

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 12-2-2014 Revision date: 26-7-2023 Supersedes: 1-11-2022 Version: 3.0

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

1.1. Product identifier

Product form	
Product name	
Product code	
Product group	

:	Mixture
:	Eurol Sportbike 5W-40
	E100102

: E100102 : Trade product

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

1.2.1. Relevant identified uses

Intended for general public Main use category Use of the substance/mixture Function or use category

- : Industrial use,professional use,Consumer use
- : Lubricant
- : Lubricants and additives

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Eurol B.V. Energiestraat 12 NL-7442 DA Nijverdal The Netherlands Tel: +31 548 615 165 reach@eurol.com - www.eurol.com

1.4. Emergency telephone number

Emergency number

: For Transport Emergency Call +31 6 26 71 27 43 (24hr/day 7days/week)

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH	0344 892 0111	Only for healthcare professionals
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

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2.2. Label elements		
Labelling according to Regulation (EC) No. 1272/2008 [CLP]		
Precautionary statements (CLP)	: P102 - Keep out of reach of children.	
EUH-statements Child-resistant fastening	: EUH210 - Safety data sheet available on request. : Not applicable	
Tactile warning	: Not applicable	
2.3. Other hazards		
Other hazards not contributing to the classification	This product floats on water and may affect the oxygen-balance in the water. The base oil contains less than 3% DMSO-extract measured according IP 346, therefore it is NOT classified as H350: May cause cancer" (Note L).". USED ENGINE OILS: Combustion products resulting from the operation of internal combustion engines contaminate engine	

classified as H350: May cause cancer" (Note L).". USED ENGINE OILS: Combustion products resulting from the operation of internal combustion engines contaminate engine oils during use. Used engine oil may contain hazardous components which have the potential to cause skin cancer. Frequent or prolonged contact with all types and makes of used engine oil must therefore be avoided and a high standard of personal hygiene maintained.

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched (121158-58- 5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Component	
phenol, dodecyl-, branched; phenol, 2-dodecyl-,	The substance is included in the list established in accordance with Article 59(1) of
	disrupting properties in accordance with the criteria set out in Commission Delegated
	Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Distillates (petroleum), hydrotreated heavy paraffinic; Baseoil— unspecified; [A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.]	CAS-No.: 64742-54-7 EC-No.: 265-157-1 EC Index-No.: 649-467-00-8 REACH-no: 01-2119484627- 25	≥ 50	Asp. Tox. 1, H304
Highly refined mineral oil (C15 -C50) substance with a Community workplace exposure limit	REACH-no: 01-2119484627- 25; 01-2119487077-29: 01- 2119471299-27	10 – 25	Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched substance listed as REACH Candidate (Phenol, alkylation products (mainly in para position) with C12- rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)) substance identified as having endocrine disrupting properties	CAS-No.: 121158-58-5 EC-No.: 310-154-3 EC Index-No.: 604-092-00-9 REACH-no: 01-2119513207- 49	0,1 – 1	Repr. 1B, H360F Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures		
4.1. Description of first aid measures		
First-aid measures general First-aid measures after inhalation First-aid measures after skin contact First-aid measures after eye contact First-aid measures after ingestion	 Seek medical attention if ill effect develops. Remove person to fresh air and keep comfortable for breathing. Wash skin with plenty of water. Rinse eyes with water as a precaution. Call a poison center or a doctor if you feel unwell. 	
4.2. Most important symptoms and effects,	both acute and delayed	
Symptoms/effects after inhalation	: At normal ambient temperatures this product will be unlikely to present an inhalation hazard because of its low volatility. May be harmful by inhalation if exposure to vapour, mists or fumes resulting from thermal decomposition products occurs.	
Symptoms/effects after skin contact	: Unlikely to cause harm to the skin on brief or occasional contact but prolonged or repeated exposure may lead to dermatitis. High pressure injection of product into the skin may lead to local necrosis if the product is not surgically removed.	
Symptoms/effects after eye contact	: Unlikely to cause more than transient stinging or redness if accidental eye contact occurs.	
Symptoms/effects after ingestion	: Bad taste. Unlikely to cause harm if accidentally swallowed in small doses, though larger quantities may cause nausea and diarrhoea.	
Symptoms/effects upon intravenous administration	: Unknown.	
4.3. Indication of any immediate medical at	ention and special treatment needed	

Treat symptomatically.

