

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

1.1. Product identifier

Product form : Mixture
Trade name : Perma Evolution Component A1
Type of product : Medical device

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Manufacture of medical and dental instruments and supplies
Root filling material based on epoxy resin for permanent root fillings.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Alfred Becht GmbH
Carl-Zeiss-Str. 16
P.O. Box 1145
77656 Offenburg
T +49 781 60586-0 - F +49 781 60586-40

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : National Poison Information Service (NPIS)
24 hour national number professionals only
0844 892 0111

National Health Service (NHS)
24 hour national number consumer
England and Scotland: 111
Wales: 0845 46 47
Northern Ireland: call your local General Practitioner

Call 999 if there is a life-threatening incident.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2	H225
Acute toxicity (inhalation:dust,mist) Category 4	H332
Skin corrosion/irritation, Category 1, Sub-Category 1A	H314
Serious eye damage/eye irritation, Category 1	H318
Skin sensitisation, Category 1	H317
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335

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

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Harmful if inhaled. May cause respiratory irritation. Causes serious eye damage. May cause an allergic skin reaction. Causes severe skin burns and eye damage.

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2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

Contains

Hazard statements (CLP)

Precautionary statements (CLP)

- : Danger
- : diethylamine, 3-aminomethyl-3,5,5-trimethylcyclohexylamine, 2,2'-iminodiethylamine
- : H225 - Highly flammable liquid and vapour.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H332 - Harmful if inhaled.
H335 - May cause respiratory irritation.
- : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 - Do not breathe mist, vapours, spray.
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 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.
P403+P235 - Store in a well-ventilated place. Keep cool.

2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

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

Component	
Barium sulfate (7727-43-7)	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
diethylamine (109-89-7)	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
3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	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
2,2'-iminodiethylamine (111-40-0)	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
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

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 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Barium sulfate substance with national workplace exposure limit(s) (GB)	CAS-No.: 7727-43-7 EC-No.: 231-784-4	≥ 25 – < 50	Not classified
2-[1-[2-(oxiran-2-ylmethoxy)propoxy]propan-2-ylloxymethyl]oxirane	CAS-No.: 41638-13-5 EC-No.: 609-948-5	≥ 20 – < 25	Eye Irrit. 2, H319
diethylamine substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit	CAS-No.: 109-89-7 EC-No.: 203-716-3 EC Index-No.: 612-003-00-X	≥ 5 – < 10	Flam. Liq. 2, H225 Acute Tox. 4 (Oral), H302 (ATE=540 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=582 mg/kg bodyweight) Acute Tox. 4 (Inhalation:vapour), H332 (ATE=17.3 mg/l/4h) Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335
3-aminomethyl-3,5,5-trimethylcyclohexylamine	CAS-No.: 2855-13-2 EC-No.: 220-666-8 EC Index-No.: 612-067-00-9	≥ 5 – < 10	Acute Tox. 4 (Oral), H302 (ATE=1030 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Chronic 3, H412
2,2'-iminodiethylamine substance with national workplace exposure limit(s) (GB)	CAS-No.: 111-40-0 EC-No.: 203-865-4 EC Index-No.: 612-058-00-X REACH-no: 01-2119473793- 27-xxxx	≥ 2.5 – < 5	Acute Tox. 4 (Oral), H302 (ATE=1553 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1045 mg/kg bodyweight) Acute Tox. 2 (Inhalation:dust,mist), H330 (ATE=0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335
polyhexamethylene biguanide hydrochloride; PHMB	CAS-No.: 27083-27-8 EC Index-No.: 616-207-00-X	< 0.1	Carc. 2, H351 Acute Tox. 2 (Inhalation), H330 (ATE=0.37 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)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
diethylamine	CAS-No.: 109-89-7 EC-No.: 203-716-3 EC Index-No.: 612-003-00-X	(1 ≤C ≤ 100) STOT SE 3, H335
3-aminomethyl-3,5,5-trimethylcyclohexylamine	CAS-No.: 2855-13-2 EC-No.: 220-666-8 EC Index-No.: 612-067-00-9	(0.001 ≤C ≤ 100) Skin Sens. 1A, H317

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

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a physician immediately.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
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 inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction. Burns.
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

