

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11469310-00002	Date of first issue: 18.11.2024

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

1.1 Product identifier

Trade name : Betaine Formulation

Product code : Prevensa Aquador,Aquador

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

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Substances with a workplace exposure limit :			
DL-Methionine	59-51-8 200-432-1		>= 1 - < 10
Betaine	107-43-7 203-490-6		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.

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Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Silicon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal pro-

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ective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of

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engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dusts non-specific 4 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
Basis: IE OEL

10 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
DL-Methionine	59-51-8	TWA	5000 µg/m ³ (OEB 1)	Internal
Betaine	107-43-7	TWA	>= 100 < 1000 µg/m ³ (OEB2)	Internal
Silicon, amorphous	112945-52-5	OELV - 8 hrs (TWA) (Respirable dust)	2.4 mg/m ³ (Silica)	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	6 mg/m ³ (Silica)	IE OEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Betaine	Consumers	Ingestion	Acute systemic effects	11178 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4413 mg/kg bw/day

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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Betaine	Fresh water	1.2 mg/l

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Eye/face protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: powder
Colour	: brown
Odour	: characteristic
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available

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Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : partly soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : 0.45

Density : 0.45 g/cm³

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

DL-Methionine:

Acute oral toxicity	: LD50 (Rat): > 5,610 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 5.25 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity

Betaine:

Acute oral toxicity	: LD50 (Rat): 11,179 mg/kg Method: OECD Test Guideline 401
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Skin corrosion/irritation

Not classified based on available information.

Components:

DL-Methionine:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

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Betaine:

Species	: human skin
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

DL-Methionine:

Species	: Rabbit
Method	: OECD Test Guideline 405
Result	: No eye irritation

Betaine:

Species	: Rabbit
Method	: OECD Test Guideline 405
Result	: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

DL-Methionine:

Test Type	: Buehler Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406

Betaine:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Assessment	: Does not cause skin sensitisation.
Method	: OECD Test Guideline 406

Germ cell mutagenicity

Not classified based on available information.

Components:

DL-Methionine:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
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		Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials
		Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Betaine:

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Method: Directive 67/548/EEC, Annex V, B.10. Result: negative
		Test Type: Bacterial reverse mutation assay (AMES) Method: Directive 67/548/EEC, Annex, B.13/14 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Method: OECD Test Guideline 474 Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Betaine:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	104 weeks
Result	:	negative

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

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Repeated dose toxicity

Components:

DL-Methionine:

Species	: Rat, male
NOAEL	: $\geq 1,474$ mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Method	: OECD Test Guideline 408

Betaine:

Species	: Rat, female
NOAEL	: $> 5,771$ mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days
Method	: OECD Test Guideline 407

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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SECTION 12: Ecological information

12.1 Toxicity

Components:

DL-Methionine:

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): $> 3,200$ mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 324 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): $> 1,000$ mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction

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	Method: OECD Test Guideline 201
	EC10 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l
	Exposure time: 72 h
	Test substance: Water Accommodated Fraction
	Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC50 (Pseudomonas putida): 10,000 mg/l
	Exposure time: 18 h

Betaine:

Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 4,335 mg/l
	Exposure time: 48 h
	Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: NOEC (Desmodesmus subspicatus (green algae)): 312.5 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
	ErC50 (Desmodesmus subspicatus (green algae)): 1,199 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201

12.2 Persistence and degradability

Components:

DL-Methionine:

Biodegradability	: Result: Readily biodegradable.
	Biodegradation: 97 %
	Exposure time: 28 d
	Method: OECD Test Guideline 301A

Betaine:

Biodegradability	: Result: Readily biodegradable.
	Biodegradation: 88 %
	Exposure time: 28 d
	Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

DL-Methionine:

Partition coefficient: n-octanol/water	: log Pow: -2.41
	Remarks: Calculation

Betaine:

Partition coefficient: n-	: log Pow: -3.1
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||octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.2 UN proper shipping name

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ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.4 Packing group

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA (Cargo)	: Not regulated as a dangerous good
IATA (Passenger)	: Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks	: Not applicable for product as supplied.
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SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
Regulation (EC) on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EU) No 649/2012 of the European Parliament	: Not applicable

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ment and the Council concerning the export and import
of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable
(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.
Not applicable

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version
are highlighted in the body of this document by two vertical
lines.

Full text of H-Statements

Full text of other abbreviations

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-
pational Exposure Limit Values - Code of Practice, Schedule 1
and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland
Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by
Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-
ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-
tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard
of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -
European Chemicals Agency; EC-Number - European Community number; ECx - Concentration
associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-
cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-
sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good La-
boratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air
Transport Association; IBC - International Code for the Construction and Equipment of Ships car-
rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - Interna-
tional Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;
IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL
- Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization;
KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test popula-
tion; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - Interna-
tional Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified;

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NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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