

A P P E N D I X 2

Review of Annex IV of the Regulation No. 1907/2006 (REACH) Evaluation of existing entries

Evaluation of existing entries

REVIEW OF ANNEX IV OF REGULATION (EC) NO. 1907/2006 (REACH)

EVALUATION OF EXISTING ENTRIES IN ANNEX IV

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INTRODUCTION

As part of the contracted review of Annex IV of REACH, a first evaluation of the existing entries in Annex IV was presented at the CA-subgroup meeting on 18 December, 2007. Stakeholders were invited to submit additional data to the Commission before 31 January 2008 either supporting or disputing the preliminary findings of the evaluation. The present evaluation takes the additional data submitted by the stakeholders into account and the results of the evaluation are updated according to the submitted additional data.

The four noble gasses Helium, Neon, Krypton and Xenon have been added to the evaluation on request from the Commission.

EVALUATION APPROACH

The evaluation has been based on the criteria endorsed by the CA-subgroup for inclusion of substances in Annex IV and, particularly, the approach described in section 5.2 of the criteria, which implies:

- Data for the evaluation have been collected from easily accessible data sources, i.e. ECOTOX (US-EPA), GESAMP, IUCLID and HSDB, and, when available, safety data sheets for specific substances.
- The evaluation has been based on grouping and read-across principles, where relevant and necessary to substantiate the assessments, and (Q)SARs have been applied to extend the data set on ecotoxicological properties.
- Furthermore, due to the rather limited available data for the individual substances, the evaluation of the existing entries has been conducted by applying the approach outlined in the endorsed criteria by the following principles: “Bearing in mind the historical evidence on substances in Annex IV, the burden of proof is directed at identifying evidence of human health or environmental effects according to the above criteria. This is as opposed to proposals for additions to Annex IV, where the burden of proof is directed at demonstrating compliance with the criteria and information requirements...”. For example, in the evaluation of the existing Annex IV entries, fulfilment of the agreed criteria was not challenged if there were no data or information available, which would prove that the known intrinsic properties were considered to cause effects.
- The criteria document states that: “Should the contractor find indications in the information assessed leading to the conclusion that a substance does not fulfil the criteria the relevant industry association(s) shall be informed. They will be given the

opportunity to dispute this by sending information showing that the substance in question does fulfil the criteria for inclusion in Annex IV”.

RANKING OF EXISTING ANNEX IV ENTRIES

Based on the evaluation of data on the intrinsic properties, a relative ranking of the existing substances in Annex IV was made. The ranking was visualized by a so called ‘traffic light approach’ with the sole purpose to present the results of the evaluation, while leaving the decisions in relation to the inclusion/deletion of the substances in/from the future Annex IV to the Commission and based on discussions and recommendation from the CA Sub-group. The applied approach is outlined in the table below.

Label	Description
GREEN	Passing the criteria
YELLOW	<p>Failing the criteria. No evidence of human health or environmental effects or evidence of mild effects.</p> <p>Examples of substances in this group include: Toxicological properties: Mildly skin or eye irritant (or insufficient data) Ecotoxicological properties: Passing at least one of the criteria on positive ready biodegradability or low aquatic toxicity</p>
RED	<p>Failing the criteria. Evidence of human health or environmental effects.</p> <p>Examples of substances in this group include: Toxicological properties: Irritant Ecotoxicological properties: Failing both of the key criteria on positive ready biodegradability or low aquatic toxicity</p>

The results of the evaluation of the existing Annex IV entries and the four additional noble gasses are presented below in an overview table and individual tables with clarifications of the individual assessments and data on specific substance properties.

The evaluation of carbon and graphite is presented in a separate section below (EVALUATION OF CARBON AND GRAPHITE p. 147) in order to include the discussions related to the proposals for deletion of carbon and graphite from Annex IV.

OVERVIEW TABLE

Name/group	CAS No	EINECS No	Overall evaluation			Result of assessment
			Physicochemical properties	Toxicological information	Ecotoxicological information	
Sugars and syrups						
Glucose	50-99-7	200-075-1				
Sucrose	57-50-1	200-334-9				
D-mannitol	69-65-8	200-711-8		Skin irritation		
L-sorbose	87-79-6	201-771-8		Eye irritation		
				Skin irritation		
D-glucitol (sorbitol)	50-70-4	200-061-5		Eye irritation		
				Skin irritation		
Syrups, com. dehydrated	68131-37-3	268-616-4		Eye irritation		
				Skin irritation		
Syrups, hydrolyzed starch	8029-43-4	232-436-4		Eye irritation		
Polymer of sugar						
Maltodextrin	9050-38-6	232-940-4		Skin irritation		
Cellulose Pulp	65996-61-4	265-995-8		Eye irritation		
Starch	9005-25-8	232-679-6				
				Skin irritation		
Dextrin	9004-53-9	232-675-4		Eye irritation		
Vitamins						
α -tocopheryl acetate (Vitamin E)	58-95-7	200-405-4		Repeated dose tox	Not readily biodeg. (QSAR)	
Vitamin A	11103-57-4	234-328-2		Skin sensitisation	Pot. Bioacc. (QSAR)	
Calcium pantothenate, D-form (Vitamin B5)	137-08-6	205-278-9		8, 1-8, 7	No Data	
Ascorbic acid (C6)	50-81-7	200-066-2			Not readily biodeg. (QSAR)	
Amino acids					Aquatic toxicity (QSAR)	
L-lysine	56-87-1	200-075-1		Skin irritation		
DL-methionine	59-51-8	200-432-1		Eye irritation	Aquatic toxicity (GESAMP)	
DL-phenylalanine	150-30-1	205-756-7		Skin irritation		
				Eye irritation	Not readily biodeg. (QSAR)	
Oils						
Sunflower oil	8001-21-6	232-273-9				
Soybean oil	8001-22-7	232-274-4				
Safflower oil	8001-23-8	232-276-5				
Linseed oil	8001-26-1	232-278-6				
Corn oil	8001-30-7	232-281-2				
Castor oil	8001-79-4	232-293-8				
Rape oil	8002-13-9	232-299-0				
					Aquatic toxicity (USEPA)	
Tallow, hydrogenated					Aquatic toxicity	
Fatty acids	8030-12-4	232-442-7				
Fatty acids, coco, Me esters	61788-59-8	262-988-1		Skin irritation		
				Eye irritation	Pot. Bioacc. (Gesamp)	
				Skin irritation	Pot. Bioacc. (Gesamp)	

Name/group	CAS No	EINECS No	Overall evaluation			Result of assessment
			Physicochemical properties	Toxicological information	Ecotoxicological information	
Fatty acids, tallow, Me esters	61788-61-2	262-989-7		Eye irritation		
Fatty acids, castor oil	61789-44-4	263-060-9		Skin irritation Eye irritation	Pot. Bioacc. (Gesamp)	
Fatty acids, tallow	61790-37-2	263-129-3		Skin irritation Eye irritation	Pot. Bioacc. (Gesamp)	
Fatty acids, C12-18	67701-01-3	266-925-9		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	
Fatty acids, C16-18	67701-03-5	266-928-5		Skin irritation Eye irritation	Pot. Bioacc.	
Fatty acids, C8-18 and C18-unsaturated	67701-05-7	266-929-0		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, C14-18 and C16-18-unsaturated	67701-06-8	266-930-6		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, C16-18 and C18-unsaturated	67701-08-0	266-932-7		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, C14-18 and C16-18-unsaturated, Me esters	67762-26-9	267-007-0		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, C6-12	67762-36-1	267-013-3		Skin irritation Eye irritation Acute inhalation tox	Aquatic toxicity (QSAR)	
Fatty acids, C14-22 and C16-22-unsaturated	68002-85-7	268-089-5		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, soya	68308-53-2	269-657-0		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	
Fatty acids, C14-22	68424-37-3	270-298-7		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, linseed oil	68424-45-3	270-304-8		Skin irritation Eye irritation	Pot. Bioacc.	
Fatty acids, C12-14	90990-10-6	292-771-7		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	
Fatty acids, C12-18 and C18-unsaturated	90990-15-1	292-776-4		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Not readily biodeg. (QSAR) Pot. Bioacc. (QSAR)	
Fatty acids, rape oil, euric acid-low	93165-31-2	296-916-5		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	
Palmitic acid (C16)	57-10-3	200-312-9		Skin irritation Eye irritation	Pot. Bioacc.	
Stearic acid (C18)	57-11-4	200-313-4		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	

Name/group	CAS No	EINECS No	Overall evaluation			Result of assessment
			Physicochemical properties	Toxicological information	Ecotoxicological information	
Oleic acid (C18)	112-80-1	204-007-1		Skin irritation Eye irritation Reproductive toxicity	Aquatic toxicity Pot. Bioacc.	
Lauric acid (C12)	143-07-7	205-582-1		Skin irritation Eye irritation Acute inhalation (Gesamp)	Aquatic toxicity Pot. Bioacc.	
Sorbitan Oleate (C24)	1338-43-8	215-665-4		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Pot. Bioacc. (QSAR)	
Salts of saturated aliphatic carboxylic acids						
Potassium oleate (C18)	143-18-0	205-590-5		Skin irritation Eye irritation Reproductive toxicity	Aquatic toxicity Pot. Bioacc.	
Sodium gluconate (C6)	527-07-1	208-407-7		Skin irritation Eye irritation		
Sodium stearate (C18)	822-16-2	212-490-5		Skin irritation Eye irritation	Pot. Bioacc.	
Calcium distearate (C18)	1592-23-0	216-472-8		Skin irritation Eye irritation	Aquatic toxicity (QSAR) Pot. Bioacc. (QSAR)	
Sodium D-gluconate (C6)	14906-97-9	238-976-7		Skin irritation Eye irritation		
Glycerides						
Glycerol stearate (C21)	123-94-4	204-664-4		Skin irritation Eye irritation	Aquatic toxicity Pot. Bioacc.	
Glycerides, C16-18 and C18-unsaturated	67701-30-8	266-948-4		Skin irritation Eye irritation		
Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3	269-658-6		Skin irritation Eye irritation	Pot. Bioacc. (QSAR)	
Glycerides, C16-18 and C18 unsaturated, mono- and di-	68424-61-3	270-312-1		Skin irritation Eye irritation	Pot. Bioacc. (QSAR)	
Glycerides, C10-18	85865-33-4	288-123-8		Skin irritation Eye irritation		
D-glucitol monostearate synonym: Sorbitol monostearate	26836-47-5	248-027-9		Skin irritation Eye irritation	Pot. Bioacc. (QSAR)	
Lecithins	8002-43-5	232-307-2		Skin irritation Eye irritation Carcinogenicity	Pot. Bioacc. (QSAR)	
Miscellaneous						
Limestone (consist mainly of CaCO3)	1317-65-3	215-279-6			No data	
Carbon C	7440-44-0	231-153-3		Skin irritation Eye irritation Repeated dose toxicity Acute toxicity	Aquatic toxicity	

Name/group	CAS No	EINECS No	Overall evaluation			Result of assessment
			Physicochemical properties	Toxicological information	Ecotoxicological information	
Graphite (Consist of C-atoms)	7782-42-5	231-955-3		Repeated dose toxicity Carcinogenicity	No data	
Gases						
Carbondioxide	124-38-9	204-696-9				
Nitrogen N2	7727-37-9	231-783-9			Aquatic toxicity	
Argon Ar	7440-37-1	231-147-0			Aquatic toxicity	
Helium He	7440-59-7	231-168-5				
Neon Ne	7440-01-9	231-110-9				
Krypton Kr	7439-90-9	231-098-5				
Xenon Xe	7440-63-3	231-172-7				
Water H2O						
H2O	7732-18-5	31-791-2				

INDIVIDUAL TABLES

Glucose (CAS 50-99-7)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.2	Melting point	146°C	
7.7	Water solubility	Exp Sw: 5E+005 mg/L (20 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -3,24 (HSDB)	
Toxicological information			
8.1	Skin irritation	Not irritating (Gesamp, SAR, expert judgement)	
8.2	Eye irritation	Not irritating, Slightly hazardous in case of eye contact (irritant) (Gesamp, SAR, MSDS, expert judgement)	
8.3	Skin sensitisation	(Expert judgment)	
8.4	Mutagenicity	(Expert judgment)	
8.5	Acute toxicity	Oral (Spector, Handbook of Toxicology, 1956) LD50 rat 25800 mg/kg LD50 dog 10,000 mg/kg Inhalation (Gesamp) LC50 > 20 mg/L Dermal (Gesamp) LD50 > 2000 mg/kg	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 4.03e+006 (48 hr), 24347.598 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 1.9e+006 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 5.28e+006 mg/l (96 hr), 4.39e+006 mg/l (14 day), 1.14e+005 (96 hr, SW) Chronic: 3.09e+005 mg/l (30 day)</p>	
9.2	Degradation	Ready biodegradable (Gesamp, QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR) LogPow/BCF: <1 or > ca. 7 / not measurable (Gesamp) logBCF: 0.500 (BCF = 3.162) (QSAR) Hc: 9.72E-015 atm-m³/mole (25 deg C) (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 35544.789 mg/kg dw (earthworms, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

Sucrose (CAS 57-50-1)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 2,12*10 ⁶ (25°C) (HSDB) Exp Sw: 2.1E+006 mg/L (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: -3,7 (HSDB) Exp LogKow: -3.7 (QSAR)	
7.9	Flash point	Closed cup: Higher than 93.3°C (200°F) (MSDS)	
7.10	Flammability	Slightly flammable to flammable in presence of heat (MSDS)	
Toxicological information			
8.1	Skin irritation	Not irritating (Read across to glucose, expert judgement)	
8.2	Eye irritation	Dust may cause mechanical irritation. (MSDS, expert judgement)	
8.3	Skin sensitisation	(Expert judgment)	
8.4	Mutagenicity	(Expert judgment)	
8.5	Acute toxicity	LD50 29700 mg/kg (reference not available)	
8.7	Reproductive toxicity	No adverse reproductive affects have been found in humans (MSDS, expert judgement)	
8.9.1	Carcinogenicity study (if available)	Not classifiable as a human or animal carcinogen (ACGIH)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 1.38e+008 mg/l (48 hr) Chronic: 4.56e+005 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 6.02e+007 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 1.99e+008 mg/l (96 hr), 1.33e+008 mg/l (14 day), 2.2e+006 mg/l (96 hr, SW) Chronic: 9.32e+006 mg/l (30 day)</p>	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR) logBCF: 0.500 (BCF = 3.162) (QSAR) Hc: 4.47E-022 atm-m³/mole (25 deg C) (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 1.8e+005 mg/kg dw (earthworms, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

D-mannitol (CAS 69-65-8)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.2	Melting point	ca. 167C (ca. 333F) (MSDS)	
7.3	Boiling point	290 - 295C (554 - 563F) (MSDS)	
7.7	Water solubility	Sw: 2,16*10 ⁵ (25°C) (HSDB) Exp Sw: 2.16E+005 mg/L (25 deg) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -3.1 (HSDB) Exp LogKow: -3.1 (QSAR)	
7.9	Flash point	Flash Point: > 149C (300F) (MSDS)	
Toxicological information			
8.1	Skin irritation	May cause irritation and discoloration of sensitive skin areas (MSDS)	
8.2	Eye irritation	May cause irritation, redness and pain (MSDS)	
8.3	Skin sensitisation	(expert judgement)	
8.4	Mutagenicity	Negative (JECFA)	
8.5	Acute toxicity	Oral LD50 17300 mg/kg (reference not available)	
8.6	Repeated dose toxicity	No significant adverse toxicity likely at 1000 mg/kg/day (NTP)	
8.7	Reproductive toxicity	Teratogenic studies in several species did not reveal any compound-related adverse effects (JECFA)	

8.8	Toxicokinetics	Mannitol is dehydrogenated to fructose and then metabolized through the mammalian glycolytic pathway; it occurs endogenously in humans (JECFA)	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic (NTP)	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 5.24e+006 mg/l (48 hr) Chronic: 30039.234 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 2.46e+006 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 6.92e+006 mg/l (96 hr), 5.65e+006 mg/l (14 day), 1.41e+005 mg/l (96 hr, SW) Chronic: 3.97e+005 mg/l (30 day)</p>	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 5 (HSDB), Koc: 10 (QSAR) BCF: 1 (HSDB) logBCF: 0.500 (BCF = 3.162) (QSAR) Hc: 7.26E-013 atm-m³/mole (25 deg C) (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 39135.309 mg/kg dw (earthworms, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