Fire hazard	: Highly flammable liquid and vapour.
Explosion hazard	: Explosive vapour/air mixtures may be formed.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Silicon oxide. Sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Protect container with water spray.
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. No open flames, no sparks, and no smoking. Avoid contact with skin and eyes. Do not breathe mist, vapours, spray.
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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".
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6.2. Environmental precautions

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

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6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Notify authorities if product enters sewers or public waters.
- 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

- Additional hazards when processed : In use, may form flammable vapour-air mixture.
- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. 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. Use only outdoors or in a well-ventilated area. Avoid contact with skin and eyes. Do not breathe mist, vapours, spray.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Ground/bond container and receiving equipment.
- Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.
- Heat and ignition sources : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from heat and direct sunlight.
- 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

Barium sulfate (7727-43-7)	
United Kingdom - Occupational Exposure Limits	
Local name	Barium sulphate
WEL TWA (OEL TWA) [1]	10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
diethylamine (109-89-7)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Diethylamine
IOEL TWA	15 mg/m ³
IOEL TWA [ppm]	5 ppm

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diethylamine (109-89-7)	
IOEL STEL	30 mg/m ³
IOEL STEL [ppm]	10 ppm
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
United Kingdom - Occupational Exposure Limits	
Local name	Diethylamine
WEL TWA (OEL TWA) [1]	15 mg/m ³
WEL TWA (OEL TWA) [2]	5 ppm
WEL STEL (OEL STEL)	30 mg/m ³
WEL STEL (OEL STEL) [ppm]	10 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
2,2'-iminodiethylamine (111-40-0)	
United Kingdom - Occupational Exposure Limits	
Local name	2,2'-Iminodi(ethylamine)
WEL TWA (OEL TWA) [1]	4.3 mg/m ³
WEL TWA (OEL TWA) [2]	1 ppm
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
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

diethylamine (109-89-7)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	30 mg/m ³
Long-term - systemic effects, dermal	0.1 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.64 mg/m ³
Long-term - local effects, inhalation	9.6 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0.05 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.1 mg/l
PNEC aqua (marine water)	0.01 mg/l
PNEC aqua (intermittent, freshwater)	0.509 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1.2 mg/kg dwt
PNEC sediment (marine water)	0.12 mg/kg dwt

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diethylamine (109-89-7)	
PNEC (Soil)	
PNEC soil	0.181 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	100 mg/l
3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.073 mg/m ³
Long-term - local effects, inhalation	0.073 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0.3 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.06 mg/l
PNEC aqua (marine water)	0.006 mg/l
PNEC aqua (intermittent, freshwater)	0.23 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	5.784 mg/kg dwt
PNEC sediment (marine water)	0.578 mg/kg dwt
PNEC (Soil)	
PNEC soil	1.121 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	3.18 mg/l
2,2'-iminodiethylamine (111-40-0)	
DNEL/DMEL (Workers)	
Acute - systemic effects, inhalation	92.1 mg/m ³
Acute - local effects, inhalation	2.6 mg/m ³
Long-term - systemic effects, dermal	11.4 mg/kg bodyweight/day
Long-term - local effects, dermal	1.1 mg/cm ²
Long-term - systemic effects, inhalation	15.4 mg/m ³
Long-term - local effects, inhalation	0.87 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, dermal	4.88 mg/kg bodyweight/day
Acute - systemic effects, inhalation	27.5 mg/m ³
Long-term - systemic effects, inhalation	4.6 mg/m ³
Long-term - systemic effects, dermal	4.88 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.56 mg/l
PNEC aqua (marine water)	0.056 mg/l
PNEC aqua (intermittent, freshwater)	0.32 mg/l

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2,2'-iminodiethylamine (111-40-0)	
PNEC (Sediment)	
PNEC sediment (freshwater)	1072 mg/kg dwt
PNEC sediment (marine water)	107.2 mg/kg dwt
PNEC (Soil)	
PNEC soil	7.97 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	6 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. ISO 16321-1. 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:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Please follow the instructions related to the permeability and the penetration time provided by the 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. Short term exposure. Breathing apparatus with filter. P2. 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:

The above mentioned instructions regarding the protective equipment refer to the industrial use of larger quantities. 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	: yellowish.
Appearance	: Paste.
Odour	: Amine-like.

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Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive. Explosive vapour/air mixtures may be formed.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.53 – 1.87 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

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. Highly flammable liquid and vapour.

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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

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)	: Harmful if inhaled.

