EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

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European Chemicals Bureau
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2-ETHYLHEXYL ACRYLATE

CAS No: 103-11-7

EINECS No: 203-080-7

Summary Risk Assessment Report

2005 **Special Publication I.05.72**

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2005

Germany

Rapporteur for the risk assessment of 2-ethylhexyl acrylate is the Federal Institute for Occupational Safety and Health.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance 2-ethylhexyl acrylate that has been prepared by Germany in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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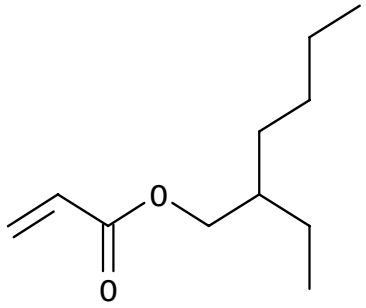
1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number:	103-11-7
EINECS Number:	203-080-7
IUPAC Name:	2-ethylhexyl acrylate
Synonyms:	Acrylic acid 2-ethylhexyl ester, 2-Ethylhexylprop-2-enoate, 2-Propenoic acid 2-ethylhexylester
Molecular weight:	184.28 g/mol
Empirical formula:	$C_{11}H_{20}O_2$
Structural formula:	



1.2 PURITY/IMPURITIES, ADDITIVES

Commercial 2-Ethylhexylacrylate has a purity of > 99%.

The following impurities are possible:

2-Ethylhexylacetate
2-Ethylhexylpropionate
2-Ethylhexanol
2-Methylstyrol
Styrol
n-Butylmethacrylate
n-Butylacrylate
Methylmethacrylate
Ethylacrylate
Methacrylate
2-Ethyl-4-methylpentylacrylate
2-Ethylhexylbutyrate
2-Ethylhexylcrotonate
2-Ethylhexylether
2-Ethylhexene
n-Hexylacetate
p-Methoxyphenol
2-Ethylhexyl 3-acryloxypropionate
2-Ethylhexyl 3-(2-ethylhexoxy)propionate
Acrylic acid
Water

1.3 PHYSICO-CHEMICAL PROPERTIES

Table 1.1 Summary of physico-chemical properties

Property	Value
Physical state	liquid at 20°C
Melting point	-90°C
Boiling point	216°C at 1,013 hPa 134°C at 80 hPa
Relative density	0.887 at 20°C
Vapour pressure	533.3 hPa at 192.2°C 133 Pa at 50°C 17.1 Pa at 20°C 12 Pa at 20°C
Water solubility	9.6 mg/l at 25°C
Partition coefficient n-octanol/water (log value)	3.67 4.6 3.9 4.09
Flash point	82°C
Autoflammability	245°C (DIN 51 794)
Flammability	non flammable
Explosive properties	not explosive
Oxidizing properties	no oxidizing properties
Surface tension	69.2 mN/m at 20°C

Remarks:

Boiling point: both data are literature values;

Vapour pressure: the values at 50°C and 192.2°C are literature values; the vapour; pressure at 20°C was extrapolated from these data;
the value of 12 Pa was used for environment section of the risk assessment;

Surface tension: experimental value, using OECD guideline 115 (ring method); the concentration of the used test solution was approximately 90 mg/l;

Partition coefficient: 3.67 is a literature value on the basis of a HPLC-method;

4.6 is an experimental value, using the OECD guideline 107 (shake flask method);

3.9 is an experimental value and has been used for the calculations in the environmental section of the risk assessment;

4.09 was calculated by the computer program KOWWIN for Microsoft Windows 3.1 of the company Syracuse Research Corporation;

Water solubility: valid experimental value based on column elution analysis.

1.4 CLASSIFICATION

Classification and labelling according to the 29th ATP of directive 67/548/EEC[1]:

Classification

Xi
R 37/38
R 43

According to the data presented below and the criteria of Directive 67/548/EEC, 2-ethylhexyl acrylate has not to be classified as dangerous to the environment.

Labelling

Xi
R: 37/38-43
S: (2-) 36/37-46

Xi	Irritant
R 37/38	Irritating to respiratory and to skin
R 43	May cause sensitisation by skin contact
2	Keep out of the reach of children
36/37	Wear suitable protective clothing and gloves
46	If swallowed, seek medical advice immediately and show this criteria or label

[1] Commission Directive 2004/73/EC of 29 April 2004, adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 216, 16.06.04, p.34.

2 GENERAL INFORMATION ON EXPOSURE

2-Ethylhexyl acrylate is produced from 2-ethyl hexanol and acrylic acid by catalytic dehydratisation in a continuous process. The spent lye of the aqueous work-up is treated in a waste water treatment plant.

6 companies are known to produce or import 2-ethylhexyl acrylate within the European Union. In 1999 the total EU production volume was 70,000 tonnes/annum, the import volume was approximately 30,000 tonnes/annum and 10,000 tonnes/annum were exported.

From the actual figures available for 1999, a total amount of 90,000 tonnes/annum is estimated to be available on the European market, 32,000 tonnes of that are used as an internal intermediate and 58,000 tonnes are sold to external processing sites. Recent information obtained from industry confirmed that no significant changes of the tonnages have to be expected for 2000 and 2001.

2-Ethylhexyl acrylate is used as a monomer in the chemical industry for the production of polymers and copolymers, which are mainly processed further to aqueous polymer dispersions. The polymers and polymer dispersions are used in adhesives and as binders for paints. Other applications include coatings raw materials and uses in the plastics and textiles industries.

In addition, 2-ethylhexyl acrylate is used as a monomer in construction-industry chemicals (e.g. floor coatings, road-marking substances) in concentrations between 0.1-21%.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

General discussion

Releases of 2-ethylhexyl acrylate into the environment are expected to occur mainly during production and processing with waste water and exhaust gases.

Further releases are expected through residual monomeric acrylate-contents in the polymeric products. According to the producer, the aqueous polymer dispersions, as the main products, contain less than 200 mg monomeric 2-ethylhexyl acrylate per kg. Therefore, 200 ppm are considered to represent a realistic worst case for the current situation in Europe and is used in the further assessment. Through storage of the polymeric products the residual monomers may partly polymerise and quantification of the releases into the environment from polymeric products can be performed only roughly.