L-sorbose (CAS 87-79-6)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: $3,6 \cdot 10^5$ at 17°C (HSDB) Exp Sw: $3.6E+005$ mg/L (17 degC) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -1.46 (QSAR)	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant) (MSDS)	
8.2	Eye irritation	Dust may cause mechanical irritation (MSDS), No irritation (expert judgement)	
8.3	Skin sensitisation	Expert judgment negative	
8.5	Acute toxicity	No toxicity (MSDS)	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: $2.01e+005$ mg/l (48 hr) Chronic: 2274.343 mg/l (16 day) Aquatic plants (algae) (QSAR) EC50: $1.03e+005$ mg/l (96 hr) Fish (QSAR) LC50: $2.39e+005$ mg/l (96 hr), $2.5e+005$ mg/l (14 day), 10267.294 mg/l (96 hr, SW) Chronic: 17613.920 mg/l (30 day)	
9.2	Degradation	Ready biodegradable (QSAR)	

9.3	Fate and behaviour in the environment	Koc: 10 (QSAR) logBCF: 0.500 (BCF = 3.162) (QSAR) Hc: 1.38E-007 atm-m ³ /mole (25 deg C) (QSAR)	
9.4	Effects on terrestrial organisms	LC50: 12892.464 mg/kg dw (earthworms, 14 day) (QSAR) No effect based on Koc and aquatic toxicity	

D-glucitol (CAS 50-70-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.7	Water solubility	Exp Sw: 2.16E+005 mg/L (25 deg) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -2,2 (HSDB) LogKow: -3.1 (QSAR)	
	Toxicological information		
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant) (MSDS)	
8.2	Eye irritation	Hazardous in case of eye contact (irritant) (MSDS)	
8.3	Skin sensitisation	Expert judgment negative	
8.5	Acute toxicity	Oral LD50 rat (M)17,500 mg/kg, (F) 15,900 mg/kg (JECFA)	
8.6	Repeated dose toxicity	Sub-chronic toxicity study (90 day) NOAEL of 15% in diet = 7500mg/kg/day in a 17 mth study in rats (JECFA)	
8.7	Reproductive toxicity	NOAEL of 15% in diet = 7500mg/kg/day in a 17 mth study in rats (JECFA)	
8.8	Toxicokinetics	Two pathways exist for the oxidation of sorbitol in the body: (a) oxidation after conversion to glucose, and (b) the direct oxidation of the primarily formed fructose (JECFA)	
8.9.1	Carcinogenicity study (if available)	NOAEL of 15% in diet = 7500mg/kg/day in a 17 mth study in rats (JECFA)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 5.24e+006 mg/l (48 hr) Chronic: 30039.234 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 2.46e+006 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 6.92e+006 mg/l (96 hr), 5.65e+006 mg/l (14 day), 1.41e+005 mg/l (96 hr, SW) Chronic: 3.97e+005 mg/l (30 day)</p>	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR) Koc: 2 (HSDB) logBCF: 0.500 (BCF = 3.162) (QSAR) BCF= 1 (HSDB) Hc: 7.26E-013 atm-m³/mole (25 deg C) (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 39135.309mg/kg dw (earthworms, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

Syrups, corn, dehydrated (CAS 68131-37-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.1	State of the substance	Powder (MSDS)	
7.9	Flash point	Minimum ignition temperature (dust cloud): 430 - 450°C (MSDS)	
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant) (MSDS)	
8.2	Eye irritation	Eye contact may cause mild transient irritation (MSDS)	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	Expert judgment, anticipated to be negative	
8.5	Acute toxicity	(LD50): 25800 mg/kg [Rat] (for dextrose) (MSDS)	
8.6	Repeated dose toxicity	Adverse effects from chronic inhalation or ingestion are not known (MSDS)	
Ecotoxicological information			
	Read across to glucose		

Syrups, hydrolyzed starch (CAS 8029-43-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Expert judgment and read across from Syrups, corn, dehydrated (CAS 68131-37-3) (MSDS)	
8.2	Eye irritation	Expert judgment and read across from Syrups, corn, dehydrated (CAS 68131-37-3)	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	Expert judgment, anticipated to be negative	
8.5	Acute toxicity	Expert judgment and read across from Syrups, corn, dehydrated (CAS 68131-37-3) (MSDS)	
8.6	Repeated dose toxicity	Adverse effects from chronic inhalation or ingestion are not known (MSDS)	
Ecotoxicological information			
	Read across to glucose		

Maltodextrin (CAS 9050-36-6)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Hazardous in case of skin contact (irritant). may cause mild transient irritation (MSDS)	
8.2	Eye irritation	Hazardous in case of eye contact (irritant). may cause mild transient irritation (MSDS)	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	No data, not expected to be genotoxic	
8.5	Acute toxicity	No data, LD50 expected to be > 5000 mg/kg (expert judgment and read-across from LD 50 for dextrose, (LD50): 25800 mg/kg [Rat])	
8.6	Repeated dose toxicity	Chronic effects from inhalation are not established	
Ecotoxicological information			
	Ecotoxicological properties of polymers of sugars are evaluated based on expert judgment as no data were found. Minimum risk is concluded based on a biodegradable structure of the compound in addition to read across to glucose for the aquatic toxicity		

Cellulose pulp (CAS 65996-61-4)

Result of assessment: Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information, expert judgement		
	Toxicological information		
8.1	Skin irritation	No data, not expected to be irritant	
8.2	Eye irritation	No data, not expected to be irritant	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	No data, not expected to be genotoxic	
8.5	Acute toxicity	Oral LD50 >3160 mg/kg Inhalation LC50 (rats, inhalation) = 5,800 mg/m ³ /4 hours	
8.6	Repeated dose toxicity	Sub-chronic toxicity study NOAEL > 5000 mg/kg, rat, 8 week study	
8.7	Reproductive toxicity	No adverse effects were found on reproduction or neonate development in rats and mice	
8.8	Toxicokinetics	Expert judgement, not readily absorbed	
8.9.1	Carcinogenicity study (if available)	The chronic ingestion of purified cellulose over the entire lifespans in rats and mice does not result in any increase in spontaneous disease or neoplasia (JECFA)	

	Ecotoxicological information	
	Ecotoxicological properties of polymers of sugars are evaluated based on expert judgment as no data were found. Minimum risk is concluded based on a biodegradable structure of the compound in addition to read across to glucose for the aquatic toxicity	

Starch (CAS 9005-25-8)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information, expert judgement		
	Toxicological information		
8.1	Skin irritation	No data, not expected to be irritant	
8.2	Eye irritation	No data, not expected to be irritant	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	No data, not expected to be genotoxic	
8.5	Acute toxicity	Oral LD50 >50,000 mg/kg (Boyd et al, 1968)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg (Boyd et al, 1968)	
8.7	Reproductive toxicity	Not anticipated to have adverse effects on reproduction, read-across from data on various modified starches	
8.8	Toxicokinetics	Expert judgement	
8.9.1	Carcinogenicity study (if available)	Not anticipated to have adverse effects, read-across from data on various modified starches	
	Ecotoxicological information		
	Ecotoxicological properties of polymers of sugars are evaluated based on expert judgment as no data were found. Minimum risk is concluded based on a biodegradable structure of the compound in addition to read across to glucose for the aquatic toxicity		

Dextrin (CAS 9004-53-9)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	May cause skin irritation (MSDS)	
8.2	Eye irritation	May cause eye irritation (MSDS)	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	No data, not expected to be genotoxic	
8.5	Acute toxicity	No data, LD50 expected to be > 5000 mg/kg (expert judgment and read-across from LD 50 for dextrose, (LD50): 25800 mg/kg [Rat])	
8.6	Repeated dose toxicity	NOAEL ~ 10,000 mg/kg, dietary study 20 months (JECFA)	
Ecotoxicological information			
	Ecotoxicological properties of polymers of sugars are evaluated based on expert judgment as no data were found. Minimum risk is concluded based on a biodegradable structure of the compound in addition to read across to glucose for the aquatic toxicity		

α -tocopheryl acetate (Vitamin E) (CAS 58-95-7)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Exp Sw: 3.653e-008 mg/l (25 deg) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 12.26 (QSAR)	
7.9	Flash point	232.22°C (450°F) (MSDS)	
Toxicological information			
8.1	Skin irritation	Overall considered to be non-irritating to skin. In clinical studies, Tocopheryl Acetate was not irritant (Zondlo Fiume 2002, MSDS) Not irritating (racemic Tocopheryl Acetate) SH3 unpublished report, 1989)	
8.2	Eye irritation	Overall considered to be non-irritating to eyes. In clinical studies, Tocopheryl Acetate was not irritant (Zondlo Fiume 2002, MSDS) Not irritating (racemic Tocopheryl Acetate) (SH3 unpublished report, 1989)	
8.3	Skin sensitisation	Tocopheryl Acetate produced sensitization in one animal test. In clinical studies, Tocopheryl Acetate was not sensitizing (Zondlo Fiume 2002) No photo-allergenic potential (SH4 unpublished report 1996) GPMT: negative OET: positive (> 30% tocopheryl acetate) (Cosmetic Ingredient Review 2002)	
8.4	Mutagenicity	Not genotoxic (SCF)	
8.5	Acute toxicity	Oral (LD50, mouse): 5000 mg/kg (MSDS)	

8.6	Repeated dose toxicity	Short-term repeated dose toxicity study (28 days) Rat: NOAEL: 1111 mg/kg bw (racemic Tocopheryl Acetate) Dog: NOAEL: >360 mg/kg bw (racemic Tocopheryl Acetate) (SH3, unpublished report, 1983) Sub-chronic toxicity study (90 day) NOAEL 125 mg/kg bw/day (SCF) Rat: NOAEL: 2000 mg/kg bw/d (SH4 unpublished report 2000) Minipig: NOEL: 2000 mg/kg bw/d (SH4 unpublished report 2000)	
8.7	Reproductive toxicity	No adverse effects (SCF)	
8.8	Toxicokinetics	No concern (expert judgement)	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic (Zondlo Fiume 2002, MSDS)	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 1.73e-007 mg/l (48 hr, >Sw) Aquatic plants (algae) (QSAR) EC50: 2.7e-005 mg/l (96 hr, >Sw) Fish (QSAR) LC50: 7.35e-007 mg/l (14 day, > Sw), 0.000232 mg/l (96 hr, >Sw) Chronic: 8.8e-008 mg/l Fish, juvenile growth test: NOEC: 100 mg/L (SH4 report, 2001)	
9.2	Degradation	Not readily degradable (QSAR) Moderately biodegradable 54%/28 days (SH4 report 2000) Moderately biodegradable 30-40% after 39 days (SH3, unpublished report, 1988)	

9.3	Fate and behaviour in the environment	Koc: 1.39e+007 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) LogKow: 12.26 (QSAR) HC: 4.11E-004 atm-m3/mole (25 deg C) (QSAR)	
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Vitamin A (CAS 11103-57-4)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information		
	Toxicological information		
8.1	Skin irritation	Hazardous in case of skin contact (irritant) (MSDS)	
8.2	Eye irritation	Hazardous in case of eye contact (irritant) (MSDS)	
8.4	Mutagenicity	Positive in mamalian cells (MSDS)	
8.5	Acute toxicity	LD 50 rat 2000 mg/kg LD 50 mouse 1510 mg/kg (MSDS)	
8.6	Repeated dose toxicity	Excessive dosages of vitamin A may result in a number of adverse effects, including skin disorders, nausea, vomiting, bone pain (SCF)	
8.7	Reproductive toxicity	Teratogenicity due to retinol and its metabolite TRA (SCF)	
	Ecotoxicological information		
	No information		

Calcium pantothenate, D-form (Vitamin B5) (CAS 137-08-6)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Exp Sw: 1e+006 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -5.35 (QSAR)	
Toxicological information			
8.1	Skin irritation	Non-irritating (SH3, unpublished report, 1980)	
8.2	Eye irritation	Dust may cause mechanical irritation of eyes. Expert judgment non irritant non-irritating (SH3, unpublished report, 1980)	
8.3	Skin sensitisation	No data, expert judgement non sensitising	
8.4	Mutagenicity	No data found, expert judgement non genotoxic	
8.5	Acute toxicity	LD 50 mouse 10,000 mg/kg (SCF)	
8.6	Repeated dose toxicity	NOAEL > 250-400 mg/kg mg/day (SCF)	
8.7	Reproductive toxicity	No reproductive or teratogenic effects (SCF)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 1.85e+009 mg/l (48 hr) Chronic: 3.8e+006 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 7.57e+008 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 2.86e+009 mg/l (96 hr), 1.61e+009 mg/l (14 day), 1.88e+007 mg/l (96 hr, SW) Chronic: 1.13e+008 mg/l (30 day)</p>	
9.2	Degradation	Not readily degradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 1.285E-030 atm-m³/mole (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 5.38e+005 mg/l (earthworm, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

Ascorbic acid (C6) (CAS 50-81-7)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.2	Melting point	190-192 °C (OECD)	
7.7	Water solubility	Sw: 330 mg/l (HSDB) Exp Sw: 4E+005 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -2,15 (23 °C) and -2 (37 °C) (HSDB) Exp LogKow: -1.85 (QSAR)	
7.10	Flammability	Not flammable (OECD)	
7.11	Explosive properties	Not explosive (except as dust) (OECD)	
7.13	Oxidising properties	Not oxidising (OECD)	
Toxicological information			
8.1	Skin irritation	Non-irritating to the skin (OECD, SIDS). Non-irritating (SH4 unpublished report 1990)	
8.2	Eye irritation	Slightly irritating to the eye (OECD, SIDS) Non-irritating (SH4 unpublished report 1990)	
8.3	Skin sensitisation	No data, not anticipated to be sensitising	
8.4	Mutagenicity	Overall negative (-ve in vivo) (OECD, SIDS)	
8.5	Acute toxicity	LD50 >5000 mg/kg Oral (rat) LD50 11,900 mg/kg (OECD, SIDS, JECFA)	
8.6	Repeated dose toxicity	NOAEL > 2000 mg/kg mg/day, studies up to 2 years (OECD, SIDS, JECFA)	

8.7	Reproductive toxicity	Not toxic to reproduction, not teratogenic (OECD, SIDS)	
8.8	Toxicokinetics	Ascorbic acid is readily absorbed and metabolized (JECFA)	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic (OECD, SIDS)	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>Invertebrates (Daphnia) (QSAR) LC50: 1644.533 mg/l (48 hr)</p> <p>Aquatic plants (algae) (QSAR) EC50: 140.290 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 13.311 mg/l (96 hr), 5.67e+005 mg/l (14 day), 1.152 mg/l (96 hr, alcohols)</p> <p>LC50 (96h) > 1020 mg/L (SH4 unpublished report 1990)</p> <p>LC50 (96h) > 1000mg/l and < 2150mg/l (SH3, unpublished report, 1992)</p> <p>Chronic (QSAR): 17.567 mg/l (32 day), 0.536 mg/l (alcohols)</p>	
9.2	Degradation	Ready degradable (QSAR) 97% / 5days (SH4 unpublished report 1990)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR)</p> <p>Log BCF: 0.500 (BCF = 3.162) (QSAR)</p> <p>HC: 4.07E-008 atm-m3/mole (25 deg C) (QSAR)</p>	

L-lysine (CAS 56-87-1)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.2	Melting point	224°C (MSDS)	
7.7	Water solubility	Sw: 1000 mg/l (HSDB) Exp Sw: 1E+006 mg/L (20 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Exp LogKow: -3.05 (QSAR)	
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	No information found, expert judgement says likely to have irritant properties	
8.2	Eye irritation	No information found, expert judgement says likely to have irritant properties	
8.3	Skin sensitisation	No information found, expert judgement says unlikely	
8.4	Mutagenicity	Negative (EFSA)	
8.5	Acute toxicity	Oral LD50 rat 10130 mg/kg (EFSA)	
8.6	Repeated dose toxicity	Sub-chronic toxicity study (90 day) NOAEL 3360 or 3990 mg/kg bw/day) (M, F resp) (EFSA)	

8.7	Reproductive toxicity	Pre-natal development toxicity study NOAEL Maternal: 15.6 g/kg diet (equivalent to 780 mg/kg bw/day) Foetal: 15.6 g/kg diet (equivalent to 780 mg/kg bw/day). Note: highest dose tested (EFSA)	
8.9.1	Carcinogenicity study (if available)	No information found, expert judgement says unlikely	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 24382.600 mg/l (48 hr) Aquatic plants (algae) (QSAR) EC50: 8214.479 mg/l (96 hr) Fish (QSAR) LC50: 6.29e+005 mg/l (96 hr), 4.36e+006 mg/l (14 day) (Gesamp) LC/EC/IC50: >100- ≥1000 NOEC: >1	
9.2	Degradation	Readily biodegradable (Gesamp, QSAR)	
9.3	Fate and behaviour in the environment	Koc: 12.96 (QSAR) Log Pow/BCF: <1 (Gesamp) LogBCF: 0.500 (BCF = 3.162) (QSAR) HC: 3.59E-013 atm-m ³ /mole (25 deg C) (QSAR)	

