that the calculated BCF is 75, which is below the assessment criteria of DSD (BCF: 100).

FAC conclusion for C&L according DSD 67/548/EEC: "no classification"

In conclusion, fatty acids are considered very low risk to aquatic organisms from their bioaccumulation properties. The bio-concentration factors of fatty acids are generally of low concern.

Consequently, since all short-term aquatic toxicity EC50 values are above 1 mg/L and the substance is readily biodegradable and is not expected to bio-accumulate, it does not need to be classified according to the criteria of Directive 67/548/EEC.

CLP classification

New algae data provided by FAC

The CLH dossier proposes a classification as Chronic aquatic toxicity, Cat 3, based on the NOEC of 0.47 mg/L from an algae study, which has been read across from decanoic acid [14]. The Fatty Acids Consortium has conducted algae studies with octanoic acid itself as the test substance. In the CSR a NOEC value of 0.07 mg/L was given [6]. However, the test concentrations could not be monitored in a reliable way. At test start, the actual test concentrations in all test groups were in agreement with nominal concentrations (98-101%). At test end, measured concentrations were below LoD (Level of Detection) (0.008 mg/L). Consequently, the NOEC value had to be calculated as TWA. The resulting NOEC is extremely low compared to the short-term EC50 value of 31 mg/L from the same study indicating methodological deficiency [6]. It was concluded to repeat the study under improved conditions. Better recoveries of the test substance (87.6 - 90.7% at test start and 74.9 - 82.5% after 72 h), and a NOEC of 17.5 mg/L were obtained [7].

FAC conclusion for environmental hazard (algae)

The newly determined NOEC is considered to be a valid and reliable NOEC for octanoic acid. This NOEC will not lead to a C&L.

New Daphnia data provided by FAC

No data is available on the long-term toxicity of octanoic acid on aquatic invertebrates. In the registration dossier, this endpoint is covered by a read-across from decanoic acid, with a NOEC of 0.2 mg/L for *Daphnia magna* [9]. In this study, however, a solvent was used as a vehicle. Additionally, the test shows methodological deficiencies, due to which the outcome is considered ambiguous. Since the NITE test results could not be used for pesticide registrations in the USA (FIFRA, EPA) the test had to be repeated aiming at a better control of test conditions. A new longterm test (OECD 211) with decanoic acid without solvent was therefore conducted, in order to comply with global regulations for chemicals. Based on a preliminary test, a 2 mg/L concentration could be held stable under the test conditions, and 2.0 mg/L was thus used as highest test concentration. However, in the definite test, only 0.592 mg/L (TWA) was measured of the nominal 2.0 mg/L [10]. Since no mortality and no effect on reproduction were observed at the highest test concentration, it was concluded to repeat the test for the NOEC determination under stable

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concentration conditions. The present data give no reason to expect effects to occur, and the NOEC is therefore expected to be above 1 mg/L. Test data are expected by Oct 2012.

FAC conclusion for environmental hazard (daphnia)

Daphnia limit test for the read-across substance decanoic acid is in process because the present data give no reason to expect effects to occur, and the NOEC is therefore expected to be above 1 mg/L. Test results for the read-across substance decanoic acid are expected by Oct 2012 [16]. In conclusion, since new relevant data is expected on long-term toxicity to aquatic invertebrates, the Fatty Acids Consortium asks to postpone the decision of the harmonisation of classification of octanoic acid until all relevant data is available.

End of ENVIRONMENTAL HAZARDS, attachment no. 1.

Dossier Submitter's Response

No new data on eco-toxicity and fate and behaviour are available to the RMS. Therefore we cannot comment on this.

Conclusion on environmental hazards (algae):

No new data are available to the submitter, therefore we cannot comment on this.

There are algae NOEC (72 h) values available for heptanoic (C 7), octanoic (C 8), nonanoic (C 9) and decanoic acid (C 10) with 29 mg/L, 0.07 mg/L, 0.57 mg/L and 0.25 mg/L, respectively.

The observed effects are not caused by a metabolic adaptation phase with little growth but by disruption of the cell membranes with subsequent destruction of photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell content occurs. The plant tissue is destroyed visibly within 24 hours after treatment. Severe necrosis of treated plant parts can be observed (Review report for the active substance Fatty acids C₇ to C₂₀ in view of the inclusion in Annex I of Directive 91/414/EEC, 2008). For this reason, fatty acids are also used as herbicides.

For octanoic acid this justifies a classification with Aquatic Chronic 2.