The environmental behaviour of 2-ethylhexyl acrylate is determined by the following characteristics:

- hydrolysis is not a relevant degradation process in the environment
- 2-ethylhexyl acrylate can be classified as readily biodegradable
- the estimated atmospheric half-life is approximately 19 hours
- evaporation from surface water is rapid and therefore an important fate process

Based on the physical chemical properties of 2-ethylhexyl acrylate, the atmosphere is the main target compartment for distribution and only small amounts remain in the hydrosphere.

From the log Pow of 3.9 BCF- and Koc-values can be calculated indicating a moderate potential for bioaccumulation and geoaccumulation.

In waste water treatment plants 93% of the substance are estimated to be removed (56% by biodegradation, 30% by evaporation and 7% by adsorption onto sludge) and 7% are released to surface water.

Environmental releases

Predicted Environmental Concentrations (PECs) are calculated for the local aquatic environments of production and processing sites, of external processing sites, for the formulation of aqueous polymer dispersions, the processing and use of water based adhesives and paints and for paper recycling processes. The results of the calculations are compiled in the following table:

Table 3.1 Estimated local concentrations in surface water

Scenario	Total tonnage in this application	Data basis	PEC [µg/l] *
Production and processing	70,000 tonnes/annum	site specific	0.14
External processing	58,000 tonnes/annum	default	0.01
Formulation of aqueous polymer dispersions	42 tonnes/annum residual monomer	default	0.6
Processing and use of water based adhesives and paints	35.7 tonnes/annum residual monomer	default	0.1
Paper recycling	4.2 tonnes/annum residual monomer	default	0.5

* The estimated regional background concentration of 0.006 µg/l is already included here

For waste water treatment plants the highest effluent concentration of 6 µg/l obtained in the default calculation for the largest site formulating aqueous polymer dispersions is used as the PEC for microorganisms.

Releases into the atmosphere are estimated for three local scenarios. The resulting local air concentrations, the atmospheric deposition amounts and the resulting local soil concentrations are summarised in the table below.

Table 3.2 Estimated local concentrations in air and soil due to atmospheric deposition

Scenario	Data basis	PEC_{local} (air)	$DEP_{total\ ann}$	PEC_{local} (soil)	PEC_{local} (grassland)
Production and processing	site specific	8.3 [µg/m³]	9.1 [µg·m^{-2}·d^{-1}]	0.85 [µg/kg ww] 0.05 µg/l (porewater)	1.34 [µg/kg ww] 0.08 µg/l (porewater)
External processing	default	7.6 [µg/m³]	8.2 [µg·m^{-2}·d^{-1}]	0.77 [µg/kg ww] 0.05 µg/l (porewater)	1.21 [µg/kg ww] 0.07 µg/l (porewater)
Formulation of aqueous polymer dispersions	default	0.1 [µg/m³]	0.2 [µg·m^{-2}·d^{-1}]	0.01 [µg/kg ww] 0.001 µg/l (porewater)	0.02 [µg/kg ww] 0.001 µg/l (porewater)

The regional background concentrations estimated for air of $7.9 \cdot 10^{-4}$ µg /m^3 and for soil of $8.1 \cdot 10^{-5}$ µg /kg ww can be considered neglectable.

3.2 EFFECTS ASSESSMENT

Aquatic compartment (incl. sediment)

For most of the available ecotoxicological studies only nominal concentrations are reported and the possible decrease in test concentrations by volatilisation of the substance was not considered. In addition, the reported effect concentrations often significantly exceed the water solubility of 2-ethylhexyl acrylate. These studies are regarded as invalid and not suitable for risk assessment purpose.

The valid studies in fish, invertebrates and plants where the effect concentrations are based on analytical monitoring are compiled below:

Table 3.3 Ecotoxicological test results used for risk assessment

Species	Effect	Nominal concentration	Effect concentration
Rainbow trout, *Oncorhynchus mykiss*	mortality	2.15 mg/l - 3.16 mg/l	96-hour LC_{50} = 1.8 mg/l*
Crustacean, *Daphnia magna*	swimming ability	46.3 mg/l	48-hour EC_{50} = 1.3 mg/l
Green algae, *Desmodesmus*	growth	23.7 mg/l	72-hour E_RC_{50} = 1.71 mg/l
Protozoa, *Chilomonas paramaecium*	growth	2.3 mg/l	48-hour TGK (EC_5) = 2.3 mg/l**

* Mean values of the detected concentrations after 1, 24, 48 and 96 hours are reported, the LC_{50} value is calculated as the geometric mean from 1.49 mg/l < 96-hour LC_{50} < 2.19 mg/l.

** For microorganisms only studies reporting nominal concentrations are available. The result for the protozoan species is the only one not significantly exceeding the water solubility of the substance and is therefore used for risk assessment.

The Predicted No Effect Concentration (PNEC) for aquatic organisms is calculated from the lowest reported acute test result for *Daphnia magna* (48-hour EC_{50} = 1.3 mg/l) applying an assessment factor of 1,000:

$$PNEC_{aqua} = 1.3 \text{ mg/l} / 1{,}000 = 1.3 \text{ µg/l}$$

For microorganisms in waste water treatment plants the PNEC is based on the 48-hour TGK (EC_5) = 2.3 mg/l reported for protozoan using an assessment factor of 1:

$$PNEC_{microorganism} = 2.3 \text{ mg/l} / 1 = 2.3 \text{ mg/l}$$

There are no experimental results with benthic organisms available. The $PNEC_{sed}$ could provisionally be calculated using the equilibrium partitioning method, but for 2-ethylhexyl acrylate no information beyond those available for the water compartment could be obtained.

Atmosphere

Data on biotic or abiotic effects in the air compartment are not available. Because of the short half-life of 2-ethylhexyl acrylate in the atmosphere (about 19 hours) adverse effects are not to be expected.