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ATE CLP (dust,mist)	1.331 mg/l/4h
diethylamine (109-89-7)	
LD50 oral rat	100 mg/kg bodyweight (OECD 401 method)
LD50 dermal rabbit	582 mg/kg bodyweight
LC50 Inhalation - Rat (Vapours)	17.3 mg/l/4h (OECD 403 method)
3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	
LD50 oral rat	1030 mg/kg bodyweight (male; eq. (OECD 401 method))
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402 method)
LC50 Inhalation - Rat (Dust/Mist)	> 5.01 mg/l/4h (OECD 403 method)
2,2'-iminodiethylamine (111-40-0)	
LD50 oral rat	1553 mg/kg (male)
LD50 dermal rabbit	1045 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 0.07 mg/l/4h (OECD 403 method)
polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
LC50 Inhalation - Rat (Dust/Mist)	0.37 mg/l/4h

Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: 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)

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	: May cause respiratory irritation.

diethylamine (109-89-7)	
STOT-single exposure	May cause respiratory irritation.

2,2'-iminodiethylamine (111-40-0)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

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

Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
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11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Before neutralisation, the product may represent a danger to aquatic organisms.
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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) : Not classified (Based on available data, the classification criteria are not met)

Not rapidly degradable

3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	
LC50 - Fish [1]	110 mg/l (96h; <i>Leuciscus idus</i> (golden orfe); EU Method C.1)
EC50 - Crustacea [1]	23 mg/l (48h; <i>Daphnia magna</i> ; (OECD 202 method))
EC50 72h algae	37 mg/l (72h; <i>Desmodesmus subspicatus</i> ; EU Method C.3)
ErC50 algae	37 mg/l (72h; <i>Desmodesmus subspicatus</i> ; EU Method C.3)
NOEC chronic crustacea	3 mg/l (21d; <i>Daphnia magna</i>)

2,2'-iminodiethylamine	
NOEC chronic fish	> 10 mg/l (28 d; <i>Gasterosteus aculeatus</i> ; (OECD 210 method))
NOEC chronic algae	10 mg/l (72 h; <i>Pseudokirchnerella subcapitata</i> ; (OECD 201 method))

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

12.2. Persistence and degradability

Barium sulfate (7727-43-7)	
Persistence and degradability	Not applicable.

diethylamine (109-89-7)	
Persistence and degradability	Readily biodegradable.
Biodegradation	68 – 70 % (28 d, (OECD 301C method))

3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	8 % (28d; EU Method C.4-A)

2,2'-iminodiethylamine (111-40-0)	
Persistence and degradability	Readily biodegradable.
Biodegradation	87 % (21 d; (OECD 301D method))

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

12.3. Bioaccumulative potential

diethylamine (109-89-7)	
Bioconcentration factor (BCF REACH)	1.62
Partition coefficient n-octanol/water (Log Pow)	0.58 (25 °C)

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3-aminomethyl-3,5,5-trimethylcyclohexylamine (2855-13-2)	
Partition coefficient n-octanol/water (Log Pow)	0.99 (OECD 107 method)
2,2'-iminodiethylamine (111-40-0)	
BCF - Fish [1]	2.8 – 6.3 (0,2 mg/L; Cyprinus carpio; (OECD 305 method))
Partition coefficient n-octanol/water (Log Pow)	-5.58 (20 °C; pH 7; (calculated value))
polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
Partition coefficient n-octanol/water (Log Kow)	-2.29
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

2,2'-iminodiethylamine (111-40-0)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	3.4 – 4.6 (25 °C; EPA OTS 796.2750)
polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	
Ecology - soil	Adsorbs into the soil.

12.5. Results of PBT and vPvB assessment

Perma Evolution Component A1	
PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	

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.
Additional information	: Flammable vapours may accumulate in the container.

