

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 9/22/2023 Revision date: 9/22/2023 Supersedes: 12/16/2022 Version: 2.2
SDS No: 00056-0161

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

1.1. Product identifier

Product form : Mixture
Product name : Helipur H plus N
UFI : KS4V-47MQ-G00Y-A7CS

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Instrument disinfectant
Disinfection and cleaning of surgical instruments, flexible and rigid endo scopes, laboratory and anaesthesia equipment

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

Supplier

B. Braun Melsungen AG
Carl-Braun-Straße 1
D-34212 Melsungen
Germany
T +49(0) 5661 / 71-4422
logistics.service@bbraun.com

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]

Acute toxicity (oral), Category 4	H302
Acute toxicity (inhalation:dust,mist) Category 4	H332
Skin corrosion/irritation, Category 1, Sub-Category 1B	H314
Serious eye damage/eye irritation, Category 1	H318
Respiratory sensitisation, Category 1	H334
Skin sensitisation, Category 1	H317
Specific target organ toxicity – Single exposure, Category 3,	H335
Respiratory tract irritation	
Hazardous to the aquatic environment – Chronic Hazard,	H412
Category 3	

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

Adverse physicochemical, human health and environmental effects

Harmful if swallowed or if inhaled. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Contains

: Alkylether carboxylic acid; Glutaraldehyde; (R)-p-mentha-1,8-diene; d-limonene; Alcohol C11, ethoxylated

Hazard statements (CLP)

: H302+H332 - Harmful if swallowed or if inhaled.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P260 - Do not breathe mist.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water /shower.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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.
P273 - Avoid release to the environment.
P501 - Dispose of contents and container to an approved waste disposal plant.

EUH-statements

: EUH071 - Corrosive to the respiratory tract.

Labelling according to: exemption for packages of a capacity of 125ml or less

Hazard pictograms (CLP)



GHS05

GHS07

GHS08

Signal word (CLP)

: Danger

Hazardous ingredients

: Alkylether carboxylic acid; Glutaraldehyde; (R)-p-mentha-1,8-diene; d-limonene; Alcohol C11, ethoxylated

Hazard statements (CLP)

: H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P260 - Do not breathe mist.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water /shower.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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.
P501 - Dispose of contents and container to an approved waste disposal plant.

EUH-statements

: EUH071 - Corrosive to the respiratory tract.

2.3. Other hazards

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

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Mixture of the substances listed below with nonhazardous additives

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glutaraldehyde substance listed as REACH Candidate (Glutaral)	CAS-No.: 111-30-8 EC-No.: 203-856-5 EC Index-No.: 605-022-00-X REACH-no: 01-2119455549-26	12	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Resp. Sens. 1, H334 Skin Sens. 1A, H317 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
Alkylether carboxylic acid	-	< 15	Skin Irrit. 2, H315 Eye Dam. 1, H318
Propan-2-ol	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0 REACH-no: 01-2119457558-25	7,5	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Alcohol C11, ethoxylated	CAS-No.: 127036-24-2 EC-No.: 603-182-5 REACH-no: 02-2119494838-16	< 5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318
(R)-p-mentha-1,8-diene; d-limonene	CAS-No.: 5989-27-5 EC-No.: 227-813-5 EC Index-No.: 601-096-00-2 REACH-no: 01-2119529223-47	< 0,25	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Skin Sens. 1B, H317 Asp. Tox. 1, H304 Aquatic Acute 1, H400 Aquatic Chronic 3, H412

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
Glutaraldehyde	CAS-No.: 111-30-8 EC-No.: 203-856-5 EC Index-No.: 605-022-00-X REACH-no: 01-2119455549-26	(0.5 ≤ C < 100) Skin Sens. 1, H317 (0.5 ≤ C < 100) STOT SE 3, H335 (0.5 ≤ C < 2) Eye Irrit. 2, H319 (0.5 ≤ C < 10) Skin Irrit. 2, H315 (2 ≤ C < 10) Eye Dam. 1, H318 (10 ≤ C < 100) Skin Corr. 1B, H314

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

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Data of item 4 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Take off immediately all contaminated clothing. If you feel unwell, seek medical advice.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash off immediately with soap and plenty of water. Call a doctor.
First-aid measures after eye contact	: Wash immediately with plenty water (during 20 minutes), also under eyelids. Call a physician immediately.
First-aid measures after ingestion	: Do not induce vomiting. Drink plenty of water. Do not give an unconscious person anything to drink. Do not induce vomiting without medical advice. Call a physician immediately.

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

Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Corrosive to the respiratory tract. Harmful if inhaled.
Symptoms/effects after skin contact	: Causes severe burns. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Serious damage to eyes.
Symptoms/effects after ingestion	: Harmful if swallowed.