DL-methionine (CAS 59-51-8)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.2	Melting point	281°C (MSDS)	
7.7	Water solubility	Sw: 29,1 g/l (20 °C) (IUCLID) Exp Sw: 3.27E+004 mg/L (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Exp LogKow: -1.87 (QSAR)	
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Not irritating (rabbit, 4 hr, 500 mg) (IUCLID)	
8.2	Eye irritation	Not irritating (rabbit, 72 hr, 100 mg) (IUCLID)	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	Negative (EFSA)	
8.5	Acute toxicity	Expert judgment predicts > 5000 mg/kg Inhalation LC50 (rat) > 5.25 mg/L 4hr (IUCLID)	
8.6	Repeated dose toxicity	NOAEL 2000 mg/kg bw/day) (10 week study) (EFSA)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 11408.671 mg/l (48 hr)</p> <p>Aquatic plants (algae) (QSAR) EC50: 4696.075 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 2.73e+005 mg/l (96 hr), 1.39e+006 mg/l (14 day) LC50: 3200 mg/l (<i>Brachidanio rerio</i>) (IUCLID), 5000 mg/L (<i>Goldorfe</i>) (IUCLID)</p>	
9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 9.356 (QSAR) LogBCF: 0.500 (BCF = 3.162) (QSAR) HC: 2.11E-011 atm-m³/mole (25 deg C) (QSAR)</p>	

DL-phenylalanine (CAS 150-30-1)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.7	Water solubility	Exp Sw: 2.69E+004 mg/L (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Exp LogKow: -1.38 (QSAR)	
7.10	Flammability	Expert judgment not flammable	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	No data found, expected to be mildly irritant	
8.2	Eye irritation	No data found, expected to be mildly irritant	
8.3	Skin sensitisation	No data, not expected to be sensitising	
8.4	Mutagenicity	Negative (EFSA)	
8.5	Acute toxicity	LD50 i.p, rat, 5200 mg/kg (Gangolli, ed, Dictionary of substances)	
8.7	Reproductive toxicity	Study carried out at single dose of 7% in diet (equivalent to 7000 mg/kg bw/day), no NOAEL established (EFSA)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 2763.839 mg/l (48 hr)</p> <p>Aquatic plants (algae) (QSAR) EC50: 1680.787 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 57173.227 mg/l (96 hr), 1.6e+005 mg/l (14 day)</p>	
9.2	Degradation	Not readily degradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 59.98 (QSAR)</p> <p>LogBCF: 0.500 (BCF = 3.162) (QSAR)</p> <p>HC: 1.20E-001 atm-m³/mole (25 deg C) (QSAR)</p>	

Sunflower oil (CAS 8001-21-6)

Result of assessment: Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.03771 mg/l (25 deg C) (QSAR)	
7.9	Flash point	>287.78°C (550°F)	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant), expert judgment negative	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant), expert judgment negative	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	Oral > 100,000 mg/kg (read across from corn oil)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day (read across from corn oil)	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	

	Ecotoxicological information		
9.1	Aquatic toxicity	No aquatic toxicity - based on information submitted from stakeholder SH2	
9.2	Degradation	Ready biodegradable, Read across to Linoleic acid (50-80% of substances in Sunflower oil) (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 1.17e+004 Read across to Linoleic acid (50-80% of substances in Sunflower oil) (QSAR) BCF: < 10 (SH2) Hc: 3.94E-005 atm-m ³ /mole (25 deg C) Read across to Linoleic acid (50-80% of substances in Sunflower oil) (QSAR)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Soybean oil (CAS 8001-22-7)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.03771 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: 7.05 (QSAR)	
7.9	Flash point	282°C (539.6°F)	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant), expert judgment negative	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant), expert judgment negative	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.5	Acute toxicity	Oral > 100,000 mg/kg (read across from corn oil)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day (read across from corn oil, JECFA)	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	

	Ecotoxicological information		
9.1	Aquatic toxicity	No aquatic toxicity - based on information submitted from stakeholder SH2 Fish (QSAR) LC50: 0.006 mg/l (14 day, >Sw) Read across to Linoleic acid (50-80% of substances in Soybean oil) (QSAR)	
9.2	Degradation	Ready biodegradable, Read across to Linoleic acid (50-80% of substances in Soybean oil) (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 1.17e+004 Read across to Linoleic acid (50-80% of substances in Soybean oil) (QSAR) BCF: < 10 (SH2) Hc: 3.94E-005 atm-m ³ /mole (25 deg C) Read across to Linoleic acid (50-80% of substances in Soybean oil) (QSAR)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Safflower oil (CAS 8001-23-8)

Result of assessment: Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	>287.78°C (550°F)	
7.10	Flammability	Slightly flammable to flammable in presence of heat	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant), expert judgment negative	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant), expert judgment negative	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Negative (NTP)	
8.5	Acute toxicity	LD50 [mouse] - Route: Intraperitoneal; Dose: >50000 mg/kg. oral> 100,000 mg/kg (read across from corn oil) (MSDS)	
8.6	Repeated dose toxicity	Two-year survival was slightly increased in male rats receiving safflower oil relative to that of the controls at 0, 2.5, 5 or 10 ml/kg (NTP)	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	

8.9.1	Carcinogenicity study (if available)	Expert judgment negative, supported by NTP 2 year study	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >1000 (Gesamp)	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	BCF <10 (SH2)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Linseed oil (CAS 8001-26-1)

Result of assessment: Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	222.22°C (432°F) (MSDS)	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Expert judgment not skin irritant	
8.2	Eye irritation	Expert judgment not eye irritant	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	> 4763 mg/kg, can cause gastrointestinal disturbances in humans. Expert judgement LD50 > 5000 mg/kg (MSDS)	
8.6	Repeated dose toxicity	Read across from castor oil NOAEL > 2500 mg/kg/day	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >1000 (Gesamp)	
9.2	Degradation	Readily biodegradable (Gesamp)	

9.3	Fate and behaviour in the environment	BCF <10 (SH2)	
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Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Corn oil (CAS 8001-30-7)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	254°C (489.2°F) (MSDS)	
7.10	Flammability	Slightly flammable to flammable in presence of heat	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant), expert judgement negative	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant), expert judgement negative	
8.3	Skin sensitisation	Expert judgement not sensitising	
8.4	Mutagenicity	Negative (NTP)	
8.5	Acute toxicity	Oral LD 50 > 100,000 mg/kg. LD50 (5 days) was found to be 256,000 mg/kg (MSDS, Boyd et al)	
8.6	Repeated dose toxicity	Two-year survival was increased in male rats receiving corn oil, 0, 2.5, 5 or 10 ml/kg (NTP)	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (Sato et al, 2000)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative, supported by NTP 2 year study	

	Ecotoxicological information		
9.1	Aquatic toxicity	LC/EC/IC50: >10 - ≤100 (Gesamp) No aquatic toxicity based on information submitted from stakeholder SH2	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	BCF <10 (SH2)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Castor oil (CAS 8001-79-4)

Result of assessment: Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.3	Boiling point	313°C (595.4°F)	
7.7	Water solubility	Water Solubility Estimate from Log Kow (WSKOW v1.41): Water Solubility at 25 deg C (mg/L): 5.058e-016 (SH5)	
7.8	Partition coefficient n-octanol/water	log Kow: 18.10 (estimated) (SH5)	
7.9	Flash point	229° C	
7.10	Flammability	Slightly flammable to flammable in presence of open flames and sparks, of heat (MSDS)	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
	Toxicological information		
8.1	Skin irritation	Expert judgment not skin irritant	
8.2	Eye irritation	Expert judgment not eye irritant	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Ames, in vivo micronucleus negative (NTP)	
8.5	Acute toxicity	Expert judgment LD 50 > 5000 mg/kg (read across from repeat dose toxicity. May cause digestive tract irritation. It is considered a purgative and stimulates smooth muscle of the digestive tract. (MSDS)	

8.6	Repeated dose toxicity	NOAEL > 2500 mg/kg/day in rat, > 5000 mg/kg in mouse Feeding studies with castor oil in rodents provide a basis for a no observable adverse effect level (NOAEL) estimate of 7500 mg/kg/day and 5000 mg/kg/day in mice and rats, respectively (NTP, 1992)	
8.7	Reproductive toxicity	No significant changes were noted in a screening for male reproductive endpoints, including sperm count and motility, and no changes were observed in the length of estrous cycles of rats or mice given diets containing castor oil	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >10 - ≤100 (Gesamp) Toxicity higher than water solubility, ECOSAR prediction of toxicity (SH5)	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	BCF <10 (SH2)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

ECOSAR prediction (SH5)

ECOSAR Class: Acids, Fatty

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	96-hr	LC50	9.31e+018*
Daphnid	48-hr	LC50	9.31e+018*
Fish	28-day	NEC	1.43e+018*
Daphnid	21-day	NEC	1.43e+018*
Green Algae	96-hr	EC50	1.84e+017*
Green Algae	21-day	NEC	1.31e+017*

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect.

Rape oil (CAS 8002-13-9)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information		
	Toxicological information		
8.1	Skin irritation	Slightly hazardous in case of skin contact (irritant), expert judgment negative	
8.2	Eye irritation	Slightly hazardous in case of skin contact (irritant), expert judgment negative	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	Oral > 100,000 mg/kg (read across from corn oil)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day (read across from corn oil), LD 50 of methyl and ethyl rape oil > 5000 mg/kg	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	

	Ecotoxicological information		
9.1	Aquatic toxicity	LC/EC/IC50: >10 - ≤100 (Gesamp) Invertebrates (USEPA) LC50 = 73 mg/l (snail (<i>Indoplanorbis exustus</i>), 0,125 day) LC50: 400 mg/l (0,125 day, <i>Daphnia pulex</i>) Fish (USEPA) LC50: 85 mg/l (48 hr, <i>Oryzias Latipes</i> (Medaka high eyes))	
9.2	Degradation	Readily biodegradable. Read across to other vegetable oils (e.g. linseed oil, corn oil)	
9.3	Fate and behaviour in the environment	BCF <10 (SH2)	

Notes:

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Tallow, hydrogenated (CAS 8030-12-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Not soluble at 20°C (IUCLID)	
7.8	Partition coefficient n-octanol/water	LogPow: >6 (IUCLID)	
7.10	Flammability	Expert judgement may be combustible at high temperature	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
Toxicological information			
8.1	Skin irritation	Not irritating (Gesamp)	
8.2	Eye irritation	Not irritating (Gesamp)	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	LD 50 > 2,000 mg/kg (Gesamp) Expert judgement not acutely toxic	
8.6	Repeated dose toxicity	Expert judgement not toxic	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>LC/EC/IC50: >10 - ≤100 (Gesamp)</p> <p>Invertebrates (Daphnia) (IUCLID) EC0: 100 mg/l and EC100 mg/l: > 1000 (48 hr, Daphnia magna, conforms with OECD 202A)</p> <p>Aquatic plants (algae) (IUCLID) EC10: 3,9 mg/l and EC50: 13,3 mg/l (96 hr, Scenedesmus subspicatus, conforms with OECD 201)</p> <p>Fish (IUCLID) LC0: >10000 mg/l (96 hr, Branchio rerio ISO 7346/1-3)</p>	
9.2	Degradation	<p>Readily biodegradable (Bacteria from sewage. 5mg/L: 31 % degradation after 28 days. OECD guideline 301 D; 100 mg/L: 55% degradation after 28 days. Closed bottle test) (IUCLID)</p> <p>Ready degradable (Gesamp)</p>	
9.3	Fate and behaviour in the environment	BCF <10 (SH2)	
9.4	Effects on terrestrial organisms	Effects on soil micro-organisms (IUCLID) EC0: >10000 mg/l (0.5 hr, Pseudomonas putida, Respiration test. Method conforms with OECD 209)	

Notes:

Special requirements to tallow derivatives when used in cosmetic products

The criteria on flammability are considered to be likely to be passed, although there is a lack of actual data and this conclusion is therefore based on expert judgement. However, the substance may be considered to be lightly flammable to flammable in presence of heat or open flames, based on information from MSDSs on oils

Fatty acids, coco, Me esters (CAS 61788-59-8)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	53 °C (C6-C12, Me) 170 °C (C16-C18 Me)	
7.10	Flammability	May be combustible at high temperature (Read across)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to skin and eye, read across from C6-C12 Me esters and coconut oil. Note that C16-C18 Me esters are described as highly irritant	
8.2	Eye irritation	Slightly irritant to skin and eye, read across from C6-C12 Me esters and coconut oil. Note that C16-C18 Me esters are described as highly irritant	
8.3	Skin sensitisation	Not sensitising , read across from tallow acids, methyl esters and coconut oil	
8.4	Mutagenicity	No data, not anticipated to be genotoxic based on read across from uniformly negative data on fatty acids	
8.5	Acute toxicity	Oral LD 50 > 23000 mg/kg, read across from C6-C12 methyl esters, 23,500 for C8- C18 coconut oil	
8.6	Repeated dose toxicity	NOAEL assumed to be >1000 mg/kg/day; coconut oil cleared as source of dietary fat at high levels, & statement in IUCLID that higher Me esters can be used similarly	

8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	Not anticipated based on read across on carcinogenicity studies available on other members of the group	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >1000 (Gesamp)	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	LogPow/BCF: > ca. 7 (Gesamp)	

Notes:

Generally, commercial coconut fatty acid has carbon chain composition of: C10 (5% max) + C12 (45 - 55%) + C14 (20 - 25%) + C16 (10 - 15 %) + C18 (10 - 15% max, including unsaturated fatty acids). Coconut oil is stated to be a source of lauric acid. Read across is primarily based on C6-C12, Me esters and from C8 – C18 coconut oil.

Fatty acids, tallow, Me esters (CAS 61788-61-2)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	170 °C C16-C18 Me	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Highly irritating to skin, read across from C16 methyl ester and C18 methyl ester, (IUCLID)	
8.2	Eye irritation	Slightly irritating to rabbit eye, read across from C16 methyl ester and C18 methyl ester, (IUCLID)	
8.3	Skin sensitisation	Not sensitising, reported for tallow acids methyl esters in IUCLID file for C16-C18 methyl esters	
8.4	Mutagenicity	Negative in mouse micronucleus test in vivo, fatty acid methyl esters have an anti-clastogenic effect (IUCLID) Negative in Ames test (Read across from C16 methyl ester and C18 methyl ester, IUCLID)	
8.5	Acute toxicity	Oral LD 50 > 2000 mg/kg, read across from C16 methyl ester and C18 methyl ester LD 50 > 2000 mg/kg, read across from C16 methyl ester and C18 methyl ester LD 50 > C14-C18 and C16-C18 unsaturated 20,000 mg/kg, so judged to meet the criteria	

8.6	Repeated dose toxicity	No data, read across from lauric acid and oleic acid, NOAEL > 5000 mg/kg/day and 7500 mg/kg in rat, 18 week study in diet. Read across from C16 methyl ester and C18 methyl ester (IUCLID)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day Read across from lauric acid and oleic acid	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	A 2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish LC50: <i>Leuciscus idus</i> (48 hr) 5500 mg/l Read across from Fatty acid C16-18 and C18 Unsat., Me ester (IUCLID)	
9.2	Degradation	Readily biodegradable, Read across from Fatty acid C16-18 and C18 Unsat., Me ester (IUCLID)	
9.3	Fate and behaviour in the environment	Read across from Fatty acid, coco, Me ester	

Notes:

Given that tallow fatty acids has the following composition (data from supplier) C14 (3%) C16 (24%) C18 (17%) unsat C16-1 (5%) C18-1 (43%) C18-2 (5%) other (3%). There is a IUCLID data sheet on C16-C18 methyl esters, this plus the evaluation on C14-18 and C16-18-unsaturated, Me esters, Coco fatty acids, methyl esters are used for read across. Read across from Fatty acid C16-18 and C18 unsat., Me ester is done for the ecotoxicological information.

