



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Biguaton forte Neu

Version number: 1.0

First version: 14.03.2023

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

1.1 Product identifier

Trade name	<u>Biguaton forte Neu</u>
Registration number (REACH)	Not relevant (mixture)
CAS number	Not relevant (mixture)

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

Relevant identified uses	Disinfectants for instruments
Uses advised against	Do not use for squirting or spraying

1.3 Details of the supplier of the safety data sheet

PLIWA Hygiene GmbH	Telephone: +495661 / 7317 0
Pliwa-Straße 2	Telefax: +495661 / 7317 10
34323 Malsfeld-Ostheim	e-mail: info@pliwa.de
Germany	Website: www.pliwa.de

e-mail (competent person) sdb@csb-compliance.com

Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact PLIWA Hygiene GmbH.

1.4 Emergency telephone number

Emergency information	PLIWA Hygiene GmbH +49 5661 / 7317 0 This number is only available during the following office hours: Mon - Thu 09:00 - 15:00 Fri 09:00 - 12:00
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As above or nearest toxicological information centre.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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Classification				
Section	Hazard class	Category	Hazard class and category	Hazard statement
3.1O	acute toxicity (oral)	4	Acute Tox. 4	H302
3.2	skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318
4.1A	hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis.

Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word danger

Pictograms

GHS05, GHS07,
GHS09



Hazard statements

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P260 Do not breathe mist/vapours/spray.

P280 Wear protective gloves/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/doctor.

P391 Collect spillage.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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Hazardous ingredients for labelling

2-propylheptanol ethoxylate
 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
 Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt
 N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate

Additional labelling requirements

see section 15 of the safety data sheet

2.3 Other hazards

This material is combustible, but will not ignite readily.

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Contains an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients



3.1 Substances

Not relevant (mixture).







3.2 Mixtures

Description of the mixture



Aqueous solution, containing surfactants.
 Concentrate.

Hazardous ingredients					
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
propan-2-ol	CAS No 67-63-0 EC No 200-661-7 Index No 603-117-00-0	10 – <25	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319 STOT SE 3 / H336	 	GHS-HC

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Hazardous ingredients					
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
2-(2-butoxyethoxy)ethanol	CAS No 112-34-5 EC No 203-961-6 Index No 603-096-00-8 REACH Reg. No 01-2119475104-44-xxxx	10 – < 25	Eye Irrit. 2 / H319		GHS-HC IOELV
2-propylheptanol ethoxylate	CAS No 160875-66-1	5 – < 10	Acute Tox. 4 / H302 Eye Dam. 1 / H318		-
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	CAS No 2372-82-9 EC No 219-145-8	5 – < 10	Acute Tox. 3 / H301 Skin Corr. 1B / H314 Eye Dam. 1 / H318 STOT RE 2 / H373 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		-
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	CAS No 94667-33-1	5 – < 10	Acute Tox. 4 / H302 Skin Corr. 1B / H314 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		-
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	EC No 939-650-3	3 – < 5	Acute Tox. 4 / H302 Skin Corr. 1C / H314 Eye Dam. 1 / H318 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		-
alcohols, C12-15, ethoxylated	CAS No 68131-39-5 EC No 500-195-7	3 – < 5	Acute Tox. 4 / H302 Eye Dam. 1 / H318 Aquatic Chronic 3 / H412		-

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Hazardous ingredients					
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
dodecylamine	CAS No 124-22-1 EC No 204-690-6	1 – <3	Skin Corr. 1B / H314 STOT SE 3 / H335 STOT RE 2 / H373 Asp. Tox. 1 / H304 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		-
ethylene glycol	CAS No 107-21-1 EC No 203-473-3 Index No 603-027-00-1	1 – <3	Acute Tox. 4 / H302 STOT RE 2 / H373		GHS-HC IOELV

Notes

GHS- Harmonised classification (the classification of the substance corresponds to the entry in the list according to HC: 1272/2008/EC, Annex VI)

IOELV: Substance with a community indicative occupational exposure limit value

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
2-propylheptanol ethoxylate	-	-	500 mg/kg	oral
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	-	M-factor (acute) = 100 M-factor (chronic) = 1	243,6 mg/kg	oral
N,N-Didecyl-N-methylpoly(oxyethyl) ammonium propionate	-	M-factor (acute) = 10 M-factor (chronic) = 10	500 mg/kg	oral
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	M-factor (acute) = 10 M-factor (chronic) = 1	500 mg/kg	oral
alcohols, C12-15, ethoxylated	-	-	500 mg/kg	oral

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Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
dodecylamine	-	M-factor (acute) = 10 M-factor (chronic) = 1	-	-
ethylene glycol	-	-	500 mg/kg	oral

For full text of H-phrases: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air.