Terrestrial compartment

Test results with terrestrial organisms are not available. In an indicative risk assessment for the soil compartment, the aquatic PNEC can be used and compared to the concentration in soil pore water:

$$PNEC_{soil} = 1.3 \text{ µg/l (soil pore water)}$$

Secondary poisoning

To evaluate whether the substance may cause toxic effects if accumulated in higher organisms through the food chain the classification on the basis of mammalian toxicity data can be used. 2-Ethylhexyl acrylate is not classified as Very Toxic or Toxic or Harmful and there are no adequate data from dietary toxicity tests which can be used for the determination of a $PNEC_{oral}$. Therefore a quantitative assessment of secondary poisoning can not be performed but improvement of the data basis is not of high priority for 2-ethylhexyl acrylate.

3.3 RISK CHARACTERISATION

Aquatic compartment (incl. sediment)

In **Table 3.4** all PEC/PNEC ratios calculated for the aquatic compartment including waste water treatment plants are compiled:

Table 3.4 PEC/PNEC ratios for the aquatic compartment

Scenario	PEC [µg/l]	PNEC [µg/l]	PEC / PNEC
Production and processing	0.14	1.3	0.1
External processing	0.01	1.3	0.008
Formulation of aqueous polymer dispersions	0.6	1.3	0.5
Processing/use of water based adhesives and paints	0.1	1.3	0.08
Paper recycling	0.5	1.3	0.4
Waste water treatment plants	6	2,300	0.003

As for all exposure scenarios PEC/PNEC < 1, a risk for the aquatic compartment of the environment is not deduced for the present data configuration. **Conclusion (ii)**.

A quantitative risk assessment for the sediment compartment based on the equilibrium partitioning method is not necessary as no information beyond those available for the water compartment can be obtained. From the results for the water phase it can be concluded that no further testing has to be recommended for the sediment compartment because 2-ethylhexyl acrylate is neither released nor distributed to sediments in significant amounts. **Conclusion (ii)**.

Terrestrial compartment

A site specific release estimation representing a worst case situation for production, processing and use of 2-ethylhexyl acrylate was used to calculate the atmospheric deposition and the resulting concentration in the soil porewater in the vicinity of that site.

In an indicative risk assessment the $PEClocal_{porewater}$ of 0.08 µg/l is compared to the aquatic PNEC:

$$PEC/PNEC = 0.08 / 1.3 = 0.06$$

As PEC/PNEC < 1, a risk for the soil compartment is not identified. **Conclusion (ii)**.

Atmosphere

A quantitative risk characterisation for the air compartment is not possible, but due to the short atmospheric lifetime ($t_{1/2}$ = 19 hours), biotic or abiotic adverse effects upon the atmosphere are not expected from 2-ethylhexyl acrylate. Therefore, qualitatively, no risk is deduced for this compartment. **Conclusion (ii)**.

Secondary poisoning

A risk characterisation for secondary poisoning seems opportune because there are indications of a bioaccumulation potential. A $PEC_{oral,\ fish}$ of 0.1 $mg/kg_{wet\ fish}$ can be calculated from the calculated BCF of 412 $l/kg_{wet\ fish}$ assuming that half of the diet originates from a local and half from a regional environment.

Adequate data from dietary toxicity tests for the determination of a PNEC are not available. But as 2-ethylhexyl acrylate is not classified as Very Toxic or Toxic or Harmful, qualitatively no risk is identified for secondary poisoning and improvement of the data basis seems not of high priority. **Conclusion (ii)**.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

Occupational exposure

2-Ethylhexyl acrylate (2-EHA) is mainly used as a monomer in the chemical industry for the manufacture of polymeric chemicals, which are processed further to aqueous polymer dispersions. The polymers and polymer dispersions are used in different products e. g. in adhesives, in printing inks and as binder in paints. According to information provided by the manufacturers, aqueous polymer dispersions may contain residual monomer contents of 0.02% 2-EHA. In latex coatings, for instance, residual 2-EHA concentrations are generally 0.08% or less. In addition, monomeric 2-EHA is an additive in preparations, which are applied in the construction industry as floor coatings and road-marking materials. The concentration of monomeric 2-EHA amounts up to 21%.

Detailed information on the production volumes is given in Section 2.

The occupational exposure limits for 2-EHA in Germany and Austria, amounting to about 82 mg/m^3, which may not be exceeded even short-term (15-minute average).

Based on the available information the following relevant occupational exposure scenarios are to be expected:

- production of 2-EHA and polymerisation in the chemical industry (Scenario 1),
- formulation of preparations containing up to 21% 2-EHA (Scenario 2),
- use of formulations containing monomeric 2-EHA in the construction industry (Scenario 3),
- use of dispersions with residual monomeric 2-EHA (< 0.08%) (Scenario 4).

A decision on the importance of exposure scenarios is made in comparison with the “critical exposure level” derived on toxicological data. For 2-EHA, the critical exposure level amounts to 6.4 mg/m³. Concern will be expressed for scenarios with exposure levels above this concentration. Therefore, exposure scenarios with anticipated exposure levels < 1 mg/m^3, being considerably below this concentration, are regarded to be of minor relevance. These scenarios are not assessed quantitatively.

The exposure assessment is based on measured data and literature data, expert judgement and estimations according to the EASE model (Estimation and Assessment of Substance Exposure). The exposure levels are to be regarded as reasonable worst case estimates representing the highly exposed workers.

The results for the different scenarios are summarised in **Table 4.1**.

Chemical industry

For the large-scale chemical industry, it is assumed that the production and further processing of 2-EHA is mainly performed in closed systems. Exposure occurs during certain activities in the manufacturing and further processing (polymerisation) of monomeric 2-EHA (Scenario 1).

Use of monomeric 2-EHA (formulation and use of preparations)

Monomeric 2-EHA is a component of preparations, used in the construction industry, for example, in coating agents for industrial flooring or road-marking agents. According to information provided by one manufacturer the monomeric concentration amounts up to 21% 2-EHA. Exposure occurs mainly during the manufacture of preparations (Scenario 2) and their uses in the construction industry (Scenario 3).

The low vapour pressure of 2-EHA (12 Pa) leads to limited inhalation exposure levels. If the pure substance or preparations containing > 21% monomeric 2-EHA are handled it is to be assumed, that workers protect themselves against the highly irritative effect of the substance by using protective equipment (here gloves) and by applying appropriate working techniques.