Fatty acids, castor-oil (CAS 61789-44-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.7	Water solubility	EPIWIN models: Water Sol Estimate from Fragments: Wat Sol (v1.01 est) = 0.88286 mg/L	
7.8	Partition coefficient n-octanol/water	log Kow: 6.19 (estimated)	
7.9	Flash point	229° C (castor oil)	
7.10	Flammability	Slightly flammable to flammable in presence of open flames and sparks, of heat (MSDS)	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
	Toxicological information		
8.1	Skin irritation	May cause skin irritation	
8.2	Eye irritation	May cause eye irritation	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Ames, in vivo micronucleus negative	
8.5	Acute toxicity	Expert judgment LD 50 > 5000 mg/kg (read across from repeat dose toxicity. May cause digestive tract irritation. It is considered a purgative and stimulates smooth muscle of the digestive tract	

8.6	Repeated dose toxicity	NOAEL > 2500 mg/kg/day in rat, > 5000 mg/kg in mouse Feeding studies with castor oil in rodents provide a basis for a no observable adverse effect level (NOAEL) estimate of 7500 mg/kg/day and 5000 mg/kg/day in mice and rats, respectively (NTP, 1992)	
8.7	Reproductive toxicity	Screening for reproductive/developmental toxicity: No significant changes were noted in a screening for male reproductive endpoints, including sperm count and motility, and no changes were observed in the length of estrous cycles of rats or mice given diets containing castor oil	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >10 - ≤100 (Gesamp) Toxicity higher than water solubility, ECOSAR prediction of toxicity (SH5)	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	LogPow/BCF: <1 or > ca. 7/not measurable (Gesamp) Bioaccumulation Estimates from Log Kow (BCFWIN v2.17), Log BCF from regression-based method = 1.750 (BCF = 56.23) (SH5)	

Notes:

Read across from castor oil on toxicological information

Ecotar prediction (SH5)

ECOSAR Class: Acids, Fatty

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	96-hr	LC50	9.31e+018*
Daphnid	48-hr	LC50	9.31e+018*
Fish	28-day	NEC	1.43e+018*
Daphnid	21-day	NEC	1.43e+018*
Green Algae	96-hr	EC50	1.84e+017*
Green Algae	21-day	NEC	1.31e+017*

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect.

Fatty acids, tallow (CAS 61790-37-2)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance		
7.2	Melting point		
7.3	Boiling point		
7.5	Vapour pressure		
7.7	Water solubility		
7.8	Partition coefficient n-octanol/water		
7.9	Flash point	>200°C	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	Slightly irritating Read across from C16-C18 and C18 unsaturated	
8.2	Eye irritation	Slightly irritating Read across from C16-C18 and C18 unsaturated	
8.3	Skin sensitisation	Read across from lauric acid and oleic acid . In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from lauric acid and oleic acid. Potassium oleate was Ames negative	
8.5	Acute toxicity	Oral LD 50 > 20,000 mg/kg Read across from C16-C18 and C18 unsaturated	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day in rat, 18 week study in diet read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >1000 (Gesamp)	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	LogPow/BCF: > ca. 7 (Gesamp)	

Notes:

Tallow fatty acids has the following composition (data from supplier) C14 (3%) C16 (24%) C18 (17%) unsat C16-1 (5%) C18-1 (43%) C18-2 (5%) other (3%). The most appropriate read across is therefore C16-C18 and C18 unsaturated, which is used directly.

Fatty acids, C12-18 (CAS 67701-01-3)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance		
7.2	Melting point		
7.3	Boiling point		
7.5	Vapour pressure		
7.7	Water solubility		
7.8	Partition coefficient n-octanol/water		
7.9	Flash point	>200°C Read across from C12-C18, Na salt	
7.10	Flammability	May be combustible at high temperature Read across from palmitic	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	Irritant, read across from lauric acid, palmitic, oleic acid and C12-C18, sodium salts Irritant to skin (Na soap). IUCLID presents a number of studies on the Na salts all of which show irritancy but only 50% of which reach EU classification criteria	
8.2	Eye irritation	Irritant, read across from lauric acid and oleic acid and C12-C18, Na salt Irritant to eyes (Na soap). IUCLID presents a number of studies on the Na salts all of which show irritancy but only 50% of which reach EU classification criteria	
8.3	Skin sensitisation	Not sensitising, read across C12-C18, Na salt IUCLID, read across Na salts	

8.4	Mutagenicity	Read across from lauric acid and oleic acid. Ames negative	
8.5	Acute toxicity	Oral LD 50 > 5000 mg/kg (Na salt) Read across from C12-C18, Na salt	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day in rat, 18 week study in diet Read across from lauric acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across from lauric acid (C12), palmitic (C16), stearic acid (C18) and oleic acid (C18)	
9.2	Degradation	Read across from lauric acid (C12), palmitic (C16), stearic acid (C18) and oleic acid (C18)	
9.3	Fate and behaviour in the environment	Read across from lauric acid (C12), palmitic (C16), stearic acid (C18) and oleic acid (C18)	

Fatty acids, C16-18 (CAS 67701-03-5)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 4.2 mg/L (exp, 20 deg C), 0.01946 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 7.4533 (exp) (QSAR)	
7.9	Flash point	~ 200°C Read across from stearic and C16-C18 mg salt	
7.10	Flammability	May be combustible at high temperature. Read across from stearic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritating Read across from lauric acid and oleic acid	
8.2	Eye irritation	Slightly irritating Read across from stearic acid	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from lauric acid and oleic acid. Ames negative	
8.5	Acute toxicity	LD 50 > 5000 mg/kg Read across from C16-C18 Mg salt	
8.6	Repeated dose toxicity	NOAEL > 5000 and 7500 mg/kg/day respectively in rat, 18 week study in diet Read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	No evidence of carcinogenicity was seen in rats receiving 25% oleic acid (C18) in the diet (approximately 12.5 g/kg bodyweight per day) for 20 w	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish LC50: 0.007 mg/l (14 day) (QSAR)	
9.2	Degradation	Readily biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 6328 (QSAR) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 3.84E-005 atm-m ³ /mole (QSAR)	

Fatty acids, C8-18 and C18 unsaturated (CAS 67701-05-7)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.7	Water solubility	Sw: 158.35 mg/l (25 dec C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 3.51 (QSAR)	
7.9	Flash point	150°C 340°C (C18 & C18 unsatd) Read across from C8-C18 acids	
7.10	Flammability	May be combustible at high temperature. Read across from palmitic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	Irritant to eyes and skin (read across from C8-C18 acids and C12-C18, Na salt)	
8.2	Eye irritation	Irritant to eyes and skin (read across from C8-C18 acids and C12-C18, Na salt)	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from octanoic and decanoic lauric acid and oleic acid. Ames negative	
8.5	Acute toxicity	LD 50 > 10, 000 mg/kg (read across from C8 and C10)	
8.6	Repeated dose toxicity	NOAEL of a mixture of decanoic and octanoic was equivalent to 2.8 g/kg/day and 7.4 g/kg/day respectively (read across from C8 and C10, IUCLID). 47 week dietary study	
8.7	Reproductive toxicity	A three-generation reproductive study on a mixture of decanoic and octanoic equivalent to 2.8 g/kg/day and 7.4 g/kg/day did not produce any reproductive effects. No developmental effects of octanoic acid at 2.7 g/kg/day (read across from C8 and C10) IUCLID	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	decanoic acid administered at 5g/kg/day for 150 days was not carcinogenic (read across from C8 and C10) IUCLID	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 59.149 mg/l (48 hr) Chronic: 5.873 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 40.336 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 49.733 mg/l (96 hr) 11.451 mg/l (14 day), 114.508 mg/l (14 day), 23.645 mg/l (96 hr) Chronic: 8.172 mg/l (30 day)</p>	
9.2	Degradation	Not readily biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 160.8 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 7.34E-007 atm-m ³ /mole (QSAR)	

9.4	Effects on terrestrial organisms	LC50: 3715.075 mg/l (earthworm, 14 day) (QSAR) No effect based on Koc and aquatic toxicity	
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Fatty acids, C14-18 and C16-18- unsaturated (CAS 67701-06-8)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 3.796 mg/l (25 dec C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 5.04 (QSAR)	
7.9	Flash point	180°C (CP) Read across from C16-C18	
7.10	Flammability	May be combustible at high temperature. Read across from palmitic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritating Read across from C16-C18	
8.2	Eye irritation	Slightly irritating Read across from C16-C18	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from lauric acid and oleic acid. Ames negative	
8.5	Acute toxicity	Oral LD 50 > 20, 000 mg/kg (read across from C16 and C18)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day and 7500 mg/kg in rat, 18 week study in diet read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 3.105 mg/l (48 hr) Chronic: 0.602 mg/l (16 day) Aquatic plants (algae) (QSAR) EC50: 2.313 mg/l (96 hr) Fish (QSAR) LC50: 2.349 mg/l (96 hr), 0.690 mg/l (14 day), 6.897 mg/l (14 day, >Sw), 2.340 mg/l (96 hr) Chronic: 0.494 mg/l (30 day)	
9.2	Degradation	Not readily biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 1860 (QSAR) Log BCF: 0.750 (BCF = 5.623) (QSAR) HC: 1.17E-006 atm-m ³ /mole (QSAR)	
9.4	Effects on terrestrial organisms	LC50: 1626.197 mg/l (earthworm, 14 day) (QSAR) Effect based on Koc and aquatic toxicity	

Fatty acids, C16-C18 and C18 unsaturated (CAS 67701-08-0)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.8	Partition coefficient n-octanol/water	Log Pow = 4.9 (IUCLID, CAS no 68955-98-6)	
7.9	Flash point	~ 155°C	
7.10	Flammability	May be combustible at high temperature. Read across from palmitic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritating Read across from C16-C18	
8.2	Eye irritation	Slightly irritating Read across from C16-C18	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	
8.4	Mutagenicity	Read across from lauric acid and oleic acid. Ames negative	

8.5	Acute toxicity	Oral LD 50 > 20, 000 mg/kg (read across from C16 and C18)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day in rat, 18 week study in diet Read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across to C8-C18 and C18 unsat. (QSAR), Stearic acid (C18), palmitic acid (C16), and oleic acid (C18)	
9.2	Degradation	Not readily biodegradable Read across to C8-C18 and C18 unsat. (QSAR)	
9.3	Fate and behaviour in the environment	Read across to 86955-98-6	

Fatty acids, C14-18 and C16-18-unsaturated, Me esters (CAS 67762-26-9)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	170°C (OCP) Read across from C16-C18 methyl esters	
7.10	Flammability	May be combustible at high temperature. Read across from palmitic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Highly irritating to skin Read across from C16 methyl ester and C18 methyl ester (IUCLED)	
8.2	Eye irritation	Slightly irritating to rabbit eye Read across from C16 methyl ester and C18 methyl ester (IUCLED)	
8.3	Skin sensitisation	Not sensitising Read across from tallow acids methyl esters	
8.4	Mutagenicity	Negative in mouse micronucleus test in vivo, fatty acid methyl esters have an anti-clastogenic effect Ames negative, Read across from C16 methyl ester and C18 methyl ester (IUCLED)	
8.5	Acute toxicity	Oral LD 50 > 2000 mg/kg. LD 50 of the LD 50 > C14-C18 and C16-C18 unsaturated 20,000 mg/kg, so judged to meet the criteria Read across from C16 methyl ester and C18 methyl ester (IUCLED)	

8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day and 7500 mg/kg in rat, 18 week study in diet Read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	Negative. Read across from methyl stearate, 0.5 and 5 mg/injection given SC once per week for 26 weeks	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across from Fatty acid C14-18 and C16-18-unsaturated	
9.2	Degradation	Read across from Fatty acid C14-18 and C16-18-unsaturated	
9.3	Fate and behaviour in the environment	Read across from Fatty acid C14-18 and C16-18-unsaturated	
9.4	Effects on terrestrial organisms	Read across from Fatty acid C14-18 and C16-18-unsaturated	

Fatty acids, C6-12 (CAS 67762-36-1)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 1.03E+004 mg/l (25 dec C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 1.92 (exp), 2.05 (QSAR)	
7.9	Flash point	275° F (135° C) PMCC	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Corrosive and Irritant (MSDS) PII 4.5 on rabbit skin IUCLID C9-C13 mildly irritating to skin. Likely classified as mild irritant under GHS	
8.2	Eye irritation	Corrosive and Irritant (MSDS) Undiluted C8-C10 with no rinsing of the eyes produced severe ocular damage whereas rinsing the eyes with water after instillation of the test material reduced involvement to mild to moderate but transient irritation. C9-C13 moderately irritating to eyes read across (IUCLID). Likely classified as mild irritant under GHS	

8.3	Skin sensitisation	C9-C13 not sensitising (IUCLID). In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated (HERA (CIR, 1982). (CIR, 1982))	
8.4	Mutagenicity	C9-C13 negative (IUCLID) Capric acid (C10) produced negative results in the Ames test (HERA) In vitro cytogenicity study C9-C13 negative, read across (IUCLID)	
8.5	Acute toxicity	Oral Rat LD50 12.6 gm/kg of body weight (MSDS). C9-C13 LD50 2859 mg/kg read across (IUCLID) Inhalation LC50 lauric acid >2- ≤10 mg/L (Gesamp) Dermal C9-C13 LD50 >2000 mg/kg read across (IUCLID)	
8.6	Repeated dose toxicity	(NOAEL) of more than 15% (w/w) caprenin (primarily comprising caprylic (C8), capric (C10), and behenic (C22) acids) in the diet (equal to a mean exposure level of more than 13.2 g/kg/day for male rats and more than 14.6 g/kg/day for female rats (HERA)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid rich oil did not produce any reproductive effects (HERA)	
8.8	Toxicokinetics	Fatty acids that can enter normal fatty acid metabolism	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 830.925 mg/l (48 hr) Chronic: 43.557 mg/l (16 day)</p> <p>Aquatic plants (algae) (QSAR) EC50: 520.969 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 141.095 mg/l (14 day), 772.791 (96 hr), 1410.951 mg/l (14 day), 181.368 mg/l (96 hr) Chronic: 100.360 mg/l (30 day)</p>	
9.2	Degradation	Readily biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 7.53 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 1.70E-006 atm-m³/mole (QSAR)</p>	
9.4	Effects on terrestrial organisms	<p>LC50: 6897.025 mg/l (earthworm, 14 day) (QSAR) No effect based on Koc and aquatic toxicity</p>	

Fatty acids, C14-22 and C16-22-unsaturated (CAS 68002-85-7)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	Palmitic 115 °C C18-C22 > 200°C	
7.10	Flammability	May be combustible at high temperature, although less likely than lower fatty acids Read across from Palmitic and C18-C22	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritant, read across from lauric acid and oleic acid. No data provided for C18-C22	
8.2	Eye irritation	Mildly irritant, read across from lauric acid and oleic acid. No data provided for C18-C22	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans	
8.4	Mutagenicity	Read across from lauric acid and oleic acid. Ames negative	

8.5	Acute toxicity	Oral LD 50 > 5000 mg/kg (read across from C18-C22)	
8.6	Repeated dose toxicity	NOAEL > 5000 and 7500 mg/kg/day in rat, 18 week study in diet Read across from lauric acid and oleic acid	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across from Fatty acid C14-18 and C16-18-unsaturated (QSAR)	
9.2	Degradation	Not readily biodegradable Read across Fatty acid C14-18 and C16-18-unsaturated (QSAR)	
9.3	Fate and behaviour in the environment	Read across Fatty acid C14-18 and C16-18-unsaturated (QSAR)	
9.4	Effects on terrestrial organisms	Read across Fatty acid C14-18 and C16-18-unsaturated (QSAR)	

Fatty acids, soya (CAS 68308-53-2)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.10	Flammability	Expert judgement may be combustible at high temperature. Read across to Linseed oil	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
Toxicological information			
8.1	Skin irritation	Moderately irritating to skin (Read across to rape oil and reflecting content of linoleic acid)	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant)	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	Linoleic acid: ORAL (LD50): Acute: 3200 mg/kg [Mouse]. 3200 mg/kg [Rat]	
8.6	Repeated dose toxicity	NOAEL > 2000 mg/kg/day Two-year survival was increased in male rats receiving corn oil, 0, 2.5, 5 or 10 ml/kg. Read across from Corn oil	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	

	Ecotoxicological information		
9.1	Aquatic toxicity	Read across from Rape oil	
9.2	Degradation	Readily biodegradable Read across from Rape oil	
9.3	Fate and behaviour in the environment	Read across from Rape oil	

Notes:

Fatty acid, Soy oil has 11% C16, 4% stearic, 22% C18 monosatd. and 54% linoleic. Read across from fatty acid, rape oil and Rape oil

Fatty acids, C14-22 (CAS 68424-37-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.01946 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 7.45 (QSAR)	
7.9	Flash point	Palmitic 115°C C18-C22 > 200°C	
7.10	Flammability	Expert judgement may be combustible at high temperature although less likely than lower fatty acids. Read across from Palmitic and C18-C22	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritant, read across from lauric acid and oleic acid. No data provided for C18-C22	
8.2	Eye irritation	Mildly irritant, read across from lauric acid and oleic acid No data provided for C18-C22	
8.3	Skin sensitisation	Not sensitising, read across lauric acid and oleic acid No data provided for C18-C22. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from lauric acid and oleic acid . Ames negative	
8.5	Acute toxicity	Oral LD 50 > 5000 mg/kg (read across from C18-C22)	
8.6	Repeated dose toxicity	Read across from lauric acid and oleic acid. NOAEL > 5000 and 7500 mg/kg/day respectively in rat, 18 week study in diet	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish LC50: 0.007 mg/l (14 day) (QSAR)	
9.2	Degradation	Readily biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 6328 (QSAR) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 3.84E-005 atm-m ³ /mole 25 deg C) (QSAR)	

Fatty acids, linseed oil (CAS 68424-45-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	222°C (MSDS)	
7.10	Flammability	Expert judgement may be combustible at high temperature. Read across to Linseed oil	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
Toxicological information			
8.1	Skin irritation	Moderately irritating to skin (Read across to rape oil and reflecting content of linoleic acid)	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant)	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	Linoleic acid: ORAL (LD50): Acute: 3200 mg/kg [Mouse]. 3200 mg/kg [Rat]	
8.6	Repeated dose toxicity	NOAEL > 2000 mg/kg/day Two-year survival was increased in male rats receiving corn oil, 0, 2.5, 5 or 10 ml/kg. Read across from Corn oil	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day	

8.9.1	Carcinogenicity study (if available)	Expert judgment negative	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across from Linseed oil	
9.2	Degradation	Readily biodegradable Read across from Linseed oil	
9.3	Fate and behaviour in the environment	Read across from Linseed oil	

Notes:

Fatty acid, linseed oil has 6% C16, 2.5% stearic, 19% oleic, 24% C18 monosatd. (linoleic) and 47% linolenic. Read across from Fatty acids, soy.