Conclusion on environmental hazards (daphnia):

If the chronic daphnia NOEC (21d) values from nonanoic and heptanoic acid are additionally taken into account for read-across, then the value from nonanoic acid (9.93 mg/L) would probably be the most appropriate, considering that toxicity increases with chain length and in order to have a worst case approach (reference is made to comment number 16). We do not have access on the new data mentioned by FAC and can therefore not comment on these data.

Overall conclusion:

The dossier submitter is therefore of the opinion, that the C&L proposal for octanoic acid for environmental hazards in the CLH-report shall be changed to no classification, according to DSD on basis of the algae E_rC₅₀ (72h) of 31 mg/L for octanoic acid and to Aquatic Chronic 2, according to the CLP on basis of the algae NOEC (72 h) of 0.07 mg/L for octanoic acid (both CSR on octanoic acid, reference is made to comment number 16).

RAC's response

Algae tests and classification:

RAC agrees with the original classification because the result from the REACH registration dossier is not consistent with the results obtained in daphnia and fish or with the trend observed in the algae tests carried out on the other substances of the group. When this test is not considered it appears that toxicity increases with hydrophobicity.

Furthermore, there are some deficiencies in the test from REACH registration, such as the

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inconsistency in dose-responsiveness at the lowest concentrations, the rapid loss of the test concentration and the fact that the highest effect is observed at 24 hours. Therefore, taking into account that the reliability of this test cannot fully be confirmed and that this test is not consistent with the results of the other taxonomic groups, it should not be used for classification purposes.

In relation to the new algae test performed with octanoic acid, it is not totally clear if, at the end of the test, the concentration has been measured with algae present as required by the guideline or without algae. On the other hand, if the test has been performed according to the guideline, it is difficult to understand why it is possible to maintain the concentration for the duration of the test for octanoic acid, and not for nonanoic, decanoic and lauric acid. Therefore the reliability of this test cannot be confirmed, and it should not be used for classification purposes

Moreover RAC agrees with the DS on the fact that the observed effects are not caused by a metabolic adaption phase with little growth. Therefore the use of measured concentrations is justified.

A read-across from nonanoic and decanoic acid is appropriate considering it as a worst case because the toxicity is higher when the hydrophobicity is also higher.

Taking into account the unreliability of the test submitted under REACH registration and the new test submitted by the industry and the justified use of measured concentrations in the algae tests, the classification is as follows.

Aquatic Chronic 3, H412 under CLP.
N, R51/53 under DSD.

Bioaccumulation:

The log kow may be an unreliable predictor of bioconcentration potential for this substance, therefore it is not appropriate to compare it with the classification criteria. No measured BCF data are available for octanoic acid itself. The C₁₂ analogue lauric acid is more hydrophobic than octanoic acid, so a direct read across of its measured fish BCF is likely to be a worst case approach. The implication in the absence of any further evidence is that the BCF of octanoic acid is below 500 L/kg, but it cannot be ruled out that the BCF is above 100 L/kg.

New Daphnia test:

The NOEC ≥ 1.3 mg/L (TWA), supports the conclusion that Daphnia is not the most sensitive species, .This new test is not going to change the classification. This conclusion is also applicable to octanoic acid if a read-across from decanoic acid is used as a worst case, providing NOEC values higher than 1 (NOEC (octanoic acid) > 1.09 mg/L).

Read-across from nonanoic acid does not change the classification.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	19
Comment received				
see confidential attachment				
<i>ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf was submitted as a separate attachment and claimed confidential. Attachment no.6</i>				
Dossier Submitter's Response				
You are kindly asked to refer to our answer to comment number 18.				
RAC's response				
See answer to comment number 18.				

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REFERENCES:

ATTACHMENTS RECEIVED: 6

1. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf**, submitted by Belgium/Oleon NV / Company-Manufacturer. *Part of document is copied in the table.*
2. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf**, submitted by Netherlands / Wilmar Europe Trading BV / Company-Importer.
3. **FAC Comments on CLH of octanoic acid - 04.08.12.pdf**, submitted by Switzerland / Company-Downstream user

Confidential attachments: 3

4. **20120806_FAC_COMMENTS_on_CLH_OCTANOIC_C8_final.pdf**, submitted by Germany/Company-Manufacturer
5. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final Omya Hamburg.pdf**, submitted by Germany/Company-Importer.
6. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_OCTANOIC_C8_final_final.pdf**, submitted by Germany/ Company-Manufacturer

ECHA note: The attachment no. 1-6 are identical in contents.