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

Following skin contact

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.

Call a physician immediately. Causes poorly healing wounds.

Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a doctor.

Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

Notes for the doctor

None.

4.2 Most important symptoms and effects, both acute and delayed

This information is not available.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

Hazardous combustion products

nitrogen oxides (NO_x), carbon monoxide (CO), carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

self-contained breathing apparatus (EN 133)

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

Ventilate affected area.

Avoid contact with skin and eyes.

Do not breathe vapour/spray.

Special danger of slipping by leaking/spilling product.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Flammability hazards

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Incompatible substances or mixtures

Incompatible materials: see section 10.

Protect against external exposure, such as

high temperatures, frost

Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

Ventilation requirements

Provision of sufficient ventilation.

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Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Notation	Source
DE	ethanediol	107-21-1	AGW	10	26	20	52	va, H, Y	TRGS 900
DE	2-(2-butoxyethoxy)ethanol	112-34-5	AGW	10	67	15	100,5	va, Y	TRGS 900
DE	butyl diglycol	112-34-5	MAK	10	67	15	100,5	va, DE-MAK-2	DFG
DE	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	MAK	-	0,05	-	0,4	i	DFG
DE	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	AGW	-	0,05	-	0,4	i, Y	TRGS 900
DE	propan-2-ol	67-63-0	AGW	200	500	400	1.000	Y	TRGS 900
EU	ethylene glycol	107-21-1	IOELV	20	52	40	104	H	2000/39/EC
EU	2-(2-butoxyethoxy)ethanol	112-34-5	IOELV	10	67,5	15	101,2	-	2006/15/EC

Notation

DE-MAK-2 MAK value for the sum of the air concentrations of butyl diglycol and butyl diglycol acetate.

H absorbed through the skin

i inhalable fraction

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

va as vapours and aerosols

Y a risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the biological limit value (BGW) are adhered to

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Biological limit values							
Country	Name of agent	Parameter	Notation	Identifier	Value	Material	Source
DE	2-propanol	acetone	-	BAT	25 mg/l	whole blood	DFG
DE	2-propanol	acetone	-	BAT	25 mg/l	urine	DFG
DE	2-propanol	acetone	-	BLV	25 mg/l	whole blood	TRGS 903
DE	2-propanol	acetone	-	BLV	25 mg/l	urine	TRGS 903

Relevant DNELs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
propan-2-ol	67-63-0	DNEL	500 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
propan-2-ol	67-63-0	DNEL	888 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
2-(2-butoxyethoxy)ethanol	112-34-5	DNEL	67,5 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	DNEL	0,789 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	DNEL	8,96 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
dodecylamine	124-22-1	DNEL	0,38 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
dodecylamine	124-22-1	DNEL	1 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
ethylene glycol	107-21-1	DNEL	35 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
ethylene glycol	107-21-1	DNEL	106 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
2-(2-butoxyethoxy)ethanol	112-34-5	PNEC	1,1 mg/l	freshwater
2-(2-butoxyethoxy)ethanol	112-34-5	PNEC	0,11 mg/l	marine water

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Relevant PNECs of components of the mixture				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
2-(2-butoxyethoxy)ethanol	112-34-5	PNEC	4,4 mg/kg	freshwater sediment
2-(2-butoxyethoxy)ethanol	112-34-5	PNEC	0,44 mg/kg	marine sediment
2-(2-butoxyethoxy)ethanol	112-34-5	PNEC	0,32 mg/kg	soil
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	0,001 mg/l	freshwater
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	0 mg/l	marine water
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	0,18 mg/l	sewage treatment plant (STP)
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	3,2 mg/kg	freshwater sediment
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	0,13 mg/kg	marine sediment
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	PNEC	45,34 mg/kg	soil
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	PNEC	0,4 µg/l	freshwater
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	PNEC	0,04 µg/l	marine water