Use of formulations containing residual 2-EHA

The widespread industrial and skilled-trade applications of polymer dispersions containing residual 2-EHA monomer (< 0.08%) comprise uses in paints, lacquers, varnishes, moulding materials, impregnating agents and applications in adhesives and adhesive tapes (Scenario 4).

On account of the low concentration of monomeric 2-EHA and the low vapour pressure, inhalation exposure is regarded to be negligible compared to the "critical exposure level" (see above). In view of the sensitising effect of 2-EHA, dermal exposure is assessed although the concentrations of monomeric 2-EHA are very low.

Summary of exposure data

Table 4.1 Summary of exposure data

Exposure scenario	Duration and frequency of activities relevant for exposure	Inhalation exposure Shift average [mg/m³]	Dermal exposure Shift average [mg/person/day]
Production and polymerisation in the chemical industry			
1) Production of 2-EHA and polymerisation	shift length, daily	2.8 (95th percentile)	negligible (1) (expert judgement) 10.5 (1, 2, 3) (EASE)
Formulation of preparations			
2) Formulation of preparations containing up to 21% 2-EHA	2 hour (assumed), daily	19 (EASE, without LEV)	negligible (1) (expert judgement) 10.5 (1, 2) (EASE)
Use of formulations			
3) Use of formulations containing monomeric 2-EHA (< 21%) in the construction-industry	shift length, not daily	3 (4) (analogous data)	880 (5) (EASE)

Table 4.1 continued overleaf

Table 4.1 continued Summary of exposure data

Exposure scenario	Duration and frequency of activities relevant for exposure	Inhalation exposure Shift average [mg/m3]	Dermal exposure Shift average [mg/person/day]
4) Use of dispersions with residual 2-EHA (< 0.08%)	daily	negligible (6) (expert judgement)	3 (5) (EASE)

1) Highly irritative substance
2) Occasional exposure, not daily
3) For cleaning and maintenance during shut down of a plant, exposure level of 27 – 270 mg/person/day should be taken (once a year, several days)
4) Analogous data: methyl methacrylate is used, in part, in the same formulation
5) Gloves are not regularly worn
6) Exposure < 1 mg/m³

EASE Estimation using the EASE model (Estimation and Assessment of Substance Exposure)
LEV Local Exhaust Ventilation

Consumer exposure

According to the Swedish product register different 2-EHA containing products are available for consumers. The respective codes of the product types are 1) lubricants/greases, 2) agricultures/forestry and 3) products offered in wholesale and retail trade, repair shops for motor vehicles, -cycles and other household goods. Additionally, 2-EHA is also used in paints and lacquers, thus it can be assumed that these products will reach the area of consumer use.

Furthermore, it might be assumed that the consumer is exposed to 2-EHA by the oral route due migration of residual monomers from plastics coming into contact with foods. An estimation of this exposure is not possible due to the lack of data about the amounts used for this purpose and the migration rate.

Although 2-EHA is also present as a residual monomer in floor coatings, the notifier has declared that these coatings are used only for industrial floors. Agricultural and forestry uses are mentioned under “indirect exposure” via environment.

For consumer exposure the categories lubricants and greases and paints and lacquers remain of interest (dermal respectively inhalation exposure). The residual monomer content of 2-EHA in such products accounts for 0.08% of the polymer.

Dermal exposure

Lubricants and greases used in cars or other vehicles may be exposed dermally to consumers for short periods of time during bringing up the grease. The quantification of this, however, is not possible because of lack of data. For a worst case estimate the following assumptions were made: the weight fraction of residual monomer in grease is assumed to be similar to paints (0.08%) of the content of the polymer which is 10%. The volume of grease contacting the hands is 8.4 cm^3 (=840 cm^2 [surface area] · 0.01 cm [thickness], TGD default, assumed density 1), then an amount of 0.672 mg/event of the residual monomer would lead to dermal contact. On a body weight basis the dermal exposure would result in 11.2 µg/kg bw per event.

For paints, the same scenario can be taken, however, with a lower contact area set to 1 cm^2 for splashes of paints. Taking the weight fraction of the residual monomer in paints of 0.00048, the dermal exposure to paints would reveal 1.3 µg/kg bw/event.

Inhalation exposure

For the estimation of the inhalatory exposure of the consumer, a computer simulation with the US-EPA model SCIES was used and using data given by BAMM for dispersion paints. All values together with SCIES default values are given in the table below. The amount of 2-EHA polymers in the paint is 60%, therefore the content of 2-EHA residual monomer is 0.048% (weight fraction of 2-EHA in paints 0.00012).

Consumer exposure with 2-EHA (dispersion paints)

Annual frequency of use	6	events/year
Mass of product	13,600	grams
Duration of use	4.9	hours
Volume of room of use (zone 1 volume)	40	m^3
Whole house volume	292	m^3
House air exchange rate	0.2	room air exchange/hr
User inhalation rate (during use)	1.3	m^3
Non-user inhalation rate	1.1	m^3
Molecular weight	184	g/mole
Vapour pressure	0.09	torr
Weight fraction	0.00048	residual monomer
Body weight	60	kg

The calculation reveals a peak room concentration during use of 22 mg/m^3 (= 2.9 ppm), the average concentration is 16 mg/m^3 (= 2.1 ppm). Measurements of 2-EHA residual monomers after painting with paints containing 940 ppm (weight fraction 0.00094) and 2,000 ppm (weight fraction 0.002) a room with restricted ventilation revealed room air peak concentrations of 2.5 ppm and 8 ppm, which is in accordance to the estimated values. 2-EHA was not detectable 25 hours after painting.

For handicraftsmen, maximum air concentrations of < 1 ppm were measured during a monitoring programme by the notifier according to the TRG 402 which may be comparable to consumer use of paints.

For risk characterization, the value of 1 ppm (respectively 0.0075 mg/l) of 2-EHA residual monomer in indoor air should be taken as a worst case value for short-term exposure scenarios. Taking into account the time of application of paints and that 2-EHA was not measured 25 hours after painting, chronic (long-term) exposure by inhalation is not given.