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HP Code

- : HP3 - "Flammable:"
 - flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C;
 - flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air;
 - flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction;
 - flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa;
 - water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities;
 - other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste.
- 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.
- HP6 - "Acute Toxicity:" waste which can cause acute toxic effects following oral or dermal administration, or inhalation exposure.
- HP8 - "Corrosive:" waste which on application can cause skin corrosion.
- HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

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 2733	UN 2733	UN 2733	UN 2733	UN 2733
14.2. UN proper shipping name				
AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine)	AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine)	Amines, flammable, corrosive, n.o.s. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine)	AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine)	AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine)
Transport document description				
UN 2733 AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine), 3 (8), II, (D/E)	UN 2733 AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine), 3 (8), II	UN 2733 Amines, flammable, corrosive, n.o.s. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine), 3 (8), II	UN 2733 AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine), 3 (8), II	UN 2733 AMINES, FLAMMABLE, CORROSIVE, N.O.S. (diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine), 3 (8), II
14.3. Transport hazard class(es)				
3 (8)	3 (8)	3 (8)	3 (8)	3 (8)
				
14.4. Packing group				
II	II	II	II	II

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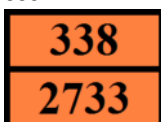
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA	ADN	RID
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) : FC
Special provisions (ADR) : 274, 544
Limited quantities (ADR) : 1I
Excepted quantities (ADR) : E2
Transport category (ADR) : 2
Hazard identification number (Kemler No.) : 338
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2WE
APP code : A(fl)

Transport by sea

Special provisions (IMDG) : 274
Limited quantities (IMDG) : 1 L
Excepted quantities (IMDG) : E2
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-C
Stowage and handling (IMDG) : SW2
Segregation (IMDG) : SGG18, SG35

Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y340
PCA limited quantity max net quantity (IATA) : 0.5L
PCA packing instructions (IATA) : 352
PCA max net quantity (IATA) : 1L
CAO max net quantity (IATA) : 5L
Special provisions (IATA) : A3, A803

Inland waterway transport

Classification code (ADN) : FC
Special provisions (ADN) : 274, 544
Limited quantities (ADN) : 1 L
Excepted quantities (ADN) : E2
Carriage permitted (ADN) : T

Rail transport

Classification code (RID) : FC
Special provisions (RID) : 274, 544
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2
Transport category (RID) : 2
Hazard identification number (RID) : 338

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

Other information, restriction and prohibition regulations : Take note of Directive 94/33/EC on the protection of young people at work.

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(a)	Perma Evolution Component A1 ; diethylamine
3(b)	Perma Evolution Component A1 ; 2-[1-[2-(oxiran-2-ylmethoxy)propoxy]propan-2-yloxyethyl]oxirane ; diethylamine ; 3-aminomethyl-3,5,5-trimethylcyclohexylamine ; 2,2'-iminodiethylamine
3(c)	3-aminomethyl-3,5,5-trimethylcyclohexylamine
40.	diethylamine

REACH Annex XIV (Authorisation List)

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

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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)

Seveso Directive (Disaster Risk Reduction)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
P5c FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5a and P5b	5000	50000

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

United Kingdom

Other information : 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

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SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
8	DNEL and PNEC	Modified	
14	UN 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

: Information provided by the manufacturer. MSDSs of the suppliers. European Chemicals Agency, <http://echa.europa.eu/>.

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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 : Dr. Maximilian Gatterdam

Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) 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 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
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
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful 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.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A

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Full text of H- and EUH-statements:	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
Skin Sens. 1B	Skin sensitisation, category 1B
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Flam. Liq. 2	H225	Calculation method
Acute Tox. 4 (Inhalation:dust,mist)	H332	Calculation method
Skin Corr. 1A	H314	Calculation method
Eye Dam. 1	H318	Calculation method
Skin Sens. 1	H317	Calculation method
STOT SE 3	H335	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.

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

1.1. Product identifier

Product form : Mixture
Trade name : Perma Evolution Component E1
Type of product : Medical device

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Manufacture of medical and dental instruments and supplies
Root filling material based on epoxy resin for permanent root fillings.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Alfred Becht GmbH
Carl-Zeiss-Str. 16
P.O. Box 1145
77656 Offenburg
T +49 781 60586-0 - F +49 781 60586-40

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : National Poison Information Service (NPIS)
24 hour national number professionals only
0844 892 0111

National Health Service (NHS)
24 hour national number consumer
England and Scotland: 111
Wales: 0845 46 47
Northern Ireland: call your local General Practitioner

Call 999 if there is a life-threatening incident.

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 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, Category 1	H317
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 an allergic skin reaction. Causes skin irritation. Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

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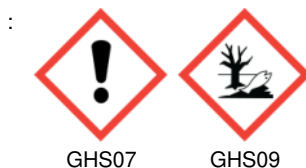
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2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP) : Warning

Contains : bis-[4-(2,3-epoxipropoxy)phenyl]propane, oxirane, mono[(C12-14-alkyloxy)methyl] derivs.