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Relevant PNECs of components of the mixture				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydro-pyrimidin-2(1H)-imine acetate salt	-	PNEC	1 mg/l	sewage treatment plant (STP)
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydro-pyrimidin-2(1H)-imine acetate salt	-	PNEC	10 mg/kg	freshwater sediment
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydro-pyrimidin-2(1H)-imine acetate salt	-	PNEC	1 mg/kg	marine sediment
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydro-pyrimidin-2(1H)-imine acetate salt	-	PNEC	3,7 mg/kg	soil
dodecylamine	124-22-1	PNEC	0,26 µg/l	freshwater
dodecylamine	124-22-1	PNEC	1,6 µg/l	water
dodecylamine	124-22-1	PNEC	550 µg/l	sewage treatment plant (STP)
dodecylamine	124-22-1	PNEC	179,4 µg/kg	freshwater sediment
dodecylamine	124-22-1	PNEC	17,94 µg/kg	marine sediment

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Relevant PNECs of components of the mixture				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
dodecylamine	124-22-1	PNEC	0,026 µg/l	marine water
dodecylamine	124-22-1	PNEC	10 mg/kg	soil
2-(2-butoxyethoxy)ethanol: PNEC Oral - Predators - Secondary poisoning - 56 mg/kg				

8.2 Exposure controls

Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection. (EN 166).

Hand protection

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
NBR: acrylonitrile-butadiene rubber	≥ 0,11 mm	>10 minutes (permeation: level 1)
NR: natural rubber, latex	≥ 0,11 mm	>10 minutes (permeation: level 1)
PVC: polyvinyl chloride	≥ 0,11 mm	>10 minutes (permeation: level 1)

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

Environmental exposure controls

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	clear - bluish
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	>80 °C
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	0,77 vol% - 13,4 vol%
Flash point	>60 °C
Auto-ignition temperature	210 °C
Decomposition temperature	not relevant
pH (value)	10 – 11 (20 °C)
Kinematic viscosity	not determined
Dynamic viscosity	not determined
Solubility(ies)	
Water solubility	miscible in any proportion
Partition coefficient n-octanol/water (log value)	not determined
Vapour pressure	not determined
Density and/or relative density	
Density	0,94 – 0,999 g/cm ³ at 20 °C
Relative vapour density	this information is not available
Particle characteristics	not relevant (liquid)

9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
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Other safety characteristics

Temperature class (EU, acc. to ATEX)

T3

(maximum permissible surface temperature on the equipment: 200°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

acids, oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification procedure

If not otherwise specified the classification is based on:

Ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful if swallowed.

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	ATE
2-propylheptanol ethoxylate	160875-66-1	oral	500 mg/kg
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	oral	243,6 mg/kg

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Name of substance	CAS No	Exposure route	ATE
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	oral	500 mg/kg
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	oral	500 mg/kg
alcohols, C12-15, ethoxylated	68131-39-5	oral	500 mg/kg
ethylene glycol	107-21-1	oral	500 mg/kg

Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
propan-2-ol	67-63-0	oral	LD50	5.840 mg/kg	rat	OECD Guideline 401	ECHA
propan-2-ol	67-63-0	dermal	LD50	13.100 mg/kg	rabbit	OECD Guideline 402	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	oral	LD50	2.410 mg/kg	mouse, male	OECD Guideline 401	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	dermal	LD50	2.764 mg/kg	rabbit, male	OECD Guideline 402	ECHA
2-propylheptanol ethoxylate	160875-66-1	oral	LD50	300 – 2.000 mg/kg	rat	-	manufacturer
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	oral	LD50	243,6 mg/kg	rat, female	OECD Guideline 401	ECHA
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	dermal	LD0	600 mg/kg	rat	-	-

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Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	oral	LD50	500 – 2.000 mg/kg	rat	OECD Guideline 401	ECHA
alcohols, C12-15, ethoxylated	68131-39-5	dermal	LD50	>2.000 – ≤5.000 mg/kg	rabbit	-	Supplier
alcohols, C12-15, ethoxylated	68131-39-5	oral	LD50	>300 – ≤2.000 mg/kg	rat	-	Supplier
dodecylamine	124-22-1	oral	LD50	>2.000 mg/kg	rat	-	ECHA
dodecylamine	124-22-1	dermal	LD50	>2.000 mg/kg	rat	-	ECHA
ethylene glycol	107-21-1	dermal	LD50	>3.500 mg/kg	mouse	-	ECHA

Skin corrosion/irritation

Causes severe burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

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Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

Endocrine disrupting properties

Contains an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (acute)

Very toxic to aquatic organisms.

Test data are not available for the complete mixture.