Oral exposure

Plastic material that comes into contact with food is regulated by the EU directive 90/128/EEC, 28th of February 1990, “Directive of materials and articles intended to come in contact with food stuff”. In this regulation, 2-EHA has not been finally evaluated. Exposure data due to limitations given by the directive are not available. Due to the presence of other plastic materials (e.g. MMA) the amounts of residual monomeric 2-EHA should be low and will therefore be neglected.

<u>Humans exposed via the environment</u>

According to Appendix VII of chapter 2 of the TGD, the indirect exposure to humans via the environment, i.e. through food, drinking water and air is estimated.

Two local scenarios are calculated for comparison purpose. Site specific data for the main production site are used to represent worst case exposure of the soil and air compartment combined with a lower but realistic concentration in surface water. On the other hand, the scenario for the formulation of aqueous polymer dispersions is used representing the highest estimated concentration in surface water and comparably low exposure of the soil and air compartment.

In addition, the average human intake due to the regional background concentrations is calculated.

The input parameters are compiled in **Table 4.2**.

Table 4.2 Local and regional scenarios for indirect exposure

		Site specific, site A	Formulation of polymer dispersions	Regional
Concentration in surface water	PEC_{water_ann}	$1.2 \cdot 10^{-4}$ mg/l	$4.9 \cdot 10^{-4}$ mg/l	$5.8 \cdot 10^{-6}$ mg/l
Concentration in the atmosphere	PEC_{air_ann}	$8.3 \cdot 10^{-3}$ mg/m³	$7.7 \cdot 10^{-5}$ mg/m³	$7.9 \cdot 10^{-7}$ mg/m³
Concentration in grassland soil	$PEC_{grassland}$	$1.3 \cdot 10^{-3}$ mg/kg	$2.2 \cdot 10^{-5}$ mg/kg	$6.8 \cdot 10^{-5}$ mg/kg
Concentration in grassland porewater	$PEC_{grassland\_pw}$	$8.2 \cdot 10^{-5}$ mg/l	$1.4 \cdot 10^{-6}$ mg/l	$4.2 \cdot 10^{-6}$ mg/l
Concentration in groundwater:	PEC_{grw}	$5.2 \cdot 10^{-5}$ mg/l	$8.7 \cdot 10^{-7}$ mg/l	$4.2 \cdot 10^{-6}$ mg/l

The resulting total daily doses and the routes of exposure are displayed in **Table 4.3**.

Table 4.3 Total daily doses and contribution of the different routes of indirect exposure

Scenario	Site specific, site A	Formulation of polymer dispersions	Regional
Total daily dose ($DOSE_{tot}$)	$2 \cdot 10^{-3}$ mg·kg $_{bw}^{-1}$·d^{-1}	$3.6 \cdot 10^{-4}$ mg·kg $_{bw}^{-1}$·d^{-1}	$6 \cdot 10^{-6}$ mg·kg $_{bw}^{-1}$·d^{-1}
% via drinking water	< 0.1	2	2
% via air	89.4	4.6	2.9
% via stem (leaf crops)	5.4	0.3	0.2
% via root crops	1.1	0.1	28.4
% via meat	< 0.1	< 0.1	< 0.1
% via milk	< 0.1	< 0.1	< 0.1
% via fish	3.9	93	66.6

The main route of indirect exposure in the local scenario is the intake via air (for site A) and via fish consumption (for formulation of polymer dispersions). Other routes of exposure do not comprise to a significant extent to the total daily dose. For the regional Scenario 2/3 of the total dose is attributed to the consumption of fish followed by nearly 30% uptake via root crops. Exposure via air is only of minor importance in the regional scenario.

4.1.2 Effects assessment

2-Ethylhexyl acrylate (2-EHA) is rapidly and extensively absorbed, distributed and eliminated after oral administration. There are no specific toxicokinetic studies available using dermal administration or inhalation exposure. Studies on rats have indicated that short-chain acrylates

such as 2-EHA undergo carboxylesterase-catalyzed hydrolysis to acrylic acid and 2-ethylhexanol.

Human data on the acute toxicity of 2-EHA are not available. In animal tests, single oral or dermal administration or inhalation of saturated atmospheres of 2-EHA demonstrated only low toxicity. Acute oral toxicity in rats is characterised by LD_{50} values of 4,000-6,000 mg/kg with slight toxic effects (scant droppings, wet yellow stained anogenital area, decreased spontaneous motoric activity and ataxia). For rabbits, a dermal LD_{50} value >10,000 mg/kg is reported. Valid data on acute inhalation toxicity tests are not available. In a test with rats, after an 8-hour inhalation of an atmosphere saturated with EHA at 20°C no mortality and no clinical signs were observed. The substance is not to be labelled because of acute toxic effects.

Information on human experience with local irritation/corrosion caused by 2-ethylhexyl acrylate is not available. In animal experiments 2-EHA caused serious lesions to the skin of rabbits which are assessed to be situated at the border between severe irritation and corrosion. As an alternative to the Draize skin irritation test the new test method according to the EU test Guideline B.40 (Skin Corrosion) has been developed for differentiation between irritation and corrosion. The result of a new study according to this guideline demonstrates that 2-EHA does not have a corrosive potential, and hence, the current classification of 2-EHA as irritant and labelling with "R 38, Irritating to skin" is confirmed. 2-EHA caused mild eye irritation in animal experiments. On the basis of these tests a labelling with R 36 is not warranted.

There exists no standard test method for the assessment of respiratory irritation. Thus, the labelling of 2-EHA with "R 37, Irritating to respiratory tract" according to current EU regulations is not based on results of a specific respiratory irritation test, but on considerations on the general irritation potential of 2-EHA (nasal and ocular irritation noted in a test on acute inhalation toxicity with rats, severe local irritation potential detected on the skin and moderate irritation potential detected on the conjunctivae of rabbits; serious lesions as seen after repeated inhalation of 2-EHA may well be initiated i.a. by primary respiratory irritation). Thus, labelling with R 37 is confirmed on the basis of all of the respective data.