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media Unsuitable extinguishing media	 Water spray. Dry powder. Foam. Carbon dioxide. Do not use a heavy water stream. Use of heavy stream of water may spread fire.
5.2. Special hazards arising from the subst	ance or mixture
Fire hazard Explosion hazard Hazardous decomposition products in case of fire	 Combustion generates: CO, CO2, POx, NOx, SOx, H2S. Metallic oxides. Not expected to be a fire/explosion hazard under normal conditions of use. Toxic fumes may be released.
5.3. Advice for firefighters	
Precautionary measures fire Firefighting instructions Protection during firefighting	 Do not enter fire area without proper protective equipment, including respiratory protection. Use water spray or fog for cooling exposed containers. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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Other information	: Prevent fire fighting water from entering the environment. Sweep up and remove to a suitable, clearly marked container for disposal in accordance with local regulations.	
SECTION 6: Accidental releas	se measures	
6.1. Personal precautions, protect	ctive equipment and emergency procedures	
General measures	: Spill area may be slippery. Prevent soil and water pollution. Prevent entry to sewers and public waters.	
6.1.1. For non-emergency personnel		
Protective equipment	When the risk of skin exposure is high (e.g. when cleaning up spillages or if there is a risk of splashing) then chemical resistant aprons and/or impervious chemical suits and boots will be required. Use protective clothing.	
Emergency procedures	: Ventilate spillage area.	
6.1.2. For emergency responders		
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".	
Emergency procedures	: No specific measures are necessary.	
6.2. Environmental precautions		
Avoid release to the environment.		
6.3. Methods and material for co	ntainment and cleaning up	
For containment Methods for cleaning up	Large quantities: Contain large spillage with sand or earth.Take up liquid spill into absorbent material.	

: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Other information

For further information refer to section 13.

SECTION 7: Handling and storage		
7.1. Precautions for safe handling		
Additional hazards when processed	: Empty containers retain product residue (solid, liquid, and/or vapor) and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, static electricity, or other sources of ignition. They may explode and cause injury or death. Empty containers should be completely drained, properly closed, and promptly returned to a drum reconditioner or disposed of properly.	
Precautions for safe handling Hygiene measures	 Ensure good ventilation of the work station. Wear personal protective equipment. Do no eat, drink or smoke when using this product. Always wash hands after handling the product. 	
7.2. Conditions for safe storage, includin	g any incompatibilities	
Technical measures Storage conditions Incompatible products Maximum storage period Storage temperature Information on mixed storage Storage area Special rules on packaging	 Keep container tightly closed and in well ventilated place. Store in a well-ventilated place. Keep cool. Reacts vigorously with strong oxidizers and acids. 5 year ≤ 40 °C Keep away from : Oxidizing materials. Strong acids. Store at ambient temperature. Keep container tightly closed and dry. 	
7.3. Specific end use(s)		

No additional information available

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SECTION 8: Exposure controls/personal protection		
8.1. Control parameters		
8.1.1 National occupational exposure and biological limit values		
Highly refined mineral oil (C15 -C50)		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOELV TWA (mg/m ³)	5 mg/m³	
8.1.2. Recommended monitoring procedures		
No additional information available		
8.1.3. Air contaminants formed		
No additional information available		
8.1.4. DNEL and PNEC		
Exposure-value for oil mist	: 10 mg/m3 (15 min.) or 5 mg/m3 (8 hours).	
8.1.5. Control banding		

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. In case of splash hazard: safety glasses. Eye protection should only be necessary where liquid could be splashed or sprayed. **Personal protective equipment symbol(s):**



8.2.2.1. Eye and face protection

Eye protection: Safety glasses

8.2.2.2. Skin protection

Skin and body protection: Wear suitable protective clothing

Hand protection: Protective gloves

Other skin protection Materials for protective clothing: PVC gloves. Neoprene or nitrile rubber gloves

8.2.2.3. Respiratory protection

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.2.4. Thermal hazards

No additional information available

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8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Consumer exposure controls:

PVC gloves. Neoprene or nitrile rubber gloves.