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
propan-2-ol	67-63-0	LC50	9.640 mg/l	96 h	fathead minnow (Pimephales promelas)	OECD Guideline 203	ECHA
propan-2-ol	67-63-0	LC50	>10.000 mg/l	24 h	daphnia magna	OECD Guideline 202	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	LC50	1.300 mg/l	96 h	bluegill (Lepomis macrochirus)	OECD Guideline 203	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	EC50	>100 mg/l	48 h	daphnia magna	EU method C.2	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	ErC50	1.101 mg/l	72 h	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA

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Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
2-(2-butoxyethoxy)ethanol	112-34-5	EbC50	>100 mg/l	96 h	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
2-propylheptanol ethoxylate	160875-66-1	EC50	>10 – 100 mg/l	48 h	daphnia magna	-	manufacturer
2-propylheptanol ethoxylate	160875-66-1	LC50	>10 – 100 mg/l	96 h	goldfish (Carassius auratus)	-	-
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	LC50	0,431 mg/l	96 h	zebra fish (Danio rerio)	OECD Guideline 203	ECHA
N,N-Didecyl-N-methylpoly(oxyethyl) ammonium propionate	94667-33-1	LC50	0,52 mg/l	96 h	bluegill (Lepomis macrochirus)	EPA OPPTS 850.1075	ECHA
N,N-Didecyl-N-methylpoly(oxyethyl) ammonium propionate	94667-33-1	LC50	0,62 mg/l	96 h	carp (cyprinus carpio)	OECD Guideline 203	ECHA
N,N-Didecyl-N-methylpoly(oxyethyl) ammonium propionate	94667-33-1	EC50	0,1 mg/l	48 h	daphnia magna	OECD Guideline 202	ECHA
N,N-Didecyl-N-methylpoly(oxyethyl) ammonium propionate	94667-33-1	ErC50	0,34 mg/l	72 h	algae (Scenedesmus subspicatus)	OECD Guideline 201	ECHA

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Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	LC50	0,707 mg/l	96 h	zebra fish (Danio rerio)	OECD Guideline 203	ECHA
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	EC50	58,3 µg/l	48 h	daphnia magna	OECD Guideline 202	ECHA

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Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	ErC50	19,7 µg/l	72 h	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
alcohols, C12-15, ethoxylated	68131-39-5	LC50	>1 – ≤10 mg/l	96 h	fish	-	Supplier
alcohols, C12-15, ethoxylated	68131-39-5	EC50	>1 – ≤10 mg/l	48 h	crustacean	-	Supplier
alcohols, C12-15, ethoxylated	68131-39-5	EC50	>1 – ≤10 mg/l	72 h	algae	-	Supplier
dodecylamine	124-22-1	LC50	0,42 – 0,54 mg/l	96 h	zebra fish (Danio rerio)	OECD Guideline 203	ECHA
dodecylamine	124-22-1	EC50	0,15 mg/l	48 h	daphnia magna	OECD Guideline 202	ECHA
dodecylamine	124-22-1	ErC50	0,05 mg/l	72 h	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
ethylene glycol	107-21-1	LC50	>72.860 mg/l	96 h	fathead minnow (Pimephales promelas)	-	ECHA
ethylene glycol	107-21-1	EC50	>100 mg/l	48 h	daphnia magna	OECD Guideline 202	ECHA
ethylene glycol	107-21-1	IC 50	10.940 mg/l	96 h	algae (pseudokirchneriella subcapitata)	-	ECHA

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Aquatic toxicity (chronic)

Very toxic to aquatic life with long lasting effects.
Test data are not available for the complete mixture.

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
propan-2-ol	67-63-0	NOELR	>1.000 mg/l	28 d	fish	Qsar	ECHA
propan-2-ol	67-63-0	NOELR	>1.000 mg/l	21 d	daphnia magna	Qsar	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	NOEC	≥100 mg/l	96 h	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
2-(2-butoxyethoxy)ethanol	112-34-5	growth (Eb-Cx) 10%	>1.995 mg/l	30 min	Bacteria (activated sludge)	OECD Guideline 209	ECHA
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	NOEC	0,125 mg/l	9 d	zebra fish (Danio rerio)	OECD Guideline 212	ECHA

