Endo Star Neu

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)
Issue date: 18/05/2021 Revision date: 18/05/2021 Version: 3.00

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

1.1. Product identifier

Trade name : Endo Star Neu
UFI : V5C0-Y0H0-7009-TPM7

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

1.2.1. Relevant identified uses

Main use category : Professional uses
Use of the substance/mixture : Medical device (IIb)

1.2.2. Uses advised against

Restrictions on use : no spraying

1.3. Details of the supplier of the safety data sheet

Supplier
Laboratorium Dr. Deppe GmbH
Hooghe Weg 35
D-47906 Kempen
T +49 21 52 55 65 0 - F +49 21 52 50 84 9
sdb@dr-deppe.de - www.dr-deppe.de

Email competent person
sdb@dr-deppe.de

Distributor

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 1, Sub-Category 1C	H314
Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity — Repeated exposure, Category 2	H373
Hazardous to the aquatic environment — Acute Hazard, Category 1	H400
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

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

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure. Causes serious eye damage. Causes severe skin burns and eye damage. Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS05 GHS08 GHS09

Signal word (CLP) : Danger

Contains	:	Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates; Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt; Amines, N-C12-14-alkyltrimethylenedi-; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
Hazard statements (CLP)	:	H314 - Causes severe skin burns and eye damage. H373 - May cause damage to organs through prolonged or repeated exposure. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	:	P260 - Do not breathe mist, vapours, spray. P273 - Avoid release to the environment. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER, a doctor. P391 - Collect spillage.
EUH-statements	:	EUH208 - Contains POLYAMINOPROPYL BIGUANIDE. May produce an allergic reaction.

2.3. Other hazards

PBT: not relevant – no registration required
vPvB: not relevant – no registration required

Component	
Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	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
Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	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
propan-2-ol (67-63-0)	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
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	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
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	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
polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	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

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]
Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates	(CAS-No.) 1474044-65-9 (REACH-no) 01-2119977130-42-xxxx	≥ 2.5 – < 5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Amines, N-C12-14-alkyltrimethylenedi-	(CAS-No.) 90640-43-0 (EC-No.) 292-562-0 (REACH-no) 01-2119957843-25-xxxx	≥ 2.5 – < 5	Acute Tox. 3 (Oral), H301 (ATE=200 mg/kg bodyweight) Skin Corr. 1B, H314 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410
propan-2-ol substance with national workplace exposure limit(s) (GB)	(CAS-No.) 67-63-0 (EC-No.) 200-661-7 (EC Index-No.) 603-117-00-0 (REACH-no) 01-2119457558-25-xxxx	≥ 2.5 – < 5	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	(REACH-no) 01-2119980967-14-xxxx	≥ 1 – < 2.5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Corr. 1C, H314 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	(CAS-No.) 2372-82-9 (EC-No.) 219-145-8 (REACH-no) 01-2119980592-29-xxxx	≥ 1 – < 2.5	Acute Tox. 3 (Oral), H301 (ATE=261 mg/kg bodyweight) Skin Corr. 1B, H314 STOT RE 2, H373 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
polyhexamethylene biguanide hydrochloride; PHMB	(CAS-No.) 27083-27-8 (EC-No.) 608-042-7 (EC Index-No.) 616-207-00-X	≥ 0.25 – < 1	Carc. 2, H351 Acute Tox. 2 (Inhalation), H330 (ATE=0.05 mg/l/4h) Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) STOT RE 1, H372 Eye Dam. 1, H318 Skin Sens. 1B, H317 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 : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing. Call a physician immediately.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : Burns. May cause an allergic skin reaction.
Symptoms/effects after eye contact : Serious damage to eyes.
Symptoms/effects after ingestion : Burns.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Hydrogen chloride. Nitrogen oxides.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Do not breathe mist, vapours, spray. Avoid contact with skin and eyes.

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".