Fatty acids, C12-14 (CAS 90990-10-6)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.8	Partition coefficient n-octanol/water	Log Kow: 4.2 Read across to lauric acid (HSDB)	
7.9	Flash point	165 °C (C10-C14) >160 °C (C12-C16)	
7.10	Flammability	Expert judgement may be combustible at high temperature. Read across to Lauric acid	
7.11	Explosive properties	Expert judgement not explosive	
7.13	Oxidising properties	Expert judgement not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritating (Gesamp). Slightly irritant to rabbit skin, reversible by 72 hr (GHS 2B) (Read across to Lauric acid)	
8.2	Eye irritation	Irritant (likely R36) (Read across to Lauric acid)	
8.3	Skin sensitisation	In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans	
8.4	Mutagenicity	Ames negative (Read across to Lauric acid)	

8.5	Acute toxicity	(LD50): Acute: 12000 mg/kg, Oral LD 50 > 2000 mg/kg (Gesamp) Inhalation >2- ≤10 mg/L (Gesamp) On balance, on read across, given is C12- C14, meets criteria Dermal LD 50 > 2000 mg/kg (Gesamp) (Read across to Lauric acid)	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day in rat, 18 week study in diet (Read across to Lauric acid)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Lauric acid is a fatty acid that can enter normal fatty acid metabolism	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >0,1- ≤1 (Gesamp) Read across from Lauric acid Invertebrates (<i>Daphnia</i>) (USEPA, Lauric acid) EC50: 169 mg/l (48 hr, <i>Daphnia magna</i>) NOEC: 1000 mg/l (21 day, <i>Daphnia magna</i>) Fish (USEPA, Lauric acid) LC50: 350 mg/l (96 hr, <i>Lepomis macrochirus</i>) Rotifer (<i>Brachionus calyciflorus</i>): EC50: 291 mg/l (48 hr) and NOEC: 250 mg/l (48 hr) (USEPA, Lauric acid)	
9.2	Degradation	Readily biodegradable (Gesamp) Read across from Lauric acid	
9.3	Fate and behaviour in the environment	Read across from Lauric acid	

Fatty acids, C12-18 and C18-unsaturated (CAS 90990-15-1)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	> 200°C (C12-C18, Na salt) 340°C (C18 & C18 unsatd)	
7.10	Flammability	May be combustible at high temperature. Read across from palmitic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Irritant, read across from lauric acid, palmitic, oleic acid and C12-C18, sodium salts. Irritant to skin (Na soap). IUCLID presents a number of studies on the Na salts all of which show irritancy but only 50% of which reach EU classification criteria	
8.2	Eye irritation	Irritant, read across from lauric acid, palmitic, oleic acid and C12-C18, sodium salts. Irritant to eye (Na soap). IUCLID presents a number of studies on the Na salts all of which show irritancy but only 50% of which reach EU classification criteria	
8.3	Skin sensitisation	Not sensitising, read across C12-C18, Na salt	
8.4	Mutagenicity	Negative read across from lauric acid and oleic acid. Ames negative (Potassium oleate)	

8.5	Acute toxicity	Oral LD 50 > 5000 mg/kg (Na salt) LD 50 > 19243 mg/kg (oleic acid) Read across from C12-C18, Na salt	
8.6	Repeated dose toxicity	Read across read across from lauric acid NOAEL > 5000 mg/kg/day in rat, 18 week study in diet, NOAEL of oleic acid > 7500 mg/kg/day, 18 week study in diet	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	2 year study in rats, read across Na oleate 12,500 mg/kg/day, not carcinogenic	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across to C8-C18 and C18 unsat. (QSAR), Stearic acid (C18), palmitic acid (C16), and oleic acid (C18)	
9.2	Degradation	Not readily biodegradable. Read across to C8-C18 and C18 unsat. (QSAR)	
9.3	Fate and behaviour in the environment	Read across to C8-C18 and C18 unsat. (QSAR)	

Fatty acids, rape-oil, erucic acid-low (CAS 93165-31-2)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.10	Flammability	May be combustible at high temperature. Read across from rape oil	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
	Toxicological information		
8.1	Skin irritation	Moderately irritating to skin (Zn salt)	
8.2	Eye irritation	Slightly hazardous in case of eye contact (irritant)	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	Oral LD 50 > 3100 mg/kg (Zn salt)	
8.6	Repeated dose toxicity	LD 50 of methyl and ethyl rape oil > 5,000 mg/kg.	
8.7	Reproductive toxicity	NOAEL > 2000 mg/kg/day (read across from corn oil)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	

	Ecotoxicological information		
9.1	Aquatic toxicity	Read across from Rape oil	
9.2	Degradation	Read across from Rape oil	
9.3	Fate and behaviour in the environment	Read across from Rape oil	

Notes:

Rape oil is 54% C18 unsat. 7% C18, 37% linoleic (polyunsaturated). Read across from fatty acid, rape oil, Zn salt and Rape oil.

Palmitic acid (CAS 57-10-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.82 (25° C) (HSDB) Sw: 0.04 mg/L (25 deg C, exp) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: 7.17 (HSDB) Exp LogKow: 7.17 (QSAR)	
7.10	Flammability	May be combustible at high temperature (MSDS) Read across to Stearic acid and Lauric acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritant, read across from lauric acid and oleic acid	
8.2	Eye irritation	Mildly irritant, read across from lauric acid and oleic acid	
8.3	Skin sensitisation	Read across from lauric acid and oleic acid . In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982) No evidence of sensitisation in humans (HERA)	
8.4	Mutagenicity	Read across from lauric acid and oleic acid . Ames negative (HERA, IUCLID)	

8.5	Acute toxicity	Oral LD 50 >10,000 mg/kg (HERA) Dermal LD 50 > 2000 mg/kg (HERA)	
8.6	Repeated dose toxicity	Read across from lauric acid and oleic acid. NOAEL > 5000 mg/kg/day in rat, 18 week study in diet (HERA)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established (JECFA, 1986)	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish (USEPA) LT50: 120 mg/l (96 hr, Oncorhynchus kisutch) >SW LC0: > 1000 mg/l (nominal value) (96 hr, Danio rerio) (SH2)	
9.2	Degradation	Ready degradable (QSAR) BODIS test 65% (fails 10-day window) (SH2)	
9.3	Fate and behaviour in the environment	Koc: 189 (HSDB) Koc: 3431 (QSAR) BCF: 166 (HSDB) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 2.89E-005 atm-m ³ /mole (25 deg C) (QSAR)	

Stearic acid (CAS 57-11-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.568 mg/l (25 °C) (HSDB) Sw: 0.597 mg/L (25 deg C, exp), 0.003512 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: 8,23 (HSDB) LogKow: 8.23 (exp) (QSAR)	
7.9	Flash point	196.11°C (385°F) (MSDS)	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant, read across from lauric acid and oleic acid (HERA)	
8.2	Eye irritation	Slightly irritant (HERA)	
8.3	Skin sensitisation	Read across from lauric acid and oleic acid. In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans	

8.4	Mutagenicity	Ames negative (HERA)	
8.5	Acute toxicity	Oral (HERA) LD 50 > 5000 mg/kg Dermal (HERA) LD 50 > 5000 mg/kg	
8.6	Repeated dose toxicity	Read across from lauric acid and oleic acid. NOAEL > 5000 and 7500 mg/kg/day respectively in rat, 18 week study in diet	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established (JECFA)	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish (USEPA) LT50: 120 mg/L (96 hr, Oncorhynchus kitush) >Sw Fish (QSAR) LC50: 0.003 mg/l (14 day)	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 7,2*10 ⁵ (HSDB) Koc: 1,17E+04 (QSAR) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 5.10E-005 atm-m ³ /mole (25 deg C) (QSAR)	

Oleic acid (CAS 112-80-1)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: not in water but in org. solvent (HSDB) Sw: 7.64 mg/l (25 deg C, exp), 0.01151 mg/l (25 deg C, est) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: 7,73 (HSDB) LogKow: 7.64 (QSAR)	
7.9	Flash point	188.89°C (372°F). OPEN CUP: 198.89°C (390°F) - 218.33 C (425 F)	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritant (HERA, Gesamp)	
8.2	Eye irritation	Not irritant (HERA). Mildly irritant (Gesamp) On read across judge slightly irritant	
8.3	Skin sensitisation	In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans	

8.4	Mutagenicity	Ames negative (IUCLID)	
8.5	Acute toxicity	Oral (IUCLID) LD 50 > 19243 mg/kg Dermal (IUCLID) LD 50 > 3000 mg/kg	
8.6	Repeated dose toxicity	NOAEL > 7500 mg/kg/day 18 wk study in rats (IUCLID)	
8.7	Reproductive toxicity	15% oleic acid (C18) in the diet [approximately 7.5 g/kg bw/day] (the only dose tested) for 10 to 16 weeks did not affect the fertility of male rats but appeared to impair reproductive capacity in the females by interfering with parturition and mammary gland development. Mortality in the offspring was increased. Very high dose. A three-generation reproductive study on a C10 fatty did not produce any reproductive effects (HERA)	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established (JECFA)	
8.9.1	Carcinogenicity study (if available)	No evidence of carcinogenicity was seen in rats receiving 25% oleic acid (C18) in the diet (approximately 12.5 g/kg bodyweight per day) for 20 weeks (IUCLID)	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >100 - ≤1000 (Gesamp) Fish (USEPA) LT50: 2050 mg/L (96 hr, Pimephales promelas) , >Sw Fish (QSAR) LC50: 0.004 mg/l (14 day)	
9.2	Degradation	Ready biodegradable (QSAR, HSDB)	

9.3	Fate and behaviour in the environment	Koc: 38 (HSDB) Koc: 1,17E+04 (QSAR) BCF: 44 (HSDB) LogPow/BCF: <1 or > ca. 7/not measurable (Gesamp) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 4.48E-005 atm-m ³ /mole (25 deg C) (QSAR)	
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Lauric acid (CAS 143-07-7)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 4.81 mg/l (25°C)/insoluble (HSDB) Sw: 4.81mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	Log Kow: 4.2 (HSDB) LogKow: 5.00 (QSAR)	
7.9	Flash point	110°C (230°F) (MSDS)	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Mildly irritant (HERA, Gesamp) Slightly irritant to rabbit skin, reversible by 72 hr (GHS 2B)	
8.2	Eye irritation	Irritant, likely R36 (HERA, Gesamp)	
8.3	Skin sensitisation	In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans (HERA)	
8.4	Mutagenicity	Ames negative (HERA, IUCLID)	

8.5	Acute toxicity	Oral (HERA) LD50: Acute: 12000 mg/kg, Oral (Gesamp) LD 50 > 2000 mg/kg LD 50 > 19243 mg/kg Inhalation (Gesamp) >2- ≤10 mg/L Dermal (Gesamp) LD 50 > 2000 mg/kg	
8.6	Repeated dose toxicity	NOAEL > 5000 mg/kg/day in rat, 18 week study in diet (HERA)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Lauric acid is a fatty acid that can enter normal fatty acid metabolism (EFSA)	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic (IUCLID)	
Ecotoxicological information			
9.1	Aquatic toxicity	LC/EC/IC50: >0,1- ≤1 (Gesamp) Invertebrates (USEPA) EC50: 169 mg/l (48 hr, Daphnia magna) >Sw NOEC: 1000 mg/l (21 day, Daphnia magna) >Sw Fish (USEPA) LC50: 350 mg/l (96 hr, Lepomis macrochirus) >Sw Fish (QSAR) LC50: 0.656 mg/l (14 day) Rotifer (Brachionus calyciflorus): EC50: 291 mg/l (48 hr) and NOEC: 250 mg/l (48 hr) (USEPA)	
9.2	Degradation	Ready biodegradable (QSAR, Gesamp)	

9.3	Fate and behaviour in the environment	Koc: 300 (HSDB) Koc: 297 (QSAR) LogPow/BCF: ≥ 4 -<5 / ≥ 500 -<4000 (Gesamp) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 9.31E-006 atm-m ³ /mole (25 deg C) (QSAR)	
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Sorbitan oleate (CAS 1338-43-8)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.01914 mg/l (25 deg C, exp) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 5.89 (exp) (QSAR)	
7.9	Flash point	OPEN CUP: >148.89°C (300°F)	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	It may cause slight skin irritation (MSDS)	
8.2	Eye irritation	It may cause slight eye irritation, although no irritation is likely to develop following contact with human eyes (MSDS)	
8.3	Skin sensitisation	No data, expert judgement not sensitising	
8.4	Mutagenicity	Sorbitan stearate, at concentrations of 0.01 to 300 pg/ml, did not induce in vitro transformation of hamster ovary cells and was not mutagenic in S. typhimurium strains with or without metabolic activation	
8.5	Acute toxicity	Oral LD50 of orally administered sorbitan (monooleate) was 39.8 g/kg (JECFA)	

8.6	Repeated dose toxicity	NOAEL = 1250 mg/kg/day in a 16 wk study in rats. Effects on liver and kidney at higher levels (JECFA)	
8.7	Reproductive toxicity	No data reported by JECFA, but not anticipated to have reproductive effects at 1000 mg/kg/day, although positive result with oleic acid should be noted	
8.8	Toxicokinetics	Metabolic studies indicate that a significant portion of the sorbitan esters are hydrolysed to the fatty acid moiety and anhydrides of sorbitol (JECFA)	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic at 2500 mg/kg/day (JECFA)	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 0.098 mg/l (48 hr, >Sw) Aquatic plants (algae) (QSAR) EC50: 0.049 mg/l (96 hr, >Sw) Fish (QSAR) LC50: 0.538 mg/l (96 hr, >Sw), 0.235 (14 day, >Sw) Chronic: 0.015 mg/l	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 565 (QSAR) Log BCF: 2.832 (BCF = 678.5) (QSAR) HC: 1.42E-012 atm-m ³ /mole (25 deg C) (QSAR)	

Potassium oleate (CAS 143-18-0)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: yes (HSDB) Sw: 4.187 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 3.92 (exp) (QSAR)	
7.10	Flammability	Read across oleic acid. May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Using the rabbit Draize eye test, potassium oleate (12% aq) caused considerable eye irritation compared to a 70% isopropyl alc std. Potassium oleate is corrosive to skin (HERA, Gesamp, IUCLID)	
8.2	Eye irritation	Using the rabbit Draize eye test, potassium oleate (12% aq) caused considerable eye irritation compared to a 70% isopropyl alc std. Potassium oleate is corrosive to skin (HERA, Gesamp, IUCLID)	
8.3	Skin sensitisation	In two Magnusson and Kligman guinea pig maximisation tests, carried out in conformity with OECD Guideline No. 406 and EC test method B.6 as described in the Annex of EC Directive 84/449/EEC, using two different types of mixed fatty acid sodium salts, no skin sensitisation potential was demonstrated in either material (CIR, 1982). No evidence of sensitisation in humans	