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Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	NOEC	25 µg/l	21 d	daphnia magna	OECD Guideline 211	ECHA
alcohols, C12-15, ethoxylated	68131-39-5	NOEC	>0,1 – ≤10 mg/l	72 h	algae	-	Supplier
dodecylamine	124-22-1	ErC50	0,05 mg/l	3 d	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
dodecylamine	124-22-1	EC50	0,34 mg/l	21 d	daphnia magna	OECD Guideline 211	ECHA
dodecylamine	124-22-1	NOEC	0,013 mg/l	21 d	daphnia magna	OECD Guideline 211	ECHA
dodecylamine	124-22-1	NOEC	0,0125 mg/l	3 d	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
dodecylamine	124-22-1	LOEC	0,032 mg/l	21 d	daphnia magna	OECD Guideline 211	ECHA
dodecylamine	124-22-1	LOEC	0,0313 mg/l	3 d	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
ethylene glycol	107-21-1	LC50	>1.500 mg/l	28 d	tidewater silverside (Menidia peninsulae)	-	ECHA

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Name of substance	CAS No	Endpoint	Value	Exposure time	Species	Method	Source
ethylene glycol	107-21-1	NOEC	>40 mg/l	28 d	tidewater silverside (<i>Menidia peninsulae</i>)	-	ECHA
ethylene glycol	107-21-1	NOEC	>100 mg/l	72 h	algae (<i>pseudokirchneriella subcapitata</i>)	-	ECHA
ethylene glycol	107-21-1	NOEC	8.590 mg/l	7 d	<i>Ceriodaphnia dubia</i> (water flea)	-	ECHA
ethylene glycol	107-21-1	growth (Eb-Cx) 20%	>1.995 mg/l	30 min	activated sludge, domestic	DIN EN ISO 8192	ECHA

12.2 Persistence and degradability

Biodegradation

The relevant substances of the mixture are readily biodegradable.

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
propan-2-ol	67-63-0	oxygen depletion	53 %	5 d	EU method C.5	ECHA
2-(2-but-oxyethoxy)ethanol	112-34-5	oxygen depletion	85 %	28 d	OECD Guideline 301 C	ECHA
2-propylheptanol ethoxylate	160875-66-1	oxygen depletion	>70 %	28 d	-	-
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	oxygen depletion	68 %	28 d	OECD Guideline 306	ECHA

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Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	carbon dioxide generation	20 %	6 d	-	ECHA
ethylene glycol	107-21-1	DOC removal	90 – 100 %	10 d	OECD Guideline 301 A	ECHA
ethylene glycol	107-21-1	oxygen depletion	≥83 %	14 d	OECD Guideline 301 C	ECHA

Persistence

No data available.

12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW
propan-2-ol	67-63-0	-	0,05 (20 °C)
2-(2-butoxyethoxy)ethanol	112-34-5	-	1 (pH value: 7, 20 °C)
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	3,16	4,46 (20 °C)

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Name of substance	CAS No	BCF	Log KOW
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	-	-	3,6 (pH value: 6,3, 20 °C)
alcohols, C12-15, ethoxylated	68131-39-5	12,7	-
ethylene glycol	107-21-1	-	-1,36

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

12.6 Endocrine disrupting properties

Contains an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

12.7 Other adverse effects

Data are not available.

Remarks

Wassergefährdungsklasse, WGK (water hazard class): 3

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

Completely emptied packages can be recycled.
Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions.

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SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN1903
IMDG-Code	UN1903
ICAO-TI	UN1903

14.2 UN proper shipping name

ADR/RID/ADN	DISINFECTANT, LIQUID, CORROSIVE, N.O.S.
IMDG-Code	DISINFECTANT, LIQUID, CORROSIVE, N.O.S.
ICAO-TI	Disinfectant, liquid, corrosive, n.o.s.
Technical name (hazardous ingredients)	Dialkylmethoxyethyl ammonium propionate

14.3 Transport hazard class(es)

ADR/RID/ADN	8
IMDG-Code	8
ICAO-TI	8

14.4 Packing group

ADR/RID/ADN	II
IMDG-Code	II
ICAO-TI	II

14.5 Environmental hazards

hazardous to the aquatic environment

Environmentally hazardous substance (aquatic environment) N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

14.6 Special precautions for user

-

14.7 Maritime transport in bulk according to IMO instruments

-

14.8 Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) Additional information

Particulars in the transport document	UN1903, DISINFECTANT, LIQUID, CORROSIVE, N.O.S., (Dialkylmethoxyethyl ammonium propionate), 8, II, (E), environmentally hazardous
Classification code	C9
Danger label(s)	8, fish and tree