Other information:

Do not put the product-soaked rags into the pockets of working clothes. Do not use cloths stained with the product to dry hands. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use. Wash contaminated clothing before reuse.

SECTION 9: Phy	sical and chemi	cal properties

9.1. Information on	basic physical an	nd chemical properties

Physical state	: Liquid
Colour	: brown.
Appearance	: Oily. Liquid.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: -45 °C ASTM D 97
Freezing point	: Not available
Boiling point	: > 280 °C
Flammability (solid, gas)	: Non flammable.
Explosive limits	: 0,6 – 7 vol %
Lower explosive limit (LEL)	: 0,6 vol %
Upper explosive limit (UEL)	: 7 vol %
Flash point	: 201 °C ASTM D 93
Auto-ignition temperature	: >240 °C
Decomposition temperature	: Not available
рН	: Not available
Viscosity, kinematic	: 50 – 150 mm²/s at 40 °C, ASTM D 445
Solubility	: insoluble in water.
Log Kow	: Not available
Log Pow	: > 3
Vapour Pressure 20°C	: < 0,1 hPa
Vapour pressure at 50°C	: Not available
Density	: 0,845 – 0,855 kg/l ASTM D 4052
Relative density	: Not available
Relative vapour density at 20°C	: > 1 (air=1)
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes		
Explosion limits	: 0,6 – 7 vol %	
9.2.2. Other safety characteristics		
Relative evaporation rate (butylacetate=1)	: < 0,1	
VOC content	: 0 %	
Other properties	: Gas/vapour heavier than air at 20°C	

SECTION 10: Stability and reactivity			
10 1	Reactivity		

Stable under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions.

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0.3. Possibility of hazardous reactions	
efer to section 10.1 on Reactivity.	
0.4. Conditions to avoid	
oisture. Overheating.	
0.5. Incompatible materials	
rong oxidizing agents. Strong acids.	
0.6. Hazardous decomposition products	
CO, CO2, POx, NOx, SOx, H2S. Metallic oxides.	

SECTION 11: Toxicological information		
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008		
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	 Not classified Not classified Not classified 	
Distillates (petroleum), hydrotreated heavy paraffinic; Baseoil— unspecified; [A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.] (64742-54-7)		
LD50 oral rat	> 5000 mg/kg	
LD50 dermal rat	> 2000 mg/kg	
LC50 Inhalation - Rat	> 5,53 mg/l	
phenol, dodecyl-, branched; phenol, 2-dode	ecyl-, branched; phenol, 3-dodecyl-, branched (121158-58-5)	
LD50 oral rat	2100 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 1620 - 2730	
LD50 dermal rabbit	 ≈ 15000 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 402 (Acute Dermal Toxicity) 	
Skin corrosion/irritation	: Not classified	
Serious eye damage/irritation	: Not classified	
Respiratory or skin sensitisation	: Not classified	
Germ cell mutagenicity	: Not classified	
Carcinogenicity	: Not classified	
Reproductive toxicity	: Not classified	
STOT-single exposure	: Not classified	
STOT-repeated exposure	: Not classified	
Aspiration hazard	: Not classified	
Eurol Sportbike 5W-40		
Viscosity, kinematic	50 – 150 mm²/s at 40 °C, ASTM D 445	
phenol, dodecyl-, branched; phenol, 2-dode	ecyl-, branched; phenol, 3-dodecyl-, branched (121158-58-5)	
Viscosity, kinematic	450 mm²/s	

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11.2. Information on other hazards	
11.2.1. Endocrine disrupting properties	
Component	
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched(121158-58-5)	The substance is identified for having endocrine disrupting properties but there is no additional data available
11.2.2. Other information	
Other information :	Toxicological data have not been determined specifically for this product. Information given is based on a knowledge of the components and the toxicology of similar products,Likely route of exposure: ingestion, skin and eye.