8.4	Mutagenicity	Read across from oleic acid Ames negative. Potassium oleate was negative (IUCLID)	
8.5	Acute toxicity	Oral (IUCLID) Read across from oleic acid LD 50 >19243 mg/kg Dermal (IUCLID) Read across from oleic acid LD 50 > 3000 mg/kg	
8.6	Repeated dose toxicity	Read across from oleic acid NOAEL > 7500 mg/kg/day 18 wk study in rats	
8.7	Reproductive toxicity	Read across from oleic acid 15% oleic acid (C18) in the diet [approximately 7.5 g/kg bw/day] (the only dose tested) for 10 to 16 weeks did not affect the fertility of male rats but appeared to impair reproductive capacity in the females by interfering with parturition and mammary gland development. Mortality in the offspring was increased. Very high dose. A three-generation reproductive study on a C10 fatty did not produce any reproductive effects (HERA)	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	It was concluded that sodium oleate does not induce tumours when given orally to rats. No evidence of carcinogenicity was seen in rats receiving 25% oleic acid (C18) in the diet (approximately 12.5 g/kg bodyweight per day) for 20 weeks (HERA, Hiasa et al. 1985)	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>LC/EC/IC50: >0,1 - ≤1 (Gesamp)</p> <p>Invertebrates (<i>Daphnia</i>) (USEPA) EC50: 5,7 mg/l >Sw (48 hr, <i>Daphnia magna</i>)</p> <p>Fish (USEPA) LC50: 919 mg/l >Sw (96 hr, <i>Oncorhynchus mykiss</i>) Fish (QSAR) LC50: 9.154 mg/l (14 day) >Sw</p>	
9.2	Degradation	Readily biodegradable (Gesamp)	
9.3	Fate and behaviour in the environment	<p>Koc: 1.17e+004 (QSAR)</p> <p>LogPow/BCF: ≥3-<4 / ≥100- <500 (Gesamp)</p> <p>Log BCF: 1.000 (BCF = 10) (QSAR)</p> <p>HLC: 7.858E-014 atm-m³/mole (QSAR)</p>	

Sodium gluconate (CAS 527-07-1)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: yes (slowly) (HSDB) Sw: 5.9E+005 mg/L (25 deg C, exp) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -5.99 (QSAR, OECD)	
7.10	Flammability	May be combustible at high temperature. Read across to Sucrose and D-mannitol (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.12	Self-ignition temperature	> 200 degree C (IUCRID)	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to rabbit skin, not classified (OECD)	
8.2	Eye irritation	Slightly irritant to rabbit eye, not classified (OECD)	
8.3	Skin sensitisation	No data, expert judgement not sensitising	
8.4	Mutagenicity	Micronucleus in vivo negative, Ames negative (OECD)	
8.5	Acute toxicity	Oral LDL0 > 2000 mg/kg bw, LD50 potassium gluconate = 6060 mg/kg bw (OECD)	

8.6	Repeated dose toxicity	NOAEL = 1000 mg/kg bw male, 2000 mg/kg bw female (OECD)	
8.7	Reproductive toxicity	CD Rat NOAEL maternal tox.: >4000 mg/kg bw, NOAEL teratogen.:> 4000 mg/kg bw (OECD)	
8.8	Toxicokinetics	Metabolic fate is well established	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) EC50: 3.23e+009 (48 hr) Chronic: 5.03e+006 mg/l (16 day) NOEC: >1000 mg/l (24-48 hr) (OECD)</p> <p>Aquatic plants (algae) (QSAR) EC50: 1.28e+009 (96 hr) EC50: >1000 mg/l (24-72 hr) NOEC: 560 mg/l (24-72 hr) (OECD)</p> <p>Fish (QSAR) LC50: 5.24e+009 (96 hr), 2.67e+009 (14 day), 2.52e+007 (96 hr, SW) Chronic: 1.86e+008 mg/l (30 day) LC0: >100 mg/l (OECD)</p>	
9.2	Degradation	Ready degradable (closed bottle test, 28 days) (OECD)	
9.3	Fate and behaviour in the environment	Koc: 10 (QSAR) Log BCF: (BCF = 3.162) (QSAR) HLC: 4.76E-013 atm-m ³ /mole (25 deg C) (QSAR)	
9.4	Effects on terrestrial organisms	LC50: 3.88e+005 mg/kg dw (earthworm, 14 day) (QSAR)	

Sodium stearate (CAS 822-16-2)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: yes (slowly) (HSDB) Sw: 3.322 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 4.13 (QSAR)	
7.9	Flash point	>350°F (C.O.C) (MSDS)	
7.10	Flammability	May be combustible at high temperature (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.12	Self-ignition temperature	>700°F (MSDS)	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Hazardous in case of skin contact (irritant) (MSDS), Non irritant (HERA)	
8.2	Eye irritation	Very hazardous in case of eye contact (irritant) (MSDS), Mildly irritant. Rabbit eye (HERA)	
8.3	Skin sensitisation	No local reactions indicative of sensitisation were seen in 100 subjects patch tested [under unspecified conditions] with a bath soap and detergent formulation containing 0.3-0.75% sodium stearate (HERA)	
8.4	Mutagenicity	Read across from stearic acid and Mg stearate, Ames negative	

8.5	Acute toxicity	Oral LD 50 > 5000 mg/kg (HERA) Dermal LD 50 > 3000 mg/kg	
8.6	Repeated dose toxicity	read across from lauric acid and oleic acid. NOAEL > 5000 mg/kg/day in rat, 18 week study in diet	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	Not classifiable as a human carcinogen	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish (QSAR) LC50: 5.743 mg/l (14 day)>Sw	
9.2	Degradation	Ready biodegradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 1.17e+004 (QSAR) Log BCF: 1.000 (BCF = 10) (QSAR) HC: 5.12E-005 atm-m ³ /mole (25 deg C) (QSAR)	

Calcium distearate (CAS 1592-23-0)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.004 g/100 CC water (15 °C) (HSDB) Sw: 2 mg/l (35 deg C, exp), 8.232e-011 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 14.34 (QSAR)	
7.10	Flammability	May be combustible at high temperature. IUCALID data sheet gives no information on flammability	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Read across from sodium stearate, hazardous in case of skin contact (irritant) (MSDS), Non irritant (HERA)	
8.2	Eye irritation	Very hazardous in case of eye contact (irritant) (MSDS) Read across from sodium stearate, hazardous in case of skin contact mildly irritant. Rabbit eye (HERA)	
8.3	Skin sensitisation	Read across from sodium stearate No local reactions indicative of sensitisation were seen in 100 subjects patch tested [under unspecified conditions] with a bath soap and detergent formulation containing 0.3-0.75% sodium stearate (HERA)	
8.4	Mutagenicity	Read across from stearic acid and Mg stearate, Ames negative (MSDS)	

8.5	Acute toxicity	Oral LD50 in rats and mice >10 g/kg bw (MSDS)	
8.6	Repeated dose toxicity	(NOAEL) rat 1 g/kg bw 9mth study (MSDS)	
8.7	Reproductive toxicity	A three-generation reproductive study on a C10 fatty acid did not produce any reproductive effects. Positive effect with oleic acid. Weight of evidence NOAEL > 1000 mg/kg/day	
8.8	Toxicokinetics	Myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats and their metabolic fate is well established	
8.9.1	Carcinogenicity study (if available)	Not classifiable as a human carcinogen	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 2.84e-009 mg/l (48 hr) Chronic: 3.22e-008 mg/l (16 day) Aquatic plants (algae) (QSAR) EC50:3.62e-009 mg/l (96 hr) Fish (QSAR) LC50: 1.13e-009 mg/l (96 hr), 1.46e-008 mg/l (14 day), 1.01e-007 mg/l (96 hr) Chronic:1.07e-009 mg/l (30 day)	
9.2	Degradation	Biodegradable STURM test 55-99 % 20-24 days (SH2)	
9.3	Fate and behaviour in the environment	Koc: 9.22e+008 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 4.366E-004 atm-m ³ /mole(QSAR)	
9.4	Effects on terrestrial organisms	LC50: 0.591 mg/kg dw (earthworm, 14 day) (QSAR) Effect based on Koc and aquatic toxicity	

Sodium D-gluconate (CAS 14906-97-9)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.004 g/100 CC water (15 °C) (HSDB) Sw: 5.9E+005 mg/L (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: -5.99 (QSAR)	
7.10	Flammability	May be combustible at high temperature Read across to Sucrose and D-mannitol (MSDS)	
7.11	Explosive properties	Expert judgment not explosive	
7.12	Self-ignition temperature	> 200 degree C (IUCPID)	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to rabbit skin, not classified (OECD)	
8.2	Eye irritation	Slightly irritant to rabbit eye, not classified (OECD)	
8.3	Skin sensitisation	No data, expert judgement not sensitising	
8.4	Mutagenicity	Micronucleus in vivo negative, Ames negative (OECD)	
8.5	Acute toxicity	LDL0 > 2000 mg/kg bw, LD50 potassium gluconate = 6060 mg/kg bw (OECD)	
8.6	Repeated dose toxicity	NOAEL = 1000 mg/kg bw male, 2000 mg/kg bw female (OECD)	

8.7	Reproductive toxicity	CD Rat NOAEL maternal tox.: >4000 mg/kg bw, NOAEL teratogen.:> 4000 mg/kg bw (OECD)	
8.8	Toxicokinetics	Metabolic fate is well established	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 3.23e+009 mg/l (48 hr) Chronic: 5.03e+006 mg/l (16 day) NOEC: >1000 mg/l (24-48 hr) Read across to sodium gluconate (OECD)</p> <p>Aquatic plants (algae) (QSAR) EC50: 1.28e+009 mg/l (96 hr) EC50: >1000 mg/l (24-72 hr) (OECD) NOEC: 560 mg/l (24-72 hr) Read across to sodium gluconate (OECD)</p> <p>Fish (QSAR) LC50: 5.24e+009 mg/l (96 hr), 2.67e+009 mg/l (14 day), 2.52e+007 mg/l (96 hr, SW) Chronic: 1.86e+008 mg/l (30 day) LC0: >100 mg/l Read across to sodium gluconate (OECD)</p>	
9.2	Degradation	Ready degradable (closed bottle test, 28 days) Read across to sodium gluconate (OECD)	
9.3	Fate and behaviour in the environment	Koc: 10 (QSAR) Log BCF: 0.500 (BCF = 3.162) (QSAR) HC: 4.76E-013 atm-m ³ /mole (25 deg C) (QSAR)	
9.4	Effects on terrestrial organisms	LC50: 3.88e+005 mg/kg dw (earthworm, 14 day) (QSAR) No effect based on Koc and aquatic toxicity	

Glycerol stearate (CAS 123-94-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.0123 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 6.62 (QSAR)	
7.9	Flash point	160°C (320°F) (glycerol) 196.11°C (385°F). (stearic acid)	
7.10	Flammability	May be combustible at high temperature. Read across to glycerol and stearic acid	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritating to skin (IUCLID)	
8.2	Eye irritation	Slightly irritating to eyes (IUCLID)	
8.3	Skin sensitisation	Not sensitising (IUCLID)	
8.4	Mutagenicity	Negative (IUCLID)	
8.5	Acute toxicity	Monoglycerides and diglycerides have no acute toxic effects at practicable dosage levels. LD 50 stearic acid > 5000 mg/kg (JECFA)	

8.6	Repeated dose toxicity	Glyceryl monostearate was fed at levels of 15% (7500 mg/kg/day) and 25% (12500 mg/kg/day) as the sole source of fat in the diet to groups of 10 male and 10 female rats over three generations. Studies carried out during the rapid growth period in each generation showed no adverse effect (JECFA). Short-term repeated dose toxicity study (28 days) Dermal application produced marked skin irritation, no other toxicity reported (IUCLID)	
8.7	Reproductive toxicity	Glyceryl monostearate was fed at levels of 15% (7500 mg/kg/day) and 25% (12500 mg/kg/day) as the sole source of fat in the diet to groups of 10 male and 10 female rats over three generations. Studies carried out during the rapid growth period in each generation showed no adverse effect (JECFA)	
8.8	Toxicokinetics	Diglycerides are readily converted in appropriate tissues either to triglycerides or to mono-glycerides. Monoglycerides can form diglycerides and triglycerides, but they are not always easily broken down to fatty acids and glycerol, although intestinal enzymes that rapidly bring this about have been described. There is no evidence that the presence of monoglycerides or diglycerides of food fats has any deleterious effect on cells or tissues (JECFA)	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 0.018 mg/l (48 hr) >Sw Aquatic plants (algae) (QSAR) EC50: 0.017 mg/l (96 hr) >Sw Fish (QSAR) LC50: 0.046 mg/l (14 day, >Sw), 0.183 mg/l (96 hr, >Sw) Chronic: 0.003 mg/l	

9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 581 (QSAR) Log BCF: 2.894 (BCF = 784.3) (QSAR) HC: 3.85E-008 atm-m ³ /mole (25 deg C) (QSAR)	

Glycerides C16-18 and C18-unsaturated (CAS 67701-30-8)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 21.22 mg/l (25 degC) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 3.40 (QSAR)	
7.9	Flash point	> 240°C Open cup Read-across from CAS 91744-20-6	
7.10	Flammability	May be combustible at high temperature Read across from fatty acids	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to skin Read across from CAS 91744-20-6	
8.2	Eye irritation	Slightly irritant to eye Read across from CAS 91744-20-6	
8.3	Skin sensitisation	No data, expert judgement not sensitising given the results on all the fatty acids	
8.4	Mutagenicity	Negative in Ames test Read across from CAS 91744-20-6	
8.5	Acute toxicity	Oral LD 50 > 2000 mg/kg, Judged to meet the criteria given very high LD50 of many of the fatty acids in the group Read across from CAS 91744-20-6	

8.6	Repeated dose toxicity	No data on CAS 91744-20-6. Partially hydrogenated fish oil (read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids at a single dose of 13000mg/kg/day produced enlargement of the liver, heart and kidney (LOAEL) JECFA states on the mono and diglycerides that "The mono- and diglycerides most likely to cause unwanted effects are those containing long-chain saturated fatty acids, especially stearic acid. Such compounds have been investigated in long-term animal studies. (The increase in liver weight reported in these studies is commonly seen in animals receiving a high fat intake; it is not regarded as having any toxicological significance.) These studies provide useful additional information to the wide experience with glycerides which are a normal constituent of the human diet.	
8.7	Reproductive toxicity	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	
8.8	Toxicokinetics	Diglycerides are readily converted in appropriate tissues either to triglycerides or to mono-glycerides. Monoglycerides can form diglycerides and triglycerides, but they are not always easily broken down to fatty acids and glycerol, although intestinal enzymes that rapidly bring this about have been described. There is no evidence that the presence of monoglycerides or diglycerides of food fats has any deleterious effect on cells or tissues (JECFA)	
8.9.1	Carcinogenicity study (if available)	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	

	Ecotoxicological information		
9.1	Aquatic toxicity	<p>No aquatic toxicity based on information submitted from stakeholder SH2</p> <p>Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 144.737 mg/l (48 hr, >Sw)</p> <p>Aquatic plants (algae) (QSAR) EC50: 7.744 mg/l (96 hr)</p> <p>Fish (QSAR) LC50: 92.380 mg/l (96 hr, >Sw), 27.745 mg/l (14 day) Chronic: 13.816 mg/l</p>	
9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	<p>Koc: 10 (QSAR)</p> <p>Log BCF: 500 (BCF = 3.162) (QSAR)</p> <p>BCF < 10 (SH2)</p> <p>HC: 7.12E-014 atm-m³/mole (25 deg) (QSAR)</p>	

Notes:

There are IUCLID data sheets for triglycerides of C14-C18 and C18-C24 unsaturated fatty acids (fish oil, CAS 8016-13-5) and for glycerides (mono, di and tri) C16-C18 and C18 unsatd, CAS 91744-20-6, that are used for read-across, particularly the latter, as description is the same, just different CAS No.

According to information from stakeholder SH2, BCF < 10 for triglycerides.

