

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019



MEtherm 50 *No Change Service!*

Version
02.05

Revision Date:
04.01.2023

Date of last issue: 12.12.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : MEtherm 50
Unique Formula Identifier (UFI) : 2JD0-20KJ-F003-EDWH

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Cleaning agent

Recommended restrictions on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Supplier : MELAG Medizintechnik GmbH & Co. KG
Geneststraße 6-10

10829 Berlin
Germany
Telephone: +4930-7579110
Telefax: +4930-75791199
MEtherm-OEM@melag.de
www.melag.com

Producer : Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.com

E-mail address of person responsible for the SDS/Contact person : ChemicalCompliance@schuelke.com

1.4 Emergency telephone number

Emergency telephone number : Carechem 24 International:+44 1235 239670

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)


Eye irritation, Category 2 H319: Causes serious eye irritation.

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Hazard pictograms :


Signal word :
Warning

Hazard statements :
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements :
Prevention:
P280 Wear protective gloves/ eye protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Additional Labelling

EUH208 Contains subtilisin.
 May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sodium p-cumenesulphonate	15763-76-5 239-854-6 - - - 01-2119489411-37-XXXX	Eye Irrit. 2; H319	>= 1 - < 10
2-aminoethanol	141-43-5 205-483-3 603-030-00-8 01-2119486455-28-XXXX	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 (Respiratory system) Aquatic Chronic 3; H412 specific concentration limit STOT SE 3; H335 >= 5 %	>= 2.5 - < 3
sodium etasulfate	126-92-1 204-812-8 - - - 01-2119971586-23-XXXX	Skin Irrit. 2; H315 Eye Dam. 1; H318 specific concentration limit Eye Irrit. 2; H319 > 10 - < 20 % Eye Dam. 1; H318 > 20 %	>= 1 - < 3
Alcohols, C12-15-branched and linear, ethoxylated propoxylated	120313-48-6 - - - - - - - - -	Skin Irrit. 2; H315 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	>= 0.25 - < 1
subtilisin	9014-01-1 232-752-2	Acute Tox. 4; H302 Skin Irrit. 2; H315	>= 0.1 - < 0.25

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	647-012-00-8 01-2119480434-38-XXXX	Eye Dam. 1; H318 Resp. Sens. 1; H334 STOT SE 3; H335 (Respiratory system) Aquatic Acute 1; H400 Aquatic Chronic 2; H411 <hr/> M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Substances with a workplace exposure limit :			
propane-1,2-diol	57-55-6 200-338-0 - - - 01-2119456809-23-XXXX		>= 10 - < 20
glycerol	56-81-5 200-289-5 - - - - - -		>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Take off all contaminated clothing immediately.
- If inhaled : If symptoms persist, call a physician.
- In case of skin contact : Wash off immediately with soap and plenty of water.
If skin irritation persists, call a physician.
- In case of eye contact : Rinse thoroughly with plenty of water, also under the eyelids.
If eye irritation persists, consult a specialist.
- If swallowed : Do NOT induce vomiting.
Drink water as a precaution.
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Treat symptomatically.
- Risks : Causes skin irritation.
Causes serious eye irritation.

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : For specialist advice physicians should contact the Poisons Information Service.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry powder
Carbon dioxide (CO₂)
Foam
Water spray jet

Unsuitable extinguishing media : Do NOT use water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Increased risk of slipping in the presence of leaked / spilled product.

6.2 Environmental precautions

Environmental precautions : Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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- Advice on safe handling : Wear personal protective equipment.
Never mix concentrates directly.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection. The product itself does not burn.
- Hygiene measures : Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Store at room temperature in the original container.
- Further information on storage conditions : Recommended storage temperature: 5 - 25°C Protect from frost, heat and direct sunlight.
- Advice on common storage : Do not store together with explosive, infectious and radioactive products.