Positive patch-tests are reported for humans. In various test models involving guinea pigs, 2-EHA proved sensitising, with and without adjuvants. 2-EHA showed a moderate sensitising potential in experimental animals. Information on respiratory sensitization is not available. According to the data 2-EHA is classified with "R 43, May cause sensitisation by skin contact".

The relevant toxic effect after 90-day inhalation exposure of rats to 2-EHA was dose-related increased degeneration of the olfactory epithelium at concentrations from 30 ppm and higher (0.225 mg/l). The NOAEC for local effects on the respiratory tract was 10 ppm (0.075 mg/l). Animals exposed to 2-EHA concentrations of 30 ppm or higher showed poor health condition (lethargy, ptosis) during exposure period and reduced body weight gain, but no toxic effect on internal organs was identified (NOAEC for systemic effects). Minimal liver damage was indicated by elevated liver enzyme activities at a concentration of 100 ppm (0.75 mg/l). Valid studies with dermal or oral application routes are not available. Cancer studies and less documented subchronic studies with dermal application revealed that 2-EHA causes skin irritation at concentrations $\geq$ 2.5% (LOAEL).

2-EHA is negative in bacterial mutation tests. Data from mammalian cells give no relevant evidence for clastogenicity; however, a fully reliable study is lacking. 2-EHA seems to have a low potential for induction of gene mutations in mammalian cells. Since this effect is limited

to doses with strong cytotoxicity, it is highly unlikely that this potential will be expressed in vivo. The data from mammalian cell indicator tests do not add relevant information. An in vivo cytogenetic assay was inconclusive (neither positive nor negative); due to severe methodological insuffiencies this study cannot be used for evaluation purposes. Cleavage products of 2-EHA were negative in *in vivo* mutagenicity tests. From all these data there is no relevant evidence that 2-EHA might be an in vivo mutagen.

There are no data available to the carcinogenic effects with respect to oral or inhalation exposure routes. Findings from the dermal mouse carcinogenicity study showed that 2-EHA induces skin tumours at concentrations which were highly irritative. However, other studies on different mouse strains did not confirm this finding. Taking into account the negative results from in-vivo genotoxicity testing, it is concluded that 2-EHA induces skin tumours by non-genotoxic mechanisms. Acrylic acid, the hydrolysis product, did not induce tumours in long term animal studies in mice treated dermally and in rats administered orally. Also, there is no concern from cancer data on 2-ethylhexanol as other product of hydrolysis. It is concluded that equivocal results from mice painting studies give no significant evidence of carcinogenic properties of 2-EHA.

There are no human data available on the reproductive toxicity of 2-EHA. From animal testing screening information on reproductive toxicity is available from a developmental toxicity study supplemented with data on reproductive organ toxicity investigations from a 3 month repeated dose study. Evaluation of the available screening information so far does not provide evidence for significant reproductive toxicity of 2-EHA. In rats no adverse effects on reproductive organs or on embryo/fetal development had been revealed for inhalation exposures to 2-EHA at concentrations of up to and including 100 ppm (approximately 0.75 mg/l).

4.1.3 Risk characterisation

4.1.3.1 Workers

4.1.3.1.1 Introduction to occupational risk assessment

2-Ethylhexyl acrylate (2-EHA) is a liquid substance with a vapour pressure of 12-17 Pa at 20°C. Inhalation exposure to vapours and skin exposure are the relevant routes of occupational exposure (for exposure scenarios see **Table 4.4**). The toxicological profile of 2-EHA is determined by its local toxicity (skin sensitisation, skin and respiratory tract irritation).

For toxicological endpoints with relevant quantitative data MOS values are calculated as quotient of experimental NOAEL (or LOAEL) and workplace exposure assessments. For dose transformation a breathing volume of 10 m³ per day is assumed at work. Scientifically based assessment factors describe the stepwise extrapolation of animal data to the worker population. The value of the minimal MOS, as decision mark between **conclusions (ii)** and **(iii)**, results from the multiplicative combination of the different assessment factors and the uncertainty factor. Minimal MOS values may be different for each toxicological endpoint. In a parallel procedure, which gives identical but more direct results, a “critical exposure level” (quotient of experimental NOAEL and minimal MOS) is identified for each endpoint, indicating concern if occupational exposure levels exceed this value.

Risk assessment for systemic health effects is based on the assumption of 100% systemic availability for all routes of exposure. Concerning local effects in the nose it is known that rodents show a nasal anatomy and respiratory physiology different from man. It is not known to what degree these species differences lead to sensitivity differences in rats and humans. Against that background for local effects by inhalation a species extrapolation factor of 1 is used. The assessment of systemic effects relies upon the concept of metabolic rate scaling.

The following occupational risk assessment is performed specifically for each toxicological endpoint. A summary table with all exposure scenarios and toxicological endpoints with **conclusion (iii)** is given at the end of the section.

4.1.3.1.2 Endpoint-specific risk assessment for workers

Acute toxicity

Inhalation

No lethality was observed in rats after 8 hours of exposure to a vapour-saturated atmosphere at 20°C (room temperature). Gross pathology revealed nasal and ocular irritation. The calculated saturation concentration for the vapour pressure of 12-17 Pa (20°C) would be ca. 920-1,310 mg/m^3 (120-170 ppm). This value is compared with the highest estimated inhalation exposure of 77 mg/m^3 (2 hours, EASE, Scenario 2) and 19 mg/m^3 (8 hours, EASE, Scenario 2). As to acute effects concern is not derived.

Dermal

A dermal LD_{50} of approximately 14,000 mg/kg was determined in rabbits. For comparison the oral LD_{50} for rats and mice lies between 4,000 and 6,000 mg/kg. Comparing the dermal LD_{50} of approximately 14,000 mg/kg with the highest acute dermal exposure of about 13 mg/kg (880 mg/person, Scenario 3) concern is not derived. **Conclusion (ii)**.

Irritation/Corrosivity

Dermal

2-EHA is strongly irritating to the skin of rabbits in studies on acute irritation, but should not be considered as corrosive. **Conclusion (ii)** is proposed on the grounds that control measures exist which can minimise exposure and risk of irritation/corrosivity, thereby reducing concern. However, these controls must be implemented and complied with to reduce the risk of damage to skin.