Hazard statements (CLP) : H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P391 - Collect spillage.

2.3. Other hazards

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

Component	
Barium sulfate (7727-43-7)	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
bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	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
oxirane, mono[(C12-14-alkyloxy)methyl] derivs. (68609-97-2)	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 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 %

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]
Barium sulfate substance with national workplace exposure limit(s) (GB)	CAS-No.: 7727-43-7 EC-No.: 231-784-4	$\geq 50 - < 70$	Not classified
bis-[4-(2,3-epoxipropoxy)phenyl]propane	CAS-No.: 1675-54-3 EC-No.: 216-823-5 EC Index-No.: 603-073-00-2	$\geq 25 - < 50$	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Chronic 2, H411

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
oxirane, mono[(C12-14-alkyloxy)methyl] derivs.	CAS-No.: 68609-97-2 EC-No.: 271-846-8 EC Index-No.: 603-103-00-4	≥ 1 – < 2.5	Skin Irrit. 2, H315 Skin Sens. 1, H317

Specific concentration limits:

Name	Product identifier	Specific concentration limits
bis-[4-(2,3-epoxipropoxy)phenyl]propane	CAS-No.: 1675-54-3 EC-No.: 216-823-5 EC Index-No.: 603-073-00-2	(5 ≤C ≤ 100) Skin Irrit. 2, H315 (5 ≤C ≤ 100) Eye Irrit. 2, H319

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	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: 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 skin contact	: May cause an allergic skin reaction. Irritation.
Symptoms/effects after eye contact	: Eye irritation.

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. Sulphur oxides.
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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.

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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. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

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. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.
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

Barium sulfate (7727-43-7)	
United Kingdom - Occupational Exposure Limits	
Local name	Barium sulphate
WEL TWA (OEL TWA) [1]	10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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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

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	0.75 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	4.93 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.87 mg/m ³
Long-term - systemic effects, dermal	89.3 µg/kg
PNEC (Water)	
PNEC aqua (freshwater)	0.006 mg/l
PNEC aqua (marine water)	0.001 mg/l
PNEC aqua (intermittent, freshwater)	0.018 mg/l
PNEC aqua (intermittent, marine water)	0.002 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.341 mg/kg dwt
PNEC sediment (marine water)	0.034 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.065 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	11 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	10 mg/l
oxirane, mono[(C12-14-alkyloxy)methyl] derivs. (68609-97-2)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	1 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	3.6 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.87 mg/m ³
Long-term - systemic effects, dermal	0.5 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.106 mg/l
PNEC aqua (marine water)	0.011 mg/l
PNEC aqua (intermittent, freshwater)	0.072 mg/l

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oxirane, mono[(C12-14-alkyloxy)methyl] derivs. (68609-97-2)	
PNEC (Sediment)	
PNEC sediment (freshwater)	307.16 mg/kg dwt
PNEC sediment (marine water)	30.72 mg/kg dwt
PNEC (Soil)	
PNEC soil	1.234 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	10 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.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Wear closed safety glasses. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Please follow the instructions related to the permeability and the penetration time provided by the 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. Short term exposure. Breathing apparatus with filter. P2. 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:

The above mentioned instructions regarding the protective equipment refer to the industrial use of larger quantities. 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	: white.
Appearance	: Paste.
Odour	: odourless.
Odour threshold	: Not available

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Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.17 – 2.09 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

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

No additional information available

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)

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bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	
LD50 oral rat	> 2000 mg/kg bodyweight (OECD 420 method)
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402 method)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: 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)

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	
NOAEL (animal/male, F0/P)	50 mg/kg bodyweight/day (Oral, rat, (OECD 416 method))
NOAEL (animal/female, F0/P)	540 mg/kg bodyweight/day (Oral, rat, (OECD 416 method))
NOAEL (animal/male, F1)	750 mg/kg bodyweight/day (Oral, rat, (OECD 416 method))
NOAEL (animal/female, F1)	750 mg/kg bodyweight/day (Oral, rat, (OECD 416 method))
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
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

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Toxic to aquatic life with long lasting effects.
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)	: Toxic to aquatic life with long lasting effects.
Not rapidly degradable	