SECTION 12	Ecological information

12.1. Toxicity		
Ecology - general : Ecology - water : Hazardous to the aquatic environment, short–term : (acute) Hazardous to the aquatic environment, long–term : (chronic)	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. This product floats on water and may affect the oxygen-balance in the water. Not classified Not classified	
Distillates (petroleum), hydrotreated heavy paraffinic; Baseoil— unspecified; [A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.] (64742-54-7)		
LC50 fish 1	100 mg/l	
EC50 Daphnia 1	10000 mg/l	
EC50 72h - Algae [1]	> 100 mg/l	
Highly refined mineral oil (C15 -C50)		
EC50 other aquatic organisms 1	1,2 mg/l	
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched (121158-58-5)		
EC50 Daphnia 1	0,037 mg/l Test organisms (species): Daphnia magna	
EC50 72h - Algae [1]	0,15 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)	
EC50 72h - Algae [2]	0,36 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)	
LOEC (chronic)	0,012 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	

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Persistence and degradability	Not readily biodegradable.
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched (121158-58-5)	
Persistence and degradability	Not readily biodegradable in water.

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12.3. Bioaccumulative potential			
Eurol Sportbike 5W-40			
Log Pow	> 3		
Bioaccumulative potential	This product is not expected to bioaccumulate through food chains in the environment.		
phenol, dodecyl-, branched; phenol, 2-dodecy	/l-, branched; phenol, 3-dodecyl-, branched (121158-58-5)		
BCF fish 1	749 – 823		
Bioconcentration factor (BCF REACH)	794,33		
Log Pow	7,14		
Log Kow	7,14		
12.4. Mobility in soil			
Eurol Sportbike 5W-40			
Ecology - soil	Not miscible with water. Spillages may penetrate the soil causing ground water contamination. This product floats on water and may affect the oxygen-balance in the water.		
phenol, dodecyl-, branched; phenol, 2-dodecy	/l-, branched; phenol, 3-dodecyl-, branched (121158-58-5)		
Surface tension 42,2 mN/m			
Log Koc	4,4 – 4,67		
12.5. Results of PBT and vPvB assessment			
Component			
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched (121158-58- 5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII		
12.6. Endocrine disrupting properties			
Component			
phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched(121158-58-5)	The substance is identified for having endocrine disrupting properties but there is no additional data available		
12.7. Other adverse effects			
No additional information available			
SECTION 13: Disposal considerations			

13.1. Waste treatment methods

Regional legislation (waste) Product/Packaging disposal recommendations	 Disposal must be done according to official regulations. Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Do not discharge into drains or the environment.
Additional information	: Hazardous waste.
Ecology - waste materials	: Every mixture with foreign substances such as solvents, brake- and cooling liquids is forbidden. Empty containers retain product residue (solid, liquid, and/or vapor) and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, static electricity, or other sources of ignition. They may explode and cause injury or death. Empty containers should be completely drained, properly closed, and promptly returned to a drum reconditioner or disposed of properly. When not empty dispose of this container at hazardous or special waste collection point.

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European List of Waste (LoW) code

: 13 02 06* - Synthetic engine, gear and lubricating oils

ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number or ID I	number			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shippir	ng name		-	
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard	class(es)		<u>.</u>	
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			·	
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental ha	zards		-	
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)			
Reference code	Applicable on		
3(b)	Distillates (petroleum), hydrotreated heavy paraffinic; Baseoil— unspecified; [A complex combination of hydrocarbon obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.]; phenol, dodecyl branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched		
3(c)	phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched		
30.	phenol, dodecyl-, branched; phenol, 2-dodecyl-, branched; phenol, 3-dodecyl-, branched		