Eye irritation

Eye irritation is reported to be evident but less significant than local effects on the skin. The mild and reversible eye irritation does not warrant labelling with R 36. Concern as to eye irritation is not derived.

Inhalation

2-EHA is considered to be a respiratory irritant. There are no experimental data to describe a precise threshold for respiratory irritation of single exposures. Subchronic inhalation exposure of rats demonstrated a local NOAEC of 77 mg/m^3 (10 ppm), which is used for the MOS calculation.

For the selection of a minimal MOS the following subfactors are applied: A factor of 1/3 is used for duration adjustment (subchronic to acute). A factor of 2 accounts for different breathing volumes (6 hours to 8 hours; light activity of workers). Concerning local effects the interspecies adjustment factor is 1. A further uncertainty factor of 3 is considered appropriate to cover intraspecies variability, the nature and severity of effect (minimal nasal effects) and the quality of the database.

Thus, a minimal MOS of 2 is derived which results in a critical exposure concentration of 39 mg/m^3 (77/2 mg/m^3; 8 hours). Comparing this concentration with the highest 8-hour concentration of 19 mg/m^3 concern is not derived. Due to the 4-fold reduced exposure time the short term exposure of 77 mg/m^3 for 2 hours (Scenario 2) is also not considered to be of concern. **Conclusion (ii)**.

Sensitisation

Dermal

2-EHA is moderately sensitising in guinea pigs. Sensitisation has also been reported in humans; however there is no indication of a high sensitising potency in humans. Since also single contacts might lead to skin sensitisation concern is raised for Scenario 1, 2 and 3. Concern is not expressed as to Scenario 4 because of the very low 2-EHA-concentration in combination with the lacking indications from a comprehensive human survey. **Conclusion (iii)**.

Inhalation

There are no reports indicating cases of respiratory sensitisation in man. Concern is not expressed. **Conclusion (ii)**.

Repeated dose toxicity

Inhalation (local effects)

For MOS calculation the NOAEC of 77 mg/m^3 (10 ppm) of the subchronic inhalation study in rats (6 hours/day) is used. Minimal degeneration was observed in the olfactory epithelium of the nose at 230 mg/m^3 (30 ppm).

For the minimal MOS the following subfactors are applied: A factor of 2 for duration adjustment (subchronic to chronic). A factor of 2 for adjustment of breathing volumes (6 hours to 8 hours; light activity of workers). Interspecies differences are not assumed (factor 1). A further uncertainty factor of 3 is considered appropriate to cover intraspecies variability, the nature and severity of effect (minimal nasal effects) and the quality of the database.

A minimal MOS of 12 is derived which results in a critical exposure concentration of 6.4 mg/m^3 (77/12 mg/m^3). Concern is raised for the exposure level of 19 mg/m³ in Scenario 2. **Conclusion (iii)**.

Inhalation (systemic effects)

Based on the above mentioned inhalation study a systemic NOAEC of 230 mg/m^3 (30 ppm) was determined. At a higher dosage there were indications of minimal liver damage.

The numerical values of the adjustment factors for the systemic effects are the same as for local effects. Thus, a minimal MOS of 12 is derived which results in a critical exposure

concentration of 19 mg/m^3 (230/12 mg/m^3). Scenario 2 is a borderline scenario (MOS: 12.1), but it is not considered to be appropriate to raise concern. **Conclusion (ii)**.

Dermal (local effects)

Based on the results of a chronic dermal study with mice concern was not derived for local effects following repeated dermal exposure. **Conclusion (ii)**.

Dermal (systemic effects)

Valid experimental data for the assessment of systemic toxicity by skin contact is not available. The subchronic inhalation study with rats is used as starting point for MOS calculation, since it is regarded as valid and included histopathological examinations in both sexes. The NOAEC of 230 mg/m^3 (30 ppm) is used for the MOS calculation and corresponds to an intake by inhalation of 66 mg/kg/day (respiratory rate of 0.8 l/min/kg for rats), that is used as internal NAEL for MOS calculation.

For the selection of a minimal MOS the following subfactors are applied: For duration adjustment (subchronic to chronic) a default value of 2 is used. Metabolic rate scaling results in an interspecies adjustment factor of 4. A further uncertainty factor of 3 is considered appropriate to cover intraspecies variability, the nature and severity of effect and the quality of the database.

A minimal MOS of 24 is derived which results in a critical exposure level of 2.8 mg/kg/day (66/24 mg/kg/day). A chronic and daily exposure was only estimated for Scenario 4. No concern is derived. **Conclusion (ii)**.

Combined inhalation and dermal exposure

With respect to repeated dose toxicity and systemic effects no additional concern was derived for combined inhalation and dermal exposure. **Conclusion (ii)**.

Mutagenicity

Based on data on 2-EHA and related compounds 2-EHA is not considered to be an in vivo mutagen. Corresponding risks at workplaces are not anticipated to occur. **Conclusion (ii)**.

Carcinogenicity

Based on the interpretation of the results of chronic dermal studies in mice and the negative in vivo mutagenicity tests it is concluded, that 2-EHA induces skin tumours by a non-genotoxic mechanism. The experimental carcinogenic effect is considered to be associated with the highly irritating concentrations tested. The daily dermal exposure is assumed to be negligible (Scenarios 1, 2) or up to 0.04 mg/kg/day (3 mg/person/day, Scenario 4). The non-daily exposure can reach 13 mg/kg/day (Scenario 3). Overall, a strong chronic irritation that might lead to skin tumours is not expected in these scenarios.

Experimental data for the assessment of carcinogenicity by inhalation is not available. Taking account of the negative in vivo mutagenicity and of negative long term inhalation studies of specific acrylates/methacrylates 2-EHA is not suspected to be carcinogenic by inhalation. Corresponding risks at workplaces are not anticipated to occur. **Conclusion (ii)**.

Fertility impairment

A fertility study on 2-EHA is not available. In the 90-day inhalation study with rats no effect was observed in reproductive organs up to the highest concentration of 770 mg/m³ (100 ppm). A MOS-calculation is not performed, since no indication of an effect on reproductive organs was observed. **Conclusion (ii)**.