7.3 Specific end use(s)

- Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
propane-1,2-diol	57-55-6	TWA (particles)	10 mg/m ³	GB EH40
		TWA (Total vapour and particles)	150 ppm 474 mg/m ³	GB EH40
glycerol	56-81-5	TWA (Mist)	10 mg/m ³	GB EH40
2-aminoethanol	141-43-5	TWA	1 ppm 2.5 mg/m ³	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	3 ppm 7.6 mg/m ³	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		TWA	1 ppm 2.5 mg/m ³	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
		STEL	3 ppm 7.6 mg/m ³	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			

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subtilisin	9014-01-1	TWA	0.00004 mg/m3	GB EH40
<p>Further information: One of the suitable measurement methods is the fluorescence polarisation technique developed by the Health and Safety Laboratory (HSL). The previous limit for subtilisin was based on high-volume static sampling to achieve sufficient sensitivity. However, improvements in the analytical methodology have improved the sensitivity and the WEL for subtilisin reflects this. The limit is based on standard personal sampling (MDHS14/4).4 Short-term reference period (15 minute) sampling is not appropriate., Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even in tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified as asthmagens or respiratory sensitisers. Further information can be found in the HSE publication Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma., Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible, the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive. For substances that can cause occupational asthma, COSHH requires that exposure be reduced to as low as is reasonably practicable. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance., Subtilisins are proteolytic enzymes derived from Bacillus subtilis. They are used in biological washing powders, animal feedstuffs etc. The enzyme preparation contains active enzyme, inactive enzyme and protein residues., Capable of causing occupational asthma., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used., The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause occupational asthma in the categories shown in Table 1. It should be remembered that other substances not in these tables may cause occupational asthma. HSE's asthma web pages (www.hse.gov.uk/asthma) provide further information.</p>				

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
propane-1,2-diol	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Workers	Inhalation	Long-term local effects	10 mg/m3
sodium p-cumenesulphonate	Workers	Skin contact	Long-term systemic effects	136.25 mg/kg
	Workers	Skin contact	Long-term local effects	0.096 mg/cm2

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			fects	
	Workers	Inhalation	Long-term systemic effects	26.9 mg/m ³
2-aminoethanol	Workers	Skin contact	Long-term systemic effects	1 mg/kg
	Workers	Inhalation	Long-term local effects	3.3 mg/m ³
sodium etasulfate	Workers	Skin contact	Long-term systemic effects	4060 mg/kg
	Workers	Inhalation	Long-term systemic effects	285 mg/m ³
subtilisin	Workers	Skin contact	Acute local effects, Long-term local effects	2000 ppm
	Workers	Inhalation	Long-term local effects	0.00006 mg/m ³

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
propane-1,2-diol	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57.2 mg/kg
	Soil	50 mg/kg
sodium p-cumenesulphonate	Fresh water	0.23 mg/l
	Marine water	0.023 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.862 mg/kg
	Marine sediment	0.0862 mg/kg
	Soil	0.037 mg/kg
2-aminoethanol	Fresh water	0.085 mg/l
	Marine water	0.0085 mg/l
	Intermittent use/release	0.028 mg/l
	Effects on waste water treatment plants	100 mg/l
	Fresh water sediment	0.434 mg/kg dry weight (d.w.)
	Marine sediment	0.0434 mg/kg dry weight (d.w.)
	Soil	0.0367 mg/kg dry weight (d.w.)
sodium etasulfate	Fresh water	0.136 mg/l
	Marine water	0.0136 mg/l
	Fresh water sediment	1.5 mg/kg
	Marine sediment	0.15 mg/kg
	Soil	0.22 mg/kg
	Effects on waste water treatment plants	1.35 mg/l
subtilisin	Fresh water	0.00006 mg/l
	Marine water	0.000006 mg/l
	Effects on waste water treatment plants	65 mg/l