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Environmental hazards	yes (hazardous to the aquatic environment)
Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	80

European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) Additional information

Number of cones/blue lights	0
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International Maritime Dangerous Goods Code (IMDG) Additional information

Marine pollutant	yes (hazardous to the aquatic environment) (N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine)
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Danger label(s)	8, fish and tree
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Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-A, S-B
Stowage category	B

International Civil Aviation Organization (ICAO-IATA/DGR) Additional information

Environmental hazards	yes (hazardous to the aquatic environment)
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Danger label(s)	8
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Special provisions (SP)	A3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	0,5 L

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SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	CAS No	Restriction
Biguaton forte Neu	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3
2-propylheptanol ethoxylate	substances in tattoo inks and permanent make-up	-	R75
alcohols, C12-15, ethoxylated	substances in tattoo inks and permanent make-up	-	R75
Reaction mass of 1-(3-((C12-18-(even numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even numbered))-alkyl-tetrahydropyrimidin-2(1H)-imine acetate salt	substances in tattoo inks and permanent make-up	-	R75
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	substances in tattoo inks and permanent make-up	-	R75
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	substances in tattoo inks and permanent make-up	-	R75
2-(2-butoxyethoxy)ethanol	2-(2-butoxyethoxy)ethanol (DEGBE)	112-34-5	R55
2-(2-butoxyethoxy)ethanol	substances in tattoo inks and permanent make-up	-	R75
dodecylamine	substances in tattoo inks and permanent make-up	-	R75
propan-2-ol	flammable / pyrophoric	-	R40
propan-2-ol	substances in tattoo inks and permanent make-up	-	R75

Legend

- R3 1. Shall not be used in:
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
 - tricks and jokes,
 - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
- can be used as fuel in decorative oil lamps for supply to the general public, and
 - present an aspiration hazard and are labelled with H304.

Legend

4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
- (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
- (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- R40
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
- metallic glitter intended mainly for decoration,
 - artificial snow and frost,
 - 'whoopie' cushions,
 - silly string aerosols,
 - imitation excrement,
 - horns for parties,
 - decorative flakes and foams,
 - artificial cobwebs,
 - stink bombs.
2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:
'For professional users only'.
3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.
- R55
1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by weight.
2. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.
3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that paints other than spray paints containing DEGBE in concentrations equal to or greater than 3 % by weight of that are placed on the market for supply to the general public are visibly, legibly and indelibly marked by 27 December 2010 as follows:
'Do not use in paint spraying equipment'.

Legend

- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
- (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
 - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
 - (ii) 0,01 % by weight, in all other cases;
 - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
 - (i) "Rinse-off products";
 - (ii) "Not to be used in products applied on mucous membranes";
 - (iii) "Not to be used in eye products";
 - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
 - (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
- (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
- (a) the statement "Mixture for use in tattoos or permanent make-up";

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Legend

- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
- (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100 200	56)

Notation

56) hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

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Regulation on the marketing and use of explosives precursors

None of the ingredients are listed.

Regulation on drug precursors

None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS)

None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC)

None of the ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 3
(water hazard class) - classification acc. to annex 1 (AwSV)

Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass concentration	Notation
5.2.5	organic substances	class I	5 - < 10 wt%	0,1 kg/h	20 mg/m ³	3)
5.2.5	organic substances	-	≥ 25 wt%	0,5 kg/h	50 mg/m ³	3)

Notation

3) a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m³, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK) 8 A
(combustible corrosive materials (except only corrosive to metals))

Other information

Observe employment restrictions for young people according to § 22 JArbSchG.
Observe occupational restrictions for mothers acc. to § 11 MuSchG!

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

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SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
AGW	Workplace exposure limit
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
Asp. Tox.	Aspiration hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EbC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule

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Abbr.	Descriptions of used abbreviations
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LGK	Lagerklasse (storage class according to TRGS 510, Germany)
LOEC	Lowest Observed Effect Concentration
log KOW	n-Octanol/water
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
NOELR	No Observed Effect Loading Rate
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)

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Abbr.	Descriptions of used abbreviations
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)
TRGS 903	Biologische Grenzwerte (TRGS 903)
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No. 1907/2006 (REACH).

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H225	Highly 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.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.

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Code	Text
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Responsible for the safety data sheet

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Disclaimer

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.

This safety data sheet is for information only and does not comply with the official language requirements of article 31 (5) of REACH.