Developmental toxicity

In a study on developmental toxicity in rats no adverse effect on embryo/fetal development was observed up to the highest tested concentration of 770 mg/m³ (100 ppm). A MOS-calculation is not performed, since no effect on development was observed. **Conclusion (ii)**.

Summary of occupational risk assessment

In the following **Table 4.4** the occupational risk assessment is summarised. Skin sensitisation gives rise to concern for dermal exposure during production and polymerisation (Scenario 1), the formulation of preparations (Scenario 2) and the use of formulations containing monomeric 2-EHA in the building trade (Scenario 3). The risk assessment reveals concern with regard to local effects after repeated inhalation during formulation of preparations (Scenario 2). All other endpoints resulted in **conclusion (ii)**.

Table 4.4 Summary of conclusions for the occupational risk assessment of 2-EHA

Area of production and use		Sensitisation Dermal	Repeated dose toxicity Local effects after inhalation
1	Production and polymerisation of 2-EHA	iii	ii
2	Formulation of preparations containing up to 21% 2-EHA	iii	iii
3	Use of formulations containing monomeric 2-EHA in the building trade	iii	ii
4	Use of dispersions with residual 2-EHA (< 0.08%)	ii	ii

4.1.3.2 Consumers

Measured maximum air concentration of 2-EHA during use of dispersion paints was < 1 ppm (respectively 0.0075 mg/l). Taking into account that monomeric 2-EHA was not detectable 25 hours after painting; there is no reasonable suspicion for repeated inhalation exposure for consumers to 2-EHA after painting. Dermal exposure (maximum 11.2 µg/kg bw per event) and oral exposure are considered to be negligible.

Acute toxicity

Following the exposure assessment, consumers are only exposed to very low concentrations of 2-EHA. Following inhalation exposure in rats there were no deaths in a saturated 2-EHA atmosphere up to 8 hours. Thus, the substance is of no concern for the consumer in relation to acute inhalation toxicity. **Conclusion (ii)**.

Irritation/Corrosivity

Following the exposure assessment, consumers might be exposed dermally to negligible amounts of residual monomeric 2-EHA via infrequent applications of products containing polymeric 2-ethylhexyl acrylate. 2-EHA caused severe irritation after application to the skin of rabbits. Eye irritation was less severe in animal experiments.

The concentration of monomeric 2-EHA in the final products for consumers (0.08%) is under the concentration limit which would lead to classification and labelling. Taking into account the very low content of monomeric 2-EHA as well as the infrequent use it is concluded that there is no concern for the consumer in relation to irritative effects. **Conclusion (ii)**.

Sensitisation

Following the exposure assessment, consumers might be exposed to negligible amounts of residual monomeric 2-EHA via infrequent applications of products containing polymeric 2-ethylhexyl acrylate. 2-EHA has shown a moderate sensitising potential in experimental animals. There is also evidence of sensitisation in humans. Taking into account the very low content of monomeric 2-EHA as well as the infrequent use it is concluded that there is no concern for the consumer in relation to sensitisation. **Conclusion (ii)**.

Repeated dose toxicity, Mutagenicity, Carcinogenicity, and Toxicity for reproduction

Repeated exposure of consumers via inhalation as well as the dermal and oral route are considered to be negligible. Thus, 2-EHA is considered without concern for consumers with regard to toxic, mutagenic, carcinogenic, fetotoxic and teratogenic effects. **Conclusion (ii)**.

4.1.3.3 Humans exposed via the environment

The main route of indirect exposure to 2-EHA is in the local scenario the intake via air (8.3 µg/m^3) and on a regional scale a predominant intake via the consumption of fish and root crops (total daily dose of 6 ng/kg bw/day).

Repeated dose toxicity

Local scenario

The most sensitive effect of 2-EHA in animals was degeneration of the olfactory ephitelium in a 90-day inhalation study on rats. The NOAEC for local effects in this study was 75 mg/m³. The margin of safety between the air exposure to a concentration of 8.3 µg/m^3 2-EHA and the NOAEC of 75 mg/m³ is judged to be sufficient. Thus, regarding repeated dose effects the substance is of no concern in relation to indirect exposure via the environmental air. **Conclusion (ii)**.

Regional scenario/systemic effects

In repeated dose toxicity studies on rats (90-day inhalation) the NOAEC for systemic effects was 0.225 mg/l. This concentration in air has been converted into an internal NOAEL of 65 mg/kg bw/day (0.225 mg/l · 0.8 l/min/kg · 360 min/day). The margin of safety for oral exposure expressed by the magnitude between the calculated dose of 6 ng/kg bw/day and the oral NOAEL of 65 mg/kg bw/day is very high. Thus, the substance is of no concern in relation to indirect exposure via the environment. **Conclusion (ii)**.

Toxicity for reproduction

Following the exposure assessment, there is evidence for very low relevant exposure to 2-EHA via the local and the regional scenario. Evaluation of the available screening information does not provide evidence for significant reproductive toxicity of 2-EHA. Thus it can be concluded that the substance is of no concern in relation to indirect exposure via the environment. **Conclusion (ii)**.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

4.2.1.1 Explosivity

2-ethylhexyl acrylate is not explosive.

4.2.1.2 Flammability

2-ethylhexyl acrylate is not flammable.

4.2.1.3 Oxidising potential

Due to its chemical structure, 2-ethylhexyl acrylate is not expected to possess any oxidising properties.

5 RESULTS

5.1 ENVIRONMENT

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

2-ethylhexyl acrylate represents, based on the present data configuration, no risk to the environment.

There is therefore at present no need for further testing or gathering of exposure information.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

5.2.1.1 Workers

Conclusion (iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

- The risk assessment reveals concern with regard to local effects after repeated inhalation for the formulation of preparations (Scenario 2).
- Skin sensitisation gives rise to concern for all dermal exposure during production and polymerisation (Scenario 1), the formulation of preparations (Scenario 2) and the use of formulations containing monomeric 2-EHA in the building trade (Scenario 3).

5.2.1.2 Consumers

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

5.2.1.3 Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

5.2.1.4 Risks to human health from physico-chemical properties

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Conclusion (ii) is reached because there are no risks from physico-chemical properties arising from the use of the substance.