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains substance(s) listed on the REACH Candidate List in concentrations ≥ 0.1 % or SCL: Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP) (EC 310-154-3, CAS 121158-58-5)

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content

: 0 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

A chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section Changed item Change Comments			
	Supersedes	Modified	
Revision date		Modified	
	Flammability (solid, gas)	Added	

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Indication of changes			
Section	Changed item	Change	Comments
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	
2.1	Adverse physicochemical, human health and environmental effects	Added	
2.3	Other hazards not contributing to the classification	Modified	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after inhalation	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
5.1	Suitable extinguishing media	Modified	
5.2	Hazardous decomposition products in case of fire	Added	
5.3	Protection during firefighting	Modified	
6.1	Protective equipment	Modified	
6.1	Emergency procedures	Modified	
6.2	Environmental precautions	Modified	
6.3	Methods for cleaning up	Modified	
6.3	Other information	Modified	
7.1	Precautions for safe handling	Modified	
7.1	Hygiene measures	Modified	
7.2	Storage conditions	Modified	
8.2	Environmental exposure controls	Modified	
8.2	Respiratory protection	Modified	
8.2	Hand protection	Modified	
8.2	Eye protection	Modified	
8.2	Appropriate engineering controls	Modified	
8.2	Skin and body protection	Modified	
9.1	Upper explosive limit (UEL)	Added	
9.1	Lower explosive limit (LEL)	Added	
9.1	Flash point	Modified	
9.1	Density	Modified	
9.1	Viscosity, kinematic	Modified	
9.1	Melting point	Modified	
12.1	Ecology - general	Modified	
13.1	Product/Packaging disposal Added recommendations		
15.2	Chemical safety assessment	Added	
16	Abbreviations and acronyms	Added	
16 Data sources Added		Added	

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Indication of changes				
Section Changed item Change Comments				
16		Other information	Added	

Abbreviations a	and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways		
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road		
ATE	Acute Toxicity Estimate		
BCF	Bioconcentration factor		
BLV	Biological limit value		
BOD	Biochemical oxygen demand (BOD)		
COD	Chemical oxygen demand (COD)		
DMEL	Derived Minimal Effect level		
DNEL	Derived-No Effect Level		
EC-No.	European Community number		
EC50	Median effective concentration		
EN	European Standard		
IARC	International Agency for Research on Cancer		
IATA	International Air Transport Association		
IMDG	International Maritime Dangerous Goods		
LC50	Median lethal concentration		
LD50	Median lethal dose		
LOAEL	Lowest Observed Adverse Effect Level		
NOAEC	No-Observed Adverse Effect Concentration		
NOAEL	No-Observed Adverse Effect Level		
NOEC	No-Observed Effect Concentration		
OECD	Organisation for Economic Co-operation and Development		
OEL	Occupational Exposure Limit		
PBT	Persistent Bioaccumulative Toxic		
PNEC	Predicted No-Effect Concentration		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail		
SDS	Safety Data Sheet		
STP	Sewage treatment plant		
ThOD	Theoretical oxygen demand (ThOD)		
TLM	Median Tolerance Limit		
VOC	Volatile Organic Compounds		
CAS-No.	Chemical Abstract Service number		
N.O.S.	Not Otherwise Specified		
vPvB	Very Persistent and Very Bioaccumulative		
ED	Endocrine disrupting properties		

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Data sources		REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE
		COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and
		amending Regulation (EC) No 1907/2006.
Other information	:	None.

Full text of H- and EUH-statements:		
Aquatic Acute 1	lazardous to the aquatic environment – Acute Hazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
Asp. Tox. 1	Aspiration hazard, Category 1	
EUH210	Safety data sheet available on request.	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
H304	<i>I</i> ay be fatal if swallowed and enters airways.	
H314	Causes severe skin burns and eye damage.	
H318	Causes serious eye damage.	
H360F	May damage fertility.	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	
Repr. 1B	Reproductive toxicity, Category 1B	
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C	

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.