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8.2 Exposure controls

Personal protective equipment

- Eye/face protection : Safety glasses with side-shields conforming to EN166
- Hand protection
Directive : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
- Remarks : Splash protection: disposable nitrile rubber gloves e.g. Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection. Prolonged contact: Nitrile rubber gloves e.g. Camatril (>480 Min., layer thickness: 0,40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0,70 mm) made by KCL or gloves from other manufacturers offering the same protection.
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : No personal respiratory protective equipment normally required.
- Protective measures : Avoid contact with skin and eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : liquid
- Colour : light yellow
- Odour : characteristic
- Odour Threshold : not determined
- pH : 11 (20 °C)
Concentration: 100 %
- Melting point/freezing point : < -5 °C
- Decomposition temperature : Not applicable
- Initial boiling point and boiling range : ca. 100 °C
- Flash point : > 100 °C
Method: DIN 51755 Part 1
- Evaporation rate : No data available
- Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower
flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Density : ca. 1.11 g/cm³ (20 °C, 1,013 hPa)

Solubility(ies)

Water solubility : completely soluble (20 °C)

Partition coefficient: n-
octanol/water : Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, dynamic : ca. 9 mPa*s
Method: ISO 3219

Explosive properties : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : Does not sustain combustion.

Metal corrosion rate : None reasonably foreseeable.

Self-ignition : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Hazardous reactions : reaction with acids.

10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : Possible incompatibility with alkali sensitive materials.

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10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not classified based on available information.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

sodium p-cumenesulphonate:

- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
- Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
- Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

2-aminoethanol:

- Acute oral toxicity : (Rat): 1,515 mg/kg
Method: OECD Test Guideline 401
Assessment: Harmful if swallowed.
- Acute inhalation toxicity : (Rat): > 1.3 mg/l
Exposure time: 6 h
Test atmosphere: vapour
Assessment: Harmful if inhaled.
- Acute dermal toxicity : Assessment: Harmful in contact with skin.

sodium etasulfate:

- Acute oral toxicity : LD50 (Rat): 2,840 mg/kg
- Acute inhalation toxicity : Remarks: No data available
- Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

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Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: Calculated value

Acute inhalation toxicity : Remarks: not determined

Acute dermal toxicity : Remarks: not determined

subtilisin:

Acute oral toxicity : LD50 (Rat): 1,800 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : Remarks: No data available

propane-1,2-diol:

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): 317.042 mg/l
Exposure time: 2 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

glycerol:

Acute oral toxicity : LD50 (Rat, female): 27,200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

sodium p-cumenesulphonate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : slight irritation
Remarks : Based on available data, the classification criteria are not met.

2-aminoethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 3 minutes to 1 hour of exposure

sodium etasulfate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

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Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Species : Rabbit
Method : Draize Test
Result : Skin irritation

subtilisin:

Method : OECD Test Guideline 404
Result : Skin irritation

propane-1,2-diol:

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

sodium p-cumenesulphonate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Eye irritation

2-aminoethanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Risk of serious damage to eyes.

sodium etasulfate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

subtilisin:

Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

propane-1,2-diol:

Result : Mildly irritant - does not need to be labelled

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Test Type : Buehler Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.

2-aminoethanol:

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.

sodium etasulfate:

Method : OECD Test Guideline 429
Result : Did not cause sensitisation on laboratory animals.

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Remarks : No data available

subtilisin:

Result : Probability of respiratory sensitisation in humans based on animal testing
Remarks : largely based on human evidence

propane-1,2-diol:

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Genotoxicity in vitro : Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: Not mutagenic in Ames Test

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse

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Application Route: Oral
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

2-aminoethanol:

Genotoxicity in vitro : Result: Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Genotoxicity in vivo : Result: Did not show mutagenic effects in animal experiments.