6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information : Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe mist, vapours, spray. Avoid contact with skin and eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Store locked up.
Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

propan-2-ol (67-63-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Propan-2-ol
WEL TWA (OEL TWA) [1]	999 mg/m³
WEL TWA (OEL TWA) [2]	400 ppm
WEL STEL (OEL STEL)	1250 mg/m³
WEL STEL (OEL STEL) [ppm]	500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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

Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	4.7 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	3.32 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	2.83 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.98 mg/m³
Long-term - systemic effects, dermal	2.83 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.00068 mg/l
PNEC aqua (marine water)	0.000068 mg/l
PNEC aqua (intermittent, freshwater)	0.00036 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	9.27 mg/kg dwt
PNEC sediment (marine water)	0.927 mg/kg dwt

PNEC (Soil)	
PNEC soil	7 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.9 mg/l

propan-2-ol (67-63-0)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	888 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	500 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	26 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	89 mg/m³
Long-term - systemic effects, dermal	319 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	140.9 mg/l
PNEC aqua (marine water)	140.9 mg/l
PNEC aqua (intermittent, freshwater)	140.9 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	552 mg/kg dwt
PNEC sediment (marine water)	552 mg/kg dwt
PNEC (Soil)	
PNEC soil	28 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	160 mg/kg
PNEC (STP)	
PNEC sewage treatment plant	2251 mg/l

Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	
PNEC (Water)	
PNEC aqua (freshwater)	0.0004 mg/l
PNEC aqua (marine water)	0.00004 mg/l
PNEC aqua (intermittent, freshwater)	0.0002 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	10 mg/kg dwt
PNEC sediment (marine water)	1 mg/kg dwt
PNEC (Soil)	
PNEC soil	3.7 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	1 mg/l

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	5.6 µg/kg bodyweight/day
Long-term - systemic effects, inhalation	39.5 µg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	2 µg/kg bodyweight/day
Long-term - systemic effects, inhalation	6.96 µg/m³
Long-term - systemic effects, dermal	2 µg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.0032 mg/l
PNEC aqua (marine water)	0.00032 mg/l
PNEC aqua (intermittent, marine water)	0.00065 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1.72 mg/kg dwt
PNEC sediment (marine water)	0.172 mg/kg dwt
PNEC (Soil)	
PNEC soil	10 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.0089 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	0.205 mg/l

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	8.96 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.789 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	0.04 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.118 mg/m³
Long-term - systemic effects, dermal	3.2 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.001 mg/l
PNEC aqua (marine water)	0.0001 mg/l
PNEC aqua (intermittent, freshwater)	0.00015 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3.2 mg/kg dwt
PNEC sediment (marine water)	0.13 mg/kg dwt
PNEC (Soil)	
PNEC soil	45.34 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.18 mg/l

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. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:
Wear closed safety glasses. EN 166. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing. EN ISO 13688. EN 13034

Hand protection:
Chemically resistant protective gloves. Nitrile rubber. EN 374. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. A-P2. Breathing apparatus with filter. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	colourless.
Appearance	:	clear.
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	≈ 100 °C
Flammability	:	Not applicable
Explosive properties	:	Product is not explosive.
Oxidising properties	:	Non oxidizing.
Explosive limits	:	Not available

Lower explosive limit (LEL)	:	2 vol %
Upper explosive limit (UEL)	:	12 vol %
Flash point	:	> 62 °C
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	9.2 – 9.6
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	48 hPa (20 °C)
Vapour pressure at 50 °C	:	Not available
Density	:	0.988 – 1 g/ml
Relative density	:	Not available
Relative vapour density at 20 °C	:	Not available
Particle size	:	Not applicable
Particle size distribution	:	Not applicable
Particle shape	:	Not applicable
Particle aspect ratio	:	Not applicable
Particle aggregation state	:	Not applicable
Particle agglomeration state	:	Not applicable
Particle specific surface area	:	Not applicable
Particle dustiness	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	:	Not classified (Based on available data, the classification criteria are not met)

Endo Star Neu	
ATE CLP (oral)	> 2000 mg/kg bodyweight
ATE CLP (dermal)	> 2000 mg/kg bodyweight
ATE CLP (dust,mist)	5.001 mg/l/4h

Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	
LD50 oral rat	≈ 570 mg/kg bodyweight (OECD 401 method)
LD50 dermal rabbit	≈ 429 mg/kg bodyweight (OECD 402 method)

Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	
LD50 oral rat	500 – 2000 mg/kg bodyweight (OECD 401 method)

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
LD50 oral rat	200 mg/kg bodyweight (OECD 423 method)

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
LC50 Inhalation - Rat (Dust/Mist)	0.37 mg/l/4h

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
LD50 oral rat	261 mg/kg (OECD 401 method)
LD50 dermal rat	> 2000 mg/kg

Skin corrosion/irritation : Causes severe skin burns.
pH: 9.2 – 9.6

Serious eye damage/irritation : Causes serious eye damage.
pH: 9.2 – 9.6

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)

Additional information : May cause sensitisation of susceptible persons

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
NOAEL (chronic, oral, animal/male, 2 years)	36 mg/kg bodyweight/day (rat)
NOAEL (chronic, oral, animal/female, 2 years)	45 mg/kg bodyweight/day (rat)

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

propan-2-ol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
STOT-repeated exposure	Causes damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation).