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	
LC50 - Fish [1]	1.75 mg/l (96 h; Oncorhynchus mykiss; (OECD 203 method))
EC50 - Crustacea [1]	2.8 mg/l (48 h; Daphnia magna; (OECD 202 method))
ErC50 algae	> 11 mg/l (72 h; Scenedesmus capricornutum; EPA-660/3-75-009)
NOEC chronic crustacea	0.3 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	4.2 mg/l (72 h; Scenedesmus capricornutum; EPA-660/3-75-009)

12.2. Persistence and degradability

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	5 % (28 d; (OECD 301F method))

oxirane, mono[(C12-14-alkyloxy)methyl] derivs. (68609-97-2)	
Persistence and degradability	Readily biodegradable.
Biodegradation	87 % (28 d; (OECD 301F method))

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Barium sulfate (7727-43-7)

Persistence and degradability	Not applicable.
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12.3. Bioaccumulative potential

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)

BCF - Other aquatic organisms [1]	31 l/kg (Quantitative structure-activity relationship (QSAR))
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Partition coefficient n-octanol/water (Log Pow)	7.1
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Bioaccumulative potential	not bioaccumulable.
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oxirane, mono[(C12-14-alkyloxy)methyl] derivs. (68609-97-2)

Partition coefficient n-octanol/water (Log Pow)	3.77 (20 °C; (OECD 107 method))
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12.4. Mobility in soil

bis-[4-(2,3-epoxipropoxy)phenyl]propane (1675-54-3)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.65 (20 °C; Quantitative structure-activity relationship (QSAR))
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Ecology - soil	Product adsorbs little onto the soil.
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12.5. Results of PBT and vPvB assessment

No additional information available

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. HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs. 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 3082	UN 3082	UN 3082	UN 3082	UN 3082

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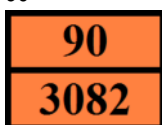
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA	ADN	RID
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)	Environmentally hazardous substance, liquid, n.o.s. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)
Transport document description				
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane), 9, III, (-)	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane), 9, III, MARINE POLLUTANT	UN 3082 Environmentally hazardous substance, liquid, n.o.s. (bis-[4-(2,3-epoxipropoxi)phenyl]propane), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane), 9, III
14.3. Transport hazard class(es)				
9	9	9	9	9
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) : M6
 Special provisions (ADR) : 274, 335, 375, 601
 Limited quantities (ADR) : 5L
 Excepted quantities (ADR) : E1
 Transport category (ADR) : 3
 Hazard identification number (Kemler No.) : 90
 Orange plates :



Tunnel restriction code (ADR) : -
 EAC code : •3Z

Transport by sea

Special provisions (IMDG) : 274, 335, 969
 Limited quantities (IMDG) : 5 L
 Excepted quantities (IMDG) : E1
 EmS-No. (Fire) : F-A
 EmS-No. (Spillage) : S-F

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Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y964
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 964
PCA max net quantity (IATA)	: 450L
CAO max net quantity (IATA)	: 450L
Special provisions (IATA)	: A97, A158, A197

Inland waterway transport

Classification code (ADN)	: M6
Special provisions (ADN)	: 274, 335, 375, 601
Limited quantities (ADN)	: 5 L
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T
Additional requirements/Remarks (ADN)	:

Rail transport

Classification code (RID)	: M6
Special provisions (RID)	: 274, 335, 375, 601
Limited quantities (RID)	: 5L
Excepted quantities (RID)	: E1
Transport category (RID)	: 3
Hazard identification number (RID)	: 90

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

Other information, restriction and prohibition regulations : Take note of Directive 94/33/EC on the protection of young people at work.

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	Perma Evolution Component E1 ; bis-[4-(2,3-epoxipropoxy)phenyl]propane ; oxirane, mono[(C12-14-alkyloxy)methyl] derivs.
3(c)	Perma Evolution Component E1 ; bis-[4-(2,3-epoxipropoxy)phenyl]propane

REACH Annex XIV (Authorisation List)

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

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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)

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Seveso Directive (Disaster Risk Reduction)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
E2 Hazardous to the Aquatic Environment in Category Chronic 2	200	500

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

United Kingdom

Other information : 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
	General revision		

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

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Abbreviations and acronyms:

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 : Information provided by the manufacturer. MSDSs of the suppliers. European Chemicals Agency, <http://echa.europa.eu/>.

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Contact person : Dr. Maximilian Gatterdam

Full text of H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	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.