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects., Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

sodium etasulfate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Bacteria
Method: OECD Test Guideline 471
Result: negative

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Result: negative

Germ cell mutagenicity- Assessment : Based on available data, the classification criteria are not met.

subtilisin:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects.

propane-1,2-diol:

Germ cell mutagenicity- Assessment : Non mutagenic

Carcinogenicity

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Species : Rat
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : no increase in tumors observed

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Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

2-aminoethanol:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

sodium etasulfate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Dose : > 1125 mg/kg body weight

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

subtilisin:

Carcinogenicity - Assessment : No data available

propane-1,2-diol:

Result : negative

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Effects on fertility : Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 300 mg/kg bw/day
General Toxicity F1: NOAEL: 1,000 mg/kg bw/day
Method: OECD Test Guideline 421

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 936 mg/kg body weight
Teratogenicity: NOAEL: 936 mg/kg bw/day

Reproductive toxicity - Assessment : study scientifically unjustified

2-aminoethanol:

Effects on fertility : Test Type: Two-generation study

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Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 300 mg/kg body weight
General Toxicity F1: NOAEL: 1,000 mg/kg body weight
General Toxicity F2: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 416
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 120 mg/kg bw/day
Teratogenicity: NOAEL: 450 mg/kg bw/day
Method: OECD Test Guideline 414
Remarks: Based on available data, the classification criteria are not met.

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.

sodium etasulfate:

Effects on foetal development : Species: Rat
Application Route: Oral
Dose: 250 milligram per kilogram
Result: negative
Remarks: Did not show teratogenic effects in animal experiments.

Reproductive toxicity - Assessment : No data available

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.

subtilisin:

Reproductive toxicity - Assessment : No data available

propane-1,2-diol:

Reproductive toxicity - Assessment : Did not show carcinogenic or teratogenic effects in animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

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2-aminoethanol:

Assessment : May cause respiratory irritation.

sodium etasulfate:

Remarks : No data available

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Remarks : No data available

subtilisin:

Target Organs : Respiratory Tract
Assessment : May cause respiratory irritation.

propane-1,2-diol:

Assessment : Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

sodium p-cumenesulphonate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

2-aminoethanol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

sodium etasulfate:

Remarks : No data available

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Remarks : No data available

Repeated dose toxicity

Components:

sodium p-cumenesulphonate:

Species : Rat
NOAEL : 763 mg/kg
Application Route : Oral
Target Organs : Cardio-vascular system
Remarks : Subchronic toxicity

Species : Rat
NOAEL : 60 mg/kg

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Application Route : Dermal
Exposure time : 2 yr
Method : OECD Test Guideline 453
Target Organs : Skin

sodium etasulfate:

Species : Rabbit
NOAEL : 488 mg/kg
Application Route : Oral
Exposure time : 90-day

Species : Mouse
NOAEL : 400 mg/kg
Application Route : Skin contact
Exposure time : 90-day

Aspiration toxicity

Not classified based on available information.

Components:

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Due to the viscosity, this product does not present an aspiration hazard.

propane-1,2-diol:

No aspiration toxicity classification

Experience with human exposure

Components:

2-aminoethanol:

General Information : Repeated and prolonged exposure to solvents may cause
brain and nervous system damage.

Further information

Product:

Remarks : The product has not been tested.

SECTION 12: Ecological information

12.1 Toxicity

Components:

sodium p-cumenesulphonate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

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aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

2-aminoethanol:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: Tested according to Directive 92/69/EEC.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna): 65 mg/l
Exposure time: 48 h
Method: EG 84/449

Toxicity to algae/aquatic plants : EC50 (Scenedesmus capricornutum (fresh water algae)): 2.5 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : 1.2 mg/l
Exposure time: 30 d
Species: Oryzias latipes (Orange-red killifish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.85 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

sodium etasulfate:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 483 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 511 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC: >= 1,357 mg/l
Exposure time: 42 d
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.4 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Toxicity to fish : LC50 (Leuciscus idus): 1 - 10 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna): 0.1 - 1 mg/l

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aquatic invertebrates		Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (algae): 0.1 - 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0.1 - < 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
subtilisin:		
Toxicity to fish	:	LC50 (Fish): 8.2 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna): 0.586 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (algae): 0.83 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.017 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
M-Factor (Chronic aquatic toxicity)	:	1
propane-1,2-diol:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss): 40,613 mg/l Exposure time: 96 h Test Type: static test Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202