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	: Product itself does not burn. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: high volume water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon monoxide. Carbon dioxide. Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters

Precautionary measures fire	: Fight fire from safe distance and protected location. Cool endangered containers with water spray jet.
Firefighting instructions	: Move containers from fire area if it can be done without personal risk.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Remove ignition sources. Ventilate spillage area. Evacuate unnecessary personnel.
------------------	-------------------------------------------------------------------------------------

6.1.1. For non-emergency personnel

Emergency procedures	: Avoid contact with skin and eyes. Do not breathe vapours.
----------------------	-------------------------------------------------------------

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

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

Do not allow to enter into surface water or drains. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Methods for cleaning up : Mechanically recover the product. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Avoid contact with skin and eyes.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Provide for a tub to collect spills.
Storage conditions : Keep container tightly closed in a dry, cool and well-ventilated place.
Incompatible materials : Strong acids. oxidizing materials.
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	A specific exposure sampling method is not available.
Biological monitoring methods	A specific exposure sampling method is not available

8.1.3. Air contaminants formed

No additional information available

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

8.1.4. DNEL and PNEC

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/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	26 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	88 mg/m ³
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 (Sediment)	
PNEC sediment (freshwater)	552 mg/kg dwt
PNEC sediment (marine water)	552 mg/kg dwt
PNEC (Soil)	
PNEC soil	28 mg/kg dwt

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:

Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

8.2.2.1. Eye and face protection

Eye protection:

Eyewash bottle with clean water (EN 15154)

Eye protection			
Type	Field of application	Characteristics	Standard
Protective goggles (EN 166)	Liquid splashes may occur		EN 166

8.2.2.2. Skin protection

Skin and body protection	
Type	Standard
apron	EN 367
Long sleeved protective clothing	EN ISO 6530

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Hand protection:

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Butyl rubber	6 (> 480 minutes)	0,5		EN ISO 374
Chemically resistant protective gloves	Chloroprene rubber (CR)	2 (> 30 minutes)	0,5		EN ISO 374
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35		EN ISO 374
Chemically resistant protective gloves	Fluoroelastomer (FKM)	6 (> 480 minutes)	0,4		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Respiratory protection			
Device	Filter type	Condition	Standard
Respiratory protective device with a gas filter	Type A		EN 14387

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 breathe vapours. Wash hands immediately after handling the product. Wash hands before breaks and at the end of workday. Do not eat, drink or smoke in areas where product is used. Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Green.
Appearance	: Liquid.
Odour	: Aldehyde-like. perfumed.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: ≈ 82 °C
Flammability (solid, gas)	: Not applicable
Explosive properties	: Product is not explosive. May form flammable/explosive vapour-air mixture.
Oxidising properties	: Not oxidising.
Lower explosive limit (LEL)	: 2 vol %
Upper explosive limit (UEL)	: Not available
Flash point	: 37 – 42 °C DIN 51755 Not sustained combustibility
Auto-ignition temperature	: ≈ 425 °C
Decomposition temperature	: Not available

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

pH	: 4 – 4.9 Concentrate
Viscosity, kinematic	: Not available
Solubility	: Water: Miscible
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1 – 1.04 g/cm ³
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not sustained combustibility : Yes

9.2.2. Other safety characteristics

VOC content : < 10 %
Solvent content : < 10 %

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored normally.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reacts with: Acids. oxidizing materials.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids. Oxidizing agent.

10.6. Hazardous decomposition products

Fire may produce: Carbon monoxide. Carbon dioxide. Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

SECTION 11: Toxicological information

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

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

Helipur H plus N	
ATE CLP (oral)	500 mg/kg bodyweight
ATE CLP (dust,mist)	1.5 mg/l/4h
Propan-2-ol (67-63-0)	
LD50 oral rat	5840 mg/kg
LD50 dermal rabbit	13900 mg/kg

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Propan-2-ol (67-63-0)	
LC50 Inhalation - Rat	> 25 mg/l 4 h
Glutaraldehyde (111-30-8)	
LD50 oral rat	151 ml/kg (OECD 401 method)
LD50 dermal rabbit	> 1000 mg/kg (US-EPA)
LC50 Inhalation - Rat (Dust/Mist)	0.48 mg/l/4h (OECD 403 method)
(R)-p-mentha-1,8-diene; d-limonene (5989-27-5)	
LD50 oral rat	> 2000 mg/kg
LD50 oral	4400 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LD50 dermal	5000 mg/kg

Skin corrosion/irritation	: Causes severe skin burns. pH: 4 – 4.9 Concentrate
Serious eye damage/irritation	: Causes serious eye damage. pH: 4 – 4.9 Concentrate
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
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)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: May cause respiratory irritation.

Propan-2-ol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.
Glutaraldehyde (111-30-8)	
STOT-single exposure	May cause respiratory irritation.