Glycerides, tallow mono-, di- and tri-, hydrogenated (CAS 68308-54-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	> 240°C Open cup Read-across from CAS 91744-20-6	
7.10	Flammability	May be combustible at high temperature Read across from fatty acids	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to skin Read across from CAS 91744-20-6	
8.2	Eye irritation	Slightly irritant to eye Read across from CAS 91744-20-6	
8.3	Skin sensitisation	No data, expert judgement not sensitising given the results on all the fatty acids	
8.4	Mutagenicity	Negative in Ames test Read across from CAS 91744-20-6	
8.5	Acute toxicity	Oral LD 50 > 2000 mg/kg, Judged to meet the criteria given very high LD50 of many of the fatty acids in the group Read across from CAS 91744-20-6	

8.6	Repeated dose toxicity	No data on CAS 91744-20-6. Partially hydrogenated fish oil (read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids at a single dose of 13000mg/kg/day produced enlargement of the liver, heart and kidney (LOAEL) JECFA states on the mono and diglycerides that "The mono- and diglycerides most likely to cause unwanted effects are those containing long-chain saturated fatty acids, especially stearic acid. Such compounds have been investigated in long-term animal studies. (The increase in liver weight reported in these studies is commonly seen in animals receiving a high fat intake; it is not regarded as having any toxicological significance.) These studies provide useful additional information to the wide experience with glycerides which are a normal constituent of the human diet.	
8.7	Reproductive toxicity	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	
8.8	Toxicokinetics	Diglycerides are readily converted in appropriate tissues either to triglycerides or to mono-glycerides. Monoglycerides can form diglycerides and triglycerides, but they are not always easily broken down to fatty acids and glycerol, although intestinal enzymes that rapidly bring this about have been described. There is no evidence that the presence of monoglycerides or diglycerides of food fats has any deleterious effect on cells or tissues (JECFA)	
8.9.1	Carcinogenicity study (if available)	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across to Glycerides C16-18 and C18-unsat.	

9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	Expert judgement	

Notes:

Since tallow fatty acids are C14 (3%) C16 (24%) C18 (17%) unsat C16-1 (5%) C18-1 (43%) C18-2 (5%) other (3%) and this is hydrogenated Glycerides, tallow mono-, di- and tri-, hydrogenated, the expert judgement is evaluation can be based on glycerides (mono, di and tri) C16-C18 and C18 unsatd, and the other triglyceride evaluations.

Glycerides, C16-18 and C18-unsaturated, mono- and di- (CAS 68424-61-3)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	> 240°C Open cup Read-across from CAS 91744-20-6	
7.10	Flammability	May be combustible at high temperature Read across from fatty acids	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to skin Read across from CAS 91744-20-6	
8.2	Eye irritation	Slightly irritant to eye Read across from CAS 91744-20-6	
8.3	Skin sensitisation	No data, expert judgement not sensitising given the results on all the fatty acids	
8.4	Mutagenicity	Negative in Ames test Read across from CAS 91744-20-6	
8.5	Acute toxicity	Oral LD 50 > 2000 mg/kg, Judged to meet the criteria given very high LD50 of many of the fatty acids in the group Read across from CAS 91744-20-6	

8.6	Repeated dose toxicity	No data on CAS 91744-20-6. Partially hydrogenated fish oil (read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids at a single dose of 13000mg/kg/day produced enlargement of the liver, heart and kidney (LOAEL) JECFA states on the mono and diglycerides that "The mono- and diglycerides most likely to cause unwanted effects are those containing long-chain saturated fatty acids, especially stearic acid. Such compounds have been investigated in long-term animal studies. (The increase in liver weight reported in these studies is commonly seen in animals receiving a high fat intake; it is not regarded as having any toxicological significance.) These studies provide useful additional information to the wide experience with glycerides which are a normal constituent of the human diet.	
8.7	Reproductive toxicity	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	
8.8	Toxicokinetics	Diglycerides are readily converted in appropriate tissues either to triglycerides or to mono-glycerides. Monoglycerides can form diglycerides and triglycerides, but they are not always easily broken down to fatty acids and glycerol, although intestinal enzymes that rapidly bring this about have been described. There is no evidence that the presence of monoglycerides or diglycerides of food fats has any deleterious effect on cells or tissues (JECFA)	
8.9.1	Carcinogenicity study (if available)	No effect at up to 8000mg/kg/day, combined carcinogenicity and reproduction study within utero phase, read across to triglycerides of C14-C18 and C18-C24 unsaturated fatty acids	
Ecotoxicological information			
9.1	Aquatic toxicity	Read across to Glycerides C16-18 and C18-unsat.	

9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	Expert judgement	

Notes:

There is a IUCLID data sheet for glycerides (mono, di and tri) C16-C18 and C18 unsatd, CAS 91744-20-6, and the evaluation for Glycerides C16-18 and C18-unsaturated (CAS 67701-30-8), that are used for read-across.

Glycerides, C10-18 (CAS 85665-33-4)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.9	Flash point	> 240°C Open cup (triglycerides C8-C10) > 100°C closed cup (glycerides C4-C22)	
7.10	Flammability	May be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Slightly irritant to skin Read across from C8-C10 and glyceryl stearate	
8.2	Eye irritation	Slightly irritant to eye Read across from C8-C10 and glyceryl stearate	
8.3	Skin sensitisation	Not sensitising Read across from C8-C10 and glyceryl stearate	
8.4	Mutagenicity	Negative Read across from C8-C10 and glyceryl stearate	
8.5	Acute toxicity	Oral LD 50 > 20,000 mg/kg read across from C8-C10, no data for the C4-C22	
8.6	Repeated dose toxicity	NOAEL 10,1000 mg/kg, , 47 week study in rats, similar findings with hydrogenated cottonseed oil (C4-C22), other than slight fatty change. Read across from C8-C10	
8.7	Reproductive toxicity	Trioctanoin reported negative at 10,000 mg/kg Read across from C4-C22 (IUCLID)	

8.8	Toxicokinetics	Diglycerides are readily converted in appropriate tissues either to triglycerides or to mono-glycerides. Monoglycerides can form diglycerides and triglycerides, but they are not always easily broken down to fatty acids and glycerol, although intestinal enzymes that rapidly bring this about have been described. There is no evidence that the presence of monoglycerides or diglycerides of food fats has any deleterious effect on cells or tissues	
8.9.1	Carcinogenicity study (if available)	Expert judgment negative	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish LC50: > 10 000 mg/l Brachydanio rerio (96 hr) Read across from Glycerides C14-18, mono- and di- (IUCLID)	
9.2	Degradation	Readily biodegradable Read across from Glycerides C14-18, mono- and di- (IUCLID)	
9.3	Fate and behaviour in the environment	BCF < 10 (SH2)	

Notes:

There are IUCLID data sheets for triglycerides C8-C10, CAS 65381-09-1, and for glycerides C4-C22, mono and di-, both of which are used for read-across. Read across from Glycerides C14-18 mono- and di- (CAS NO 67701-33-1) is done for the ecotoxicological information.

According to information from stakeholder SH2, BCF < 10 for triglycerides.

D-glucitol monostearate (CAS 26836-47-5)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 0.04916 mg/l, 240.64 mg/l (25 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 5.26 (QSAR)	
7.9	Flash point	Read across to glycerides > 100°C closed cup (glycerides C4-C22)	
7.10	Flammability	Assumed to be combustible at high temperature	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Sorbitan fatty acid esters were generally minimal to mild skin irritants in animal studies, except that Sorbitan isostearate applied to the skin was a moderate irritant in one rabbit study (EPA, Toxline)	
8.2	Eye irritation	Assumed slightly irritant to eye (EPA, Toxline)	
8.3	Skin sensitisation	Sorbitan fatty acid esters did not sensitize guinea pigs. Assumed not sensitising (EPA, Toxline)	
8.4	Mutagenicity	Sorbitan fatty acid esters had no genotoxic potential in mammalian cells treated in culture or in bacterial tests (including an Ames assay) (EPA, Toxline)	

8.5	Acute toxicity	Oral The acute oral LD50s for sorbitan monoleate and monolaurate were ~ 40 g/kg (EPA, Toxline)	
8.6	Repeated dose toxicity	Data not readily found, Expert judgement not toxic at > 1000 mg/kg/day	
8.7	Reproductive toxicity	Reproduction and foetal development were apparently unaffected in rats treated orally with Sorbitan fatty acid esters	
8.8	Toxicokinetics	In studies with rats and humans, it was demonstrated that sorbitan esters and sucrose octanoate esters were rapidly hydrolyzed and absorbed by the body	
8.9.1	Carcinogenicity study (if available)	Sorbitan monostearate (Span 60) was given to groups of 48 male and 48 female mice at dose levels of 0 (control), 0.5, 2.0 or 4.0% of the diet for 80 wk. There was no evidence of carcinogenic activity at any of these dose levels	
Ecotoxicological information			
9.1	Aquatic toxicity	Invertebrates (<i>Daphnia</i>) (QSAR) LC50: 0.385 mg/l (48 hr) Aquatic plants (algae) (QSAR) EC50: 0.385 mg/l (48 hr) Fish (QSAR) LC50: 1.224 mg/l (96 hr, >Sw), 0.872 mg/l (14 day) Chronic: 0.052 mg/l	
9.2	Degradation	Ready degradable (QSAR)	
9.3	Fate and behaviour in the environment	Koc: 1.65e+004 (QSAR) Log BCF: 2.349 (BCF = 223.1) (QSAR) HC: 4.40E-012 atm-m ³ /mole (25 deg) (QSAR)	

Notes:

Sorbitan Stearate is the monoester of stearic acid and hexitol anhydrides derived from sorbitol, which is considered to be very close to sorbitol monostearate (D-glucitol monostearate). Read across from Sorbitan fatty acid, Sorbiton mono oleate and monolaurate is done.

Lecithins (CAS 8002-43-5)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: Insoluble (HSDB)	
7.10	Flammability	May be combustible at high temperature. Read across to the glycerides	
7.11	Explosive properties	Expert judgment not explosive	
7.13	Oxidising properties	Expert judgment not oxidising	
Toxicological information			
8.1	Skin irritation	Expert judgment slightly irritant Minimal skin irritant (Final report on the safety assessment of Lecithin and hydrogenated Lecithin)	
8.2	Eye irritation	Eye contact may cause slight irritation (MSDS) Minimal eye irritant (Final report on the safety assessment of Lecithin and hydrogenated Lecithin)	
8.3	Skin sensitisation	Expert judgment not sensitising	
8.4	Mutagenicity	Expert judgment not genotoxic	
8.5	Acute toxicity	No information on the LD50 of lecithin has been found in the literature (JECFA)	
8.6	Repeated dose toxicity	Administration to human subjects of lecithin in daily doses varying from 22 to 83 g for two to four months to improve working capacity was not accompanied by any untoward reactions (JECFA)	

8.7	Reproductive toxicity	Expert judgment no reproductive effects	
8.8	Toxicokinetics	Lecithin is an essential constituent of all cells of the human body. The average diet provides a daily intake of several grams of lecithin (JECFA)	
8.9.1	Carcinogenicity study (if available)	Brain neoplasms found in mice in an oral carcinogenicity study (1969) (Final report on the safety assessment of Lecithin and hydrogenated Lecithin)	
Ecotoxicological information			
9.1	Aquatic toxicity	Lecithins is rated with “zero” which means does not lead to damage to living resources (fish and crustaceans) LC/EC/IC50: >1000 and NOEC>1 (GESAMP report)	
9.2	Degradation	Read across to Glycerides C16-18 and C18-unsat.	
9.3	Fate and behaviour in the environment	Expert judgement LogPow <1 or > ca. 7 (GESAMP report)	

Limestone (CAS 1317-65-3)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information		
	Toxicological information		
8.1	Skin irritation	Primary irritation index of 0.0, classified as NON-IRRITANT to rabbit skin (OECD 404, 2004 GLP study)	
8.2	Eye irritation	A single application of the test material to the non-irrigated eye of three rabbits produced minimal conjunctival irritation (redness and chemosis) All treated eyes appeared normal at the 72-hour observation (OECD 405, 2004 GLP study)	
8.5	Acute toxicity	LD50 6450 mg/kg (MSDS)	
	Ecotoxicological information		
	No information		

Carbon dioxide (CAS 124-38-9)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Sw: 1.45g/l (20 deg C) IUCLID Sw: 1480 mg/l (25 deg C, exp) QSAR	
7.8	Partition coefficient n-octanol/water	LogKow: 0.83 (exp) QSAR	
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
Toxicological information			
8.1	Skin irritation	Not irritant except in liquefied form , expert judgement	
8.2	Eye irritation	Not irritant except in liquefied form , expert judgement	
8.3	Skin sensitisation	Not sensitising , expert judgement	
8.4	Mutagenicity	Not genotoxic, expert judgement	
8.5	Acute toxicity	Not acutely toxic , expert judgement Inhalation LC0 (0.5 hr) 50,000 ppm (90,000 mg/m3). IUCLID cites a human LC0 of 90,000 ppm for 5 min and a LC100 of 30,000-50,000 ppm in rats exposed for 30 mins (IUCLID)	
8.6	Repeated dose toxicity	No repeat dose toxicity , expert judgement	

8.7	Reproductive toxicity	IUCLID describes studies in rats which resulted in developmental toxicity at 2 -13% in atmosphere, likely die to oxygen deprivation	
8.9.1	Carcinogenicity study (if available)	Not carcinogenic, expert judgement	
Ecotoxicological information			
9.1	Aquatic toxicity	Fish LC50: Trout: 35mg/l (96 hr) (HSDB) LC0: 35 mg/l (96 hr) (IUCLID)	

Notes:

Can cause burns in liquefied form.

Nitrogen N2 (CAS 7727-37-9)

Result of assessment: Failing the criteria. **No evidence** of human health or environmental effects or evidence of mild effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	100 vol water absorbes 2,4 vol nitrogen (HSDB) Sw: 1.81E+004 mg/L (21 deg C) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 0.67 (HSDB) LogKow: 0.67 (exp) (QSAR)	
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
Toxicological information			
	No information Expert judgement		
Ecotoxicological information			
9.1	Aquatic toxicity	LD50: 400 mg/l (Cloeon dipterum, mayfly, 48 hr) (USEPA)	

Notes:

Can cause burns in liquefied form.

Argon Ar (CAS 7440-37-1)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

Notes:

Can cause burns in liquefied form.

Helium He (CAS 7440-59-7)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance	Gas (HSDB)	
7.3	Boiling point	-268.9 °C (HSDB)	
7.7	Water solubility	2.5 mg/l (21 °C) (HSDB)	
7.11	Explosive properties	Not flammable (MSDS)	
7.12	Self-ignition temperature	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

Notes:

Can cause burns in liquefied form.

Neon Ne (CAS 7440-01-9)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance	Gas (MSDS)	
7.3	Boiling point	-246 °C (MSDS)	
7.7	Water solubility	8,9 mg/l (MSDS)	
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

Notes:

Can cause burns in liquefied form.

Krypton Kr (CAS 7439-90-9)

Result of assessment: Passing the criteria



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance	Gas (MSDS)	
7.3	Boiling point	-153°C (MSDS)	
7.7	Water solubility	221 mg/l (MSDS)	
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

Notes:

Can cause burns in liquefied form.

Xenon Xe (CAS 7440-63-3)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
7.1	State of the substance	Gas (MSDS)	
7.3	Boiling point	-108 °C (MSDS)	
7.7	Water solubility	644 mg/l (MSDS)	
7.10	Flammability	Not flammable (MSDS)	
7.11	Explosive properties	Not explosive (MSDS)	
7.13	Oxidising properties	Not oxidising (MSDS)	
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

Notes:

Can cause burns in liquefied form.

Water, distilled (CAS 7732-18-5)**Result of assessment:** Passing the criteria

Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information Expert judgement		
	Toxicological information		
	No information Expert judgement		
	Ecotoxicological information		
	No information Expert judgement		

EVALUATION OF CARBON AND GRAPHITE

Carbon C (CAS 7440-44-0)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
Physicochemical properties			
7.7	Water solubility	Not soluble (IUCLID) Sw: 22 mg/L (25 deg C), 428.49 mg/l (25 deg C, est) (QSAR)	
7.8	Partition coefficient n-octanol/water	LogKow: 1.09 (exp), 0.78 (QSAR)	
Toxicological information			
8.1	Skin irritation	May cause mild irritation and redness (MSDS)	
8.2	Eye irritation	May cause mild irritation and redness (MSDS)	
8.3	Skin sensitisation	Expert judgement: Not anticipated to be sensitising	
8.4	Mutagenicity	Not genotoxic (OECD)	

8.5	Acute toxicity	<p>Carbon nanotubes inhibited cell growth and caused cell death to human lung and kidney cells (Ref 2 Magrez et al, Ref 3 Oberdoerster et al, Data submitted by stakeholder SH6)</p> <p>Oral LD0 rat oral 8000-10,000 mg/kg bw (carbon black) (OECD)</p> <p>Inhalation LC50(rat) > 64.4 mg/L (Data from stakeholder SH1)</p> <p>Carbon nanotubes at OEL levels for graphite particles caused inflammation and early onset of fibrogenesis in mice (Ref 4 Shvedova et al, Data submitted by stakeholder SH6)</p> <p>Dermal Carbon nanotubes inhibit protein expression in outer level skin cells (human keratinocytes) (Ref 6 Witzman et al, Data submitted by stakeholder SH6)</p>	
8.6	Repeated dose toxicity	Charcoal (CAS 7440-44-0) Prolonged inhalation of excessive dust may produce pulmonary disorders (MSDS)	
Ecotoxicological information			
9.1	Aquatic toxicity	<p>LC50(fish) >10 g/L (96 hr) (SH1 data)</p> <p>Invertebrates (<i>Daphnia</i>) Byproducts of carbon nanotubes caused increased mortality and delayed development of estuarine invertebrates (Ref 5 Templeton et al, Data submitted by stakeholder SH6)</p> <p>Fish Carbon nanotubes cause delayed hatching of Zebrafish (Ref 1 Cheng et al, Data submitted by stakeholder SH6)</p>	
9.2	Degradation		

9.3	Fate and behaviour in the environment	Koc: 4.2 (QSAR) Log BCF: 0.139 (BCF = 1.378) (QSAR) HC: 4.14E-001 atm-m ³ /mole (25 deg) (QSAR)	
9.4	Effects on terrestrial organisms	LC50: 234.449 mg/kg dw (earthworm, 14 day) (QSAR) No effect based on Koc and aquatic toxicity	

Notes:

The problems related to the nanoforms of substances on Annex IV were discussed at the CASG-meeting 26 March 2003. See general note regarding nanoforms of carbon and graphite below.