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-
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)):
19,000 mg/l
Exposure time: 96 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
- Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 13,020 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)
- glycerol:**
- Toxicity to fish : LC50 (Oncorhynchus mykiss): 54,000 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

12.2 Persistence and degradability

Product:

- Biodegradability : Result: Readily biodegradable, according to appropriate OECD test.
Method: OECD 301D / EEC 84/449 C6

Components:

sodium p-cumenesulphonate:

- Biodegradability : Test Type: aerobic
Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

2-aminoethanol:

- Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Result: Readily biodegradable.
Biodegradation: > 90 %
Exposure time: 21 d
Method: OECD Test Guideline 301A

sodium etasulfate:

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 89 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

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Biodegradability : Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

subtilisin:

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301B

propane-1,2-diol:

Biodegradability : Result: Readily biodegradable, according to appropriate
OECD test.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Result: Readily biodegradable, according to appropriate
OECD test.
Biodegradation: 96 %
Exposure time: 64 d
Method: OECD Test Guideline 306

12.3 Bioaccumulative potential

Components:

sodium p-cumenesulphonate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

2-aminoethanol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.91

sodium etasulfate:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.248

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Bioaccumulation : Remarks: Accumulation in aquatic organisms is unlikely.

subtilisin:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: < 0

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propane-1,2-diol:

Bioaccumulation : Bioconcentration factor (BCF): 0.09
Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.07

glycerol:

Partition coefficient: n-octanol/water : log Pow: -1.75 (25 °C)
Method: OECD Test Guideline 107

12.4 Mobility in soil

Components:

sodium p-cumenesulphonate:

Mobility : Remarks: Not expected to adsorb on soil.

2-aminoethanol:

Mobility : Remarks: Not expected to adsorb on soil.

sodium etasulfate:

Mobility : Remarks: No data available

Alcohols, C12-15-branched and linear, ethoxylated propoxylated:

Mobility : Remarks: Substance does not evaporate from water surface into the atmosphere., Adsorption to solid soil phase is possible.

subtilisin:

Mobility : Remarks: No data available

propane-1,2-diol:

Mobility : Medium: Soil
Remarks: Mobile in soils

Distribution among environmental compartments : Koc: < 1

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Components:

propane-1,2-diol:

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).. This substance is not considered to be very persistent and very bioaccumulating (vPvB).

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Disposal together with normal waste is not allowed. Special disposal required according to local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

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14.4 Packing group

- ADR** : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

- UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3
- UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable
- The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable
- Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 3.7 %
- according to Detergents Regulation EC 648/2004 : 5 % or over but less than 15 %: Anionic surfactants
less than 5 %: Non-ionic surfactants, Polycarboxylates
Other constituents: Enzymes

The components of this product are reported in the following inventories:

- TCSI** : Not in compliance with the inventory
- TSCA** : Product contains substance(s) not listed on TSCA inventory.
- AIIC** : Not in compliance with the inventory
- DSL** : This product contains the following components that are not

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on the Canadian DSL nor NDSL.

sodium p-cumenesulphonate
Reaction mass of (2S)-Alanine, N,N-bis(carboxymethyl)-,
trisodium salt and (2R)-Alanine, N,N-bis(carboxymethyl)-,
trisodium salt
Sodium polyacrylate
Alcohols, C12-15-branched and linear, ethoxylated propox-
ylated

ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	:	May cause respiratory irritation.
H400	:	Very toxic to aquatic life.
H411	:	Toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Resp. Sens.	:	Respiratory sensitisation
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation

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STOT SE	:	Specific target organ toxicity - single exposure
2006/15/EC	:	Europe. Indicative occupational exposure limit values
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
2006/15/EC / TWA	:	Limit Value - eight hours
2006/15/EC / STEL	:	Short term exposure limit
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Skin Irrit. 2 H315
Eye Irrit. 2 H319

Classification procedure:

Calculation method
Calculation method

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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