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %
------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: No ecotoxicological data about this product are known.
Hazardous to the aquatic environment, short-term (acute)	: Not classified. (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Propan-2-ol (67-63-0)	
LC50 fish 1	9640 mg/l Pimephales promelas, 96 h
EC50 Daphnia 1	10000 mg/l Daphnia magna, 48 h
EC50 72h - Algae [1]	1800 mg/l Desmodesmus subspicatus, 72 h
Glutaraldehyde (111-30-8)	
LC50 fish 1	3.5 mg/l 96 h, ECOTOX, Oncorhynchus mykiss (Rainbow trout)
EC50 Daphnia 1	14.87 mg/l 48 h, OECD 202, Daphnia magna (Water flea)
ErC50 algae	0.6 mg/l 72 h, OECD 201, Desmodesmus subspicatus
NOEC chronic fish	1.6 mg/l 97 d, OECD 210, Oncorhynchus mykiss (Rainbow trout)
NOEC chronic crustacea	5 mg/l 21 d, OECD 211, Daphnia magna (Water flea)
(R)-p-mentha-1,8-diene; d-limonene (5989-27-5)	
LC50 fish 1	0.7 mg/l 96 h, Pimephales promelas
EC50 Daphnia 1	0.42 mg/l 48 h, Daphnia magna (Water flea)

12.2. Persistence and degradability

Helipur H plus N	
Persistence and degradability	The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.
Propan-2-ol (67-63-0)	
Persistence and degradability	Readily biodegradable.
Biodegradation	95 % 21 d, (OECD 301E method)
Glutaraldehyde (111-30-8)	
Persistence and degradability	Readily biodegradable.
Biodegradation	90 – 100 % (OECD 301A method)

12.3. Bioaccumulative potential

Propan-2-ol (67-63-0)	
Log Pow	0.05
(R)-p-mentha-1,8-diene; d-limonene (5989-27-5)	
Log Pow	4.23

12.4. Mobility in soil

No additional information available

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

12.5. Results of PBT and vPvB assessment

Helipur H plus N

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

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

Additional information : Prevent entry to sewers and public waters

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Can be incinerated according to local regulations. Recycling is preferred to disposal or incineration. Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : The precautionary statement P501 for proper disposal applies to the disinfectant concentrate.
However, it is still possible and permissible to dispose of usual quantities of the ready-to-use solution via the domestic wastewater into the sewage system.

Product/Packaging disposal recommendations : Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

European List of Waste (LoW) code : 07 06 04* - other organic solvents, washing liquids and mother liquors

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. (Glutaraldehyde)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)	Disinfectant, liquid, corrosive, n.o.s. (Glutaral)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)
Transport document description				
UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde), 8, III, (E)	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral), 8, III	UN 1903 Disinfectant, liquid, corrosive, n.o.s. (Glutaral), 8, III	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral), 8, III	UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral), 8, III
14.3. Transport hazard class(es)				
8	8	8	8	8

Helipur H plus N

Safety Data Sheet

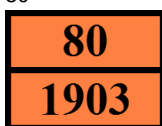
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

ADR	IMDG	IATA	ADN	RID
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
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
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : C9
Special provisions (ADR) : 274
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Transport category (ADR) : 3
Hazard identification number (Kemler No.) : 80
Orange plates :



Tunnel restriction code (ADR) : E

Transport by sea

Special provisions (IMDG) : 223, 274
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P001, LP01
IBC packing instructions (IMDG) : IBC03
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-B
Stowage category (IMDG) : A

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 packing instructions (IATA) : 856
CAO max net quantity (IATA) : 60L
Special provisions (IATA) : A3, A803
ERG code (IATA) : 8L

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Inland waterway transport

Classification code (ADN) : C9
Special provisions (ADN) : 274
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1
Equipment required (ADN) : PP, EP
Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : C9
Special provisions (RID) : 274
Limited quantities (RID) : 5L
Excepted quantities (RID) : E1
Packing instructions (RID) : P001, IBC03, LP01, R001
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

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

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 $\geq 0.1\%$ or SCL: Glutaral (EC 203-856-5, CAS 111-30-8)

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 : < 10 %

Detergent Regulation (648/2004)

Allergenic fragrances > 0.01 %:

D-LIMONENE

Labelling of contents:

Component

5 % - < 15 % anionic surfactants
< 5 % non-ionic surfactants
< 5 % Parfum
Ingredients subject to the labelling obligation according to SCCP: Limonene

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)

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

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

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
13	Waste disposal recommendations	Added	

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Asp. Tox. 1	Aspiration hazard, Category 1
EUH071	Corrosive to the respiratory tract.
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
Flam. Liq. 3	Flammable liquids, Category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Helipur H plus N

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0161

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Acute Tox. 4 (Oral)	H302	Expert judgement
Acute Tox. 4 (Inhalation:dust,mist)	H332	Expert judgement
Skin Corr. 1B	H314	Calculation method
Eye Dam. 1	H318	Calculation method
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
STOT SE 3	H335	Calculation method
Aquatic Chronic 3	H412	Calculation method

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 therefore not be construed as guaranteeing any specific property of the product.