Graphite (CAS 7782-42-5)

Result of assessment: Failing the criteria. **Evidence** of human health or environmental effects.



Ref. No.	Properties	Justifications	Evaluation per endpoint
	Physicochemical properties		
	No information		
	Toxicological information		
8.1	Skin irritation	May cause mild irritation and redness (MSDS)	
8.2	Eye irritation	May cause mild irritation and redness (MSDS)	
8.3	Skin sensitisation	Expert judgement not anticipated to be sensitising	
8.4	Mutagenicity	Expert judgment and read-across to carbon black not genotoxic	
8.5	Acute toxicity	Inhalation Dust is irritating to the respiratory tract (MSDS)	
8.6	Repeated dose toxicity	Prolonged inhalation of excessive dust may produce pulmonary disorders, Chronic inhalation exposure to natural graphite is associated with the development of pneumoconiosis. The potential for fibrotic disease relates to quartz as an impurity, not graphite.	

8.9.1	Carcinogenicity study (if available)	IARC: Group 1 carcinogen, NTP suspect carcinogen. The IARC classification as a human carcinogen relates to quartz as an impurity, not graphite. As such, the identified hazards do not apply to CAS No 7782-42-5, provided it is completely free of quartz. This does not seem to be the case, according to the MSDS, which were readily available sources of information. No evidence that CAS No 7782-42-5 is placed on the market in a pure form, free of quartz was seen.	
	Ecotoxicological information		
	No information		

Notes:

Hazardous properties identified for Graphite are possibly related to content of quartz. See general note regarding nanoforms of carbon and graphite below.

GENERAL NOTE ON NANOFORMS OF CARBON AND GRAPHITE

At meetings of CASG(Annexes), several Member States argued that nanomaterials should not be exempted from registration under REACH and should therefore not be included in Annex IV. The debate on how to ensure that nanomaterials are not exempted in Annex IV revolved around the possibility to include a general footnote indicating that nanoforms of the substances are not exempted. However, the Commission considered that this was not possible, as Annex IV exempts substances, in all their forms and uses, from the provisions on registration, evaluation and downstream users. Insertion of a footnote that will exclude some forms of the substances listed in the Annex would change the nature and scope of the Annex. Any such decision could only be taken by the co-legislators by co-decision. The Commission also concluded that in their view, should a nanoform of a substance not comply with the agreed criteria, the substance should not be an entry in Annex IV.

It was agreed that for a substance at the nanoscale or for a substance with a nanoscale form to be included in Annex IV, the same set of criteria should apply as for other forms of the same substance.

Some allotropes have specific CAS numbers and in theory, different nanoforms could be separated from non-nanoforms.

The currently used CAS numbers for carbon and graphite include the nanoforms. In the evaluation of carbon and graphite all available information on non-nanoscale and nanoscale forms of the substances were therefore considered and evaluated against the criteria. The available information included the information submitted by the stakeholders.

TECHNICAL NOTE ON THE EVALUATION OF NANOFORMS

Summary of information from the references submitted by stakeholder SH6

Proposals for deletion of carbon and graphite were received from one stakeholder, stakeholder SH6. The proposals were based on information on the substances in nanoforms from a number of references some of which are summarised below. The references 2, 3, 4, and 6 from the stakeholder SH6 were consulted to determine whether the proposal was sufficiently robust to recommend deletion of carbon and graphite from Annex IV.

For the proposals for deletion of carbon and graphite to be successful, they should satisfy the criterion in guidance document, Section 5.2: “the burden of proof is directed at identifying evidence of human health or environmental effects according to the above criteria”.

SH6 Reference 2

Carbon-based nanoparticle toxicity was studied in vitro in lung tumor cells. Toxicity was related to the structure of the carbon nanoparticles (multi-walled nanotubes, nanofibres, and nanoparticles). The article concludes that the materials are toxic, inhibiting cell proliferation and producing cell death, and the toxic effect is dependent on the size of the particle.

SH6 Reference 3

This paper concerns the development of a testing strategy for nanoparticles (in general, not carbon nanoparticles in particular), but does contain summary data. Single-walled carbon nanotubes (SWCNT) inhibit the proliferation of kidney cells by producing apoptosis and decreasing cellular adhesion.

Multi-walled carbon nanotubes (MWCNT) are persistent in the deep lung after inhalation, and are then able to induce inflammatory and fibrotic reactions.

Skin effects have been modelled in cell culture, and may initiate an irritation response in epithelial cells, and cause protein alterations. Carbon nanoparticles can affect the integrity of the blood–brain barrier.

SH6 Reference 4

Pharyngeal aspiration of SWCNT in mice elicited unusual pulmonary effects that combined acute inflammation with early onset yet progressive fibrosis and granulomas.

SH6 Reference 6

MWCNT alters protein expression in human keratinocytes, when applied in cell culture. This indicated potential for chronic inflammation potential in the skin.

Other sources

The proposal contains a weblink on page one, not cited in the references: http://www.environmentalfutures.org/nanotsca_final2.pdf. This contains some summary data which indicates that SWCNT shows excess toxicity to rats instilled in the trachea compared to quartz or carbonyl iron.

The OECD SIDS report for carbonyl black (CAS 1333-86-4) indicates low acute oral toxicity, low skin and eye irritancy, and no sensitisation potential. Inhalation (rat, 13 weeks) gave NOEL of 1.1 mg/m³, but dose-related increases in biochemical and cellular markers of inflammation and lung damage at 7.1 mg/m³. Severe lung damage (including lung tumours) was seen in two year exposure (rat, 16 h/day, 5 d/week) at 2.5 mg/m³. Skin painting studies in mice did not induce signs of skin cancer development. IARC classification is 2B - possible carcinogen to humans.

DISCUSSION

It is not possible to compare the results on nanoparticles (above) with the criteria given in the toxicological section of the criteria document, Section 2.2. To this extent, the applicant for deletion has failed to demonstrate health effects according to the criteria (as required in Section 5.2 of the criteria document).

The proposal for deletion of graphite and carbon from Annex IV is based on the fact that these substances have the same identity according to the CAS number as the nanoforms. Only anecdotal evidence is presented in the application to suggest that the CAS numbers for graphite and carbon are used for the nanoforms. As indicated above, there is also evidence that separate CAS numbers are used for the nanoforms, and would therefore potentially be treated as different substances under REACH. The purity and composition of the tested

substance is generally not given in the provided references, especially in relation to residual catalysts which may impact the toxicology.

Most of the results use cell-based methodologies, and are therefore not open to interpretation against regulatory test methods or classification criteria. The *in vitro* studies cannot be interpreted with regard to equivalent dose in an *in vivo* system. Furthermore, the test methods are not validated according to international criteria. The *in vivo* study (reference 4) uses aspiration of a solution of SWCNT into the lungs, so comparison with inhalation is confounded. Reference 2 finds carbon black more cytotoxic than the other nanoforms investigated, but carbon black is well investigated and shows fairly low overall toxicity (see OECD SIDS report, summarised above).

Other substances may produce biological responses when introduced as a nanomaterial, so it is not clear which responses are specific to the substances (carbon or graphite), and which are due to the small particle size. Animal studies routinely show an increase in pulmonary inflammation, oxidative stress and distal organ involvement upon respiratory exposure to inhaled or implanted ultrafine particulate matter. Typically, the biological activity of particles increases with decreasing particle size.

The small size of nanoparticles gives them chemical and physical properties fundamentally different from larger particles. Therefore, toxicological effects cannot be predicted by extrapolation from data with fine carbon particles. It is clear that the investigation of the toxicity of nanoforms of carbon and graphite are not yet well investigated.

CONCLUSION

The proposal gives anecdotal evidence that nanoforms of carbon and graphite have the same identity (CAS number) as graphite and carbon in other forms. The proposal also presents evidence of adverse effects in cellular toxicity tests, and in some *in vivo* studies. The composition of the tested substance and the test methodology indicate that the results are not conclusive with regard to the criteria for deletion from Annex IV. The toxicology of nanoforms is not well understood, and techniques for investigating nanoforms are not established. The results are not conclusive, but the concerns raised on possible lung- and skin-effects are greater than would be predicted from the toxicology of larger particles of carbon and graphite.

REFERENCES

Stakeholders submitting additional information are anonymized by the application of a code name for the references

ACGIH	American Conference of Industrial Hygienists
Boyd et al	Toxicity of starch administered by mouth. E. M. Boyd and S. J. Liu, Can. Med. Assoc. J. 98(10): 492–499, March 9 (1968)
EFSA	Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission related to Flavouring Group Evaluation 26: Amino acids from chemical group 34
Gangolli ed	Dictionary of substances and their effects. S. Gangolli (ed.) 1999
GESAMP	IMO (2002): The Revised GESAMP Hazard Evaluation Procedure for Chemical Substances Carried by Ships, GESAMP Reports and studies No. 64. International Maritime Organization, London, 2002.
HERA	Human & Environmental Risk Assessment on ingredients of European household cleaning products
HSDB	TOXNET (2007): Hazardous Substance Data Bank (HSDB). United States National Library of Medicine, National Institute of Health, Bethesda, Maryland, United States of America. Available at: (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB)
IUCLID	ECB (2007): European Chemical Substances Information System, Version 5.00. European Chemical Bureau, Ispra, Italy. Available at: (http://ecb.jrc.it/esis/)
JECFA	Joint FAO/WHO Expert Committee on Food Additives. WHO food additives series, IPCS INCHEM.
MSDS	Material Safety Data Sheet available at www
NTP	National Toxicology Program, Abstract for TR-426 - Corn Oil, Safflower Oil, & Tricaprylin [Carcinogenesis Bioassay D-Mannitol in F344/N Rats and B6C3F1 Mice. Technical Report Series No. 236 (1982) NIH Publication No. 82-1792 U.S. Department of Health and Human Services, National Toxicology Program, National Institute of Environmental Health Sciences, Research Technical report on the toxicity studies of castor oil in f344/n rats and b6c3f1 mice (dosed feed studies), Richard Irwin, NTP TOX 12, NIH Publication No. 92-3131, March 1992
OECD	Published OECD SIDS initial assessments of HPV chemicals

QSAR	The Epi Suite Model v3.12 was used for the QSAR analyses on ecotoxicity and biodegradability as well as the water solubility. For the analysis of ready biodegradability a number of six different models was run in the Epi Suite Model. The result on the biodegradability was based on the combined results from all six models. This is in accordance with the recommendations in TGD on risk assessment (2003) of using the combined predictions on biodegradability from three of the six models.
SAR	Expert judgement based on structure analogy
Sato et al	Influence of Corn Oil and Diet on Reproduction and the Kidney in Female Sprague-Dawley Rats. Masako Sato, Kazuyoshi Wada, Hideki Marumo, Tetsuji Nagao, Kiyoshi Imai and Hiroshi Ono. Toxicological Sciences 56, 156-164 (2000)
SCF	Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Pantothenic Acid (Vitamin B5), CF/CS/NUT/UPPLEV/61 Final, 18 April 2002 Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin E, CF/CS/NUT/UPPLEV/31 Final, 23 April 2003 Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of preformed Vitamin A, CF/CS/NUT/UPPLEV/24 Final, 7 October 2002
SH1	Additional data on Carbon submitted by stakeholder SH1
SH2	Additional data on Fatty acids, fatty acids salts & oils and glycerides submitted by stakeholder SH2
SH3	Unpublished reports by stakeholder SH3: Report on the acute dermal irritation /corrosivity to the intact dorsal skin of the white rabbit, (report No. 18H0750/882304), 16 Feb 1989. Report on the acute irritation to the eye of the white rabbit (report No. 18H0750/882305), 16 Feb 1989. Report on the testing of Vitamin E-Acetate NF XIV on toxicity in the rat in a 4-week feeding study, report No. 77/752, 17 Aug. Report on the testing of Vitamin E-Acetate NF XIV on toxicity in the dog in a 4-week feeding study, report No.77/752, 22 Dec 1982 Report on the investigation of the biological degradation in a respirometric test (EU method) (Pruefbericht ueber eine Untersuchung auf biologische Abbaubarkeit im Respirometrischer Test (EG Methode)), Test No. 588680, 14 Jan 1988.
SH4	Unpublished reports by stakeholder SH4: Report No B-166'532 Study of photoallergenicity of dl-alpha -tocopheryl acetate in the albino guinea pig (GLP, 24.6.1996)

	13-week oral toxicity (gavage) study with d-alpha tocopheryl acetate in the rat (2000, GLP)
	13-week oral toxicity (gavage) study with d-alpha tocopheryl acetate in minipigs (2000, GLP)
	Study No: L01-000306 Effect of dl-alpha-tocopheryl acetate on the growth of juvenile rainbow trout in a semistatic test. (OECD 215; GLP, 15.8.2001)
	Report G 607 06: Ready biodegradability of d-alpha-tocopheryl acetate (Manometric respirometry test). (GLP, 4.7.2000)
SH5	Additional data submitted by stakeholder SH5 on Castor oil and Fatty acids, castor oil
SH6	Additional data submitted by stakeholder SH6 on nanomaterials of carbon: <ol style="list-style-type: none"> 1. Cheng J, Flahaut E, Cheng S. 2007. Effect of carbon nanotubes on developing zebrafish (<i>Danio rerio</i>) embryos. <i>Environ Toxicol Chem</i> 26(4):708-716. 2. Magrez A., Kasa S., Salicio V., Pasquier N., Won Seo J., Celio M., Catsicas S., Schwaller B., Forro L. (2006). Cellular toxicity of carbon-based nanomaterials. <i>Nano Letters</i> 6(6):1121-1125 3. Oberdörster G, Maynard A, Donaldson K, Castranova V, Fitzpatrick J, Ausman K, Carter J, Karn B, Kreyling W, Lai D, Olin S, Monteiro- Riviere N, Warheit D, and Yang H (2005). "Principles for characterising the potential human health effects from exposure to nanomaterials: elements of a screening strategy". <i>Particle and Fibre Toxicology</i> 2:8 4. Shvedova A, Kisin E, Mercer, R, Murray A, Johnson V, Potapovich A, Tyurina Y, Gorelik O, Arepalli S, Schwegler-Berry D, Hubbs A, Antonini J, Evans D, Ku B, Ramsey D, Maynard A, Kagan V, Castranova V and Baron P (2005). "Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice". <i>American Journal of Physiology: lung, cell and molecular physiology</i> 289:698- 708. 5. Templeton P, Ferguson P, Washburn K, Scrivens W, Chandler G. 2006. Life-Cycle Effects of Single-Walled Carbon Nanotubes (SWNTs) on an Estuarine Meiobenthic Copepod. <i>Environ Sci Technol</i> 40:7387-7393. 6. Witzmann, F., Monteiro-Riviere, N. (2006). Multi-walled carbon nanotube exposure alters protein expression in human keratinocytes. <i>Nanomedicine: Nanotechnology, Biology, and Medicine</i> 2:158– 168
Spector	Handbook of Toxicology, W.S. Spector, Saunders, Philadelphia (1956)
USEPA	ACTION MEMORANDUM SUBJECT: Inert Reassessment - Members of the Sorbitan Fatty Acid Esters and the Polysorbates, May 20 (2005)

Zondlo Fiume Final Report on the Safety Assessment of Tocopherol, Tocopheryl Acetate, Tocopheryl Linoleate, Tocopheryl Linoleate/Oleate, Tocopheryl Nicotinate, Tocopheryl Succinate, Dioleoyl Tocopheryl Methylsilanol, Potassium Ascorbyl Tocopheryl Phosphate, and Tocophersolan. M. Zondlo Fiume, International Journal of Toxicology, Volume 21, Supplement 3, 15 pp. 51-116(66), November (2002)