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
STOT-repeated exposure	May cause damage to organs (kidneys) through prolonged or repeated exposure.

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	
LC50 - Fish [1]	13.8 mg/l (96 h; Danio rerio; (OECD 203 method))
EC50 - Crustacea [1]	0.036 mg/l (48 h; Daphnia magna; (OECD 202 method))
ErC50 algae	0.14 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
NOEC chronic fish	0.0322 mg/l (28 d; Pimephales promelas; Read-across; U.S. EPA FIFRA 72-4(a))
NOEC chronic crustacea	0.0068 mg/l (21 d; Daphnia magna; Read-across; (OECD 211 method))
NOEC chronic algae	0.008 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))

propan-2-ol (67-63-0)	
NOEC chronic algae	1800 mg/l (7d; Scenedesmus quadricauda)

Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	
LC50 - Fish [1]	0.707 mg/l (96 h; Danio rerio; (OECD 203 method))
EC50 - Crustacea [1]	0.0583 mg/l (48 h; Daphnia magna; (OECD 202 method))
ErC50 algae	0.0187 mg/l (72 h; Desmodesmus subspicatus; (OECD 201 method))
NOEC chronic fish	0.125 mg/l (9 d; Danio rerio; (OECD 212 method))
NOEC chronic crustacea	0.025 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.003 mg/l (EC10; 72 h; Desmodesmus subspicatus; (OECD 201 method))

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
LC50 - Fish [1]	0.148 mg/l (96 h; Danio rerio; Read-across; (OECD 203 method))
ErC50 algae	0.0652 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
NOEC chronic crustacea	0.032 mg/l (21 d; Daphnia magna; (OECD 211 method)
NOEC chronic algae	0.0406 mg/l (EC10: 72 h; Pseudokirchneriella subcapitata; (OECD 201 method))

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
LC50 - Fish [1]	0.026 mg/l (96 h; Oncorhynchus mykiss)
EC50 - Crustacea [1]	0.09 mg/l (48 h; Daphnia magna; (OECD 202 method))
ErC50 algae	0.015 mg/l (72 h; Selenastrum capricornutum)
NOEC chronic crustacea	0.0084 mg/l (21 d; Daphnia magna)
NOEC chronic algae	0.00743 mg/l (Selenastrum capricornutum)

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
LC50 - Fish [1]	0.431 mg/l (96 h; Danio rerio; (OECD 203 method))
EC50 - Crustacea [1]	0.078 mg/l (48h; Daphnia magna; (OECD 202 method))
ErC50 algae	0.015 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
NOEC chronic crustacea	0.024 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.009 mg/l (72 h; Desmodesmus subspicatus; (OECD 201 method))

12.2. Persistence and degradability

Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	
Persistence and degradability	Readily biodegradable.
Biodegradation	67.77 % (28 d; (OECD 310 method))

propan-2-ol (67-63-0)	
Persistence and degradability	Readily biodegradable.
Biodegradation	53 % (5 d)

Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	
Persistence and degradability	Readily biodegradable.

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
Persistence and degradability	Readily biodegradable.
Biodegradation	66 % (28 d; Read-across; (OECD 301D method))

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
Persistence and degradability	Not readily biodegradable.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
Persistence and degradability	Readily biodegradable.
Biodegradation	79 % (28 d; (OECD 301D method))

12.3. Bioaccumulative potential

Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	
Partition coefficient n-octanol/water (Log Pow)	3.26 Calculation method
Bioaccumulative potential	Bioaccumulation unlikely.

propan-2-ol (67-63-0)	
Partition coefficient n-octanol/water (Log Pow)	0.05 (25 °C)
Bioaccumulative potential	Bioaccumulation unlikely.

Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	
Partition coefficient n-octanol/water (Log Pow)	3.6 (20 °C; pH 6,1; Test method EU A.8; Calculation method)

Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	
Partition coefficient n-octanol/water (Log Pow)	-0.61 (24,7 °C, pH 6,8; (OECD 123 method))

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
Partition coefficient n-octanol/water (Log Kow)	-2.29
Bioaccumulative potential	Bioaccumulation unlikely.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	
Partition coefficient n-octanol/water (Log Pow)	0.34 (20 °C; Quantitative structure-activity relationship (QSAR))

12.4. Mobility in soil

propan-2-ol (67-63-0)	
Ecology - soil	Expected to be highly mobile in soil.

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
Ecology - soil	Adsorbs into the soil.

12.5. Results of PBT and vPvB assessment

Endo Star Neu
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

Component	
Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates (1474044-65-9)	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
Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0)	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
propan-2-ol (67-63-0)	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
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	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
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9)	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

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	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

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

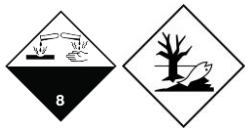
Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

HP Code : HP4 - “Irritant — skin irritation and eye damage:” waste which on application can cause skin irritation or damage to the eye.
HP5 - “Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:” waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration.
HP8 - “Corrosive:” waste which on application can cause skin corrosion.
HP14 - “Ecotoxic:” waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

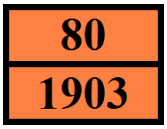
ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1903	UN 1903	UN 1903	UN 1903	UN 1903
14.2. UN proper shipping name				
DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-)	Disinfectant, liquid, corrosive, n.o.s. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-)
Transport document description				
UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-), 8, III, (E), ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-), 8, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 1903 Disinfectant, liquid, corrosive, n.o.s. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-), 8, III, ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-), 8, III, ENVIRONMENTALLY HAZARDOUS	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Quaternary ammonium compounds, C12-14 (even-numbered)-alkylethyldimethyl, ethyl sulphates ; Amines, N-C12-14-alkyltrimethylenedi-), 8, III, ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)				
8	8	8	8	8

				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : C9
Special provisions (ADR) : 274
Limited quantities (ADR) : 5l
Excepted quantities (ADR) : E1
Transport category (ADR) : 3
Hazard identification number (Kemler No.) : 80
Orange plates :



Tunnel restriction code (ADR) : E
EAC code : 2X
APP code : B

Transport by sea

Special provisions (IMDG) : 223, 274
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-B

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y841
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 852
PCA max net quantity (IATA) : 5L
CAO max net quantity (IATA) : 60L
Special provisions (IATA) : A3, A803

Inland waterway transport

Classification code (ADN) : C9
Special provisions (ADN) : 274
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1
Additional requirements/Remarks (ADN) :

Rail transport

Classification code (RID) : C9
Special provisions (RID) : 274
Limited quantities (RID) : 5L
Excepted quantities (RID) : E1
Transport category (RID) : 3
Hazard identification number (RID) : 80

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:	
Reference code	Applicable on
3(a)	propan-2-ol
3(b)	Endo Star Neu ; propan-2-ol ; Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt ; Amines, N-C12-14-alkyltrimethylenedi- ; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
3(c)	Endo Star Neu ; Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt ; Amines, N-C12-14-alkyltrimethylenedi- ; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
40.	propan-2-ol

Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Other information, restriction and prohibition regulations : Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Take note of Directive 94/33/EC on the protection of young people at work.

Directive 2012/18/EU (SEVESO III)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1	100	200

15.1.2. National regulations

United Kingdom
National regulations : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:			
Section	Changed item	Change	Comments
1.4	Emergency number	Modified	

Abbreviations 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
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
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
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : MSDSs of the suppliers. ECHA (European Chemicals Agency). Information provided by the manufacturer.

Department issuing data specification sheet : KFT Chemieservice GmbH
Im Leuschnerpark 3
D-64347 Griesheim

Phone: +49 6155-8981-400
Fax: +49 6155 8981-500
SDS Service: +49 6155 8981-522

Contact person : Barbara Stark

Other information : Version/s 1.00 is/are not available in this language.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Carc. 2	Carcinogenicity, Category 2

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Sens. 1B	Skin sensitisation, category 1B
STOT RE 1	Specific target organ toxicity — Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH208	Contains POLYAMINOPROPYL BIGUANIDE. May produce an allergic reaction.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Corr. 1C	H314	Calculation method
Eye Dam. 1	H318	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 2	H411	Calculation method

KFT SDS EU 01

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.