

# SAFETY DATA SHEET



## Amprolium Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
8633863-00009

Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

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

#### 1.1 Product identifier

Trade name : Amprolium Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

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

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1 H314: Causes severe skin burns and eye damage.  
Serious eye damage, Category 1 H318: Causes serious eye damage.  
Reproductive toxicity, Category 2 H361: Suspected of damaging fertility or the unborn child.  
Specific target organ toxicity - repeated H372: Causes damage to organs through prolonged or repeated exposure, Category 1

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 8633863-00009	Date of last issue: 06.07.2024 Date of first issue: 21.05.2021
----------------	------------------------------	------------------------------	---

H361 Suspected of damaging fertility or the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Amprolium

### 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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Amprolium	121-25-5 204-458-4	Repr. 2; H361 STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412	>= 20 - < 25

For explanation of abbreviations see section 16.

**Amprolium Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
8633863-00009Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

---

**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 : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention immediately.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention immediately.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting.  
If vomiting occurs have person lean forward.  
Call a physician or poison control centre immediately.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

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

Risks : Causes digestive tract burns.  
  
Causes serious eye damage.  
Suspected of damaging fertility or the unborn child.  
Causes damage to organs through prolonged or repeated exposure.  
Causes severe burns.

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

Treatment : Treat symptomatically and supportively.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray

**Amprolium Formulation**

Version 3.0	Revision Date: 14.04.2025	SDS Number: 8633863-00009	Date of last issue: 06.07.2024 Date of first issue: 21.05.2021
----------------	------------------------------	------------------------------	---

Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
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.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective 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.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
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 deter-

**Amprolium Formulation**

Version 3.0	Revision Date: 14.04.2025	SDS Number: 8633863-00009	Date of last issue: 06.07.2024 Date of first issue: 21.05.2021
----------------	------------------------------	------------------------------	---

mine 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.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. 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 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 locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

**7.3 Specific end use(s)**

Specific use(s)	: No data available
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**Amprolium Formulation**

Version 3.0 Revision Date: 14.04.2025 SDS Number: 8633863-00009 Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amprolium	121-25-5	TWA	40 ug/m3 (OEB 3)	Internal
		Further information: DSEN		
		Wipe limit	140 ug/100cm <sup>2</sup>	Internal

**8.2 Exposure controls****Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

**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
Remarks	: Consider double gloving.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Particulates type (P)

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance	: liquid
Colour	: light yellow
Odour	: No data available
Odour Threshold	: No data available

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 8633863-00009      Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

---

pH	:	2,0 - 3,0
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	0,900 - 1,100 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 8633863-00009 Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

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### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

#### Acute toxicity

||| Not classified based on available information.

#### Components:

##### **Amprolium:**

||| Acute oral toxicity : LD50 (Mouse): 3.980 mg/kg  
||| : LD50 (Rat): 4.000 - 4.890 mg/kg  
||| : LD50 (Dog): > 500 mg/kg  
||| Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

#### **Skin corrosion/irritation**

||| Causes severe burns.

#### Components:

##### **Amprolium:**

||| Species : Rabbit  
||| Result : No skin irritation

#### **Serious eye damage/eye irritation**

||| Causes serious eye damage.

#### Components:

##### **Amprolium:**

||| Species : Rabbit  
||| Result : No eye irritation

**Amprolium Formulation**

Version 3.0      Revision Date: 14.04.2025      SDS Number: 8633863-00009      Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021

---

**Respiratory or skin sensitisation****Skin sensitisation**

||| Not classified based on available information.

**Respiratory sensitisation**

||| Not classified based on available information.

**Components:****Amprolium:**

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Dermal
Species	:	Mouse
Result	:	Sensitiser

**Germ cell mutagenicity**

||| Not classified based on available information.

**Components:****Amprolium:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive
		Test Type: in vitro micronucleus test Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative
		Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

||| Not classified based on available information.

**Components:****Amprolium:**

Species	:	Rat
Exposure time	:	2 Years
Result	:	negative

**Amprolium Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
8633863-00009Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021**Reproductive toxicity****|| Suspected of damaging fertility or the unborn child.****Components:****Amprolium:**

Effects on fertility	: Test Type: Multi-generation study Species: Mouse Application Route: Oral Fertility: NOAEL: 200 mg/kg body weight Result: Effects on reproduction parameters Remarks: Maternal toxicity observed.
Effects on foetal development	: Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 200 mg/kg body weight Result: No significant adverse effects were reported
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

**STOT - single exposure****|| Not classified based on available information.****STOT - repeated exposure****|| Causes damage to organs through prolonged or repeated exposure.****Components:****Amprolium:**

Exposure routes	: Oral
Target Organs	: Central nervous system
Assessment	: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Amprolium:**

Species	: Rat
NOAEL	: 20 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Symptoms	: Reduced body weight

Species	: Dog
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: Central nervous system
Symptoms	: Dilatation of the pupil, paralysis

**|| Species : Dog**

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 8633863-00009 Date of last issue: 06.07.2024 Date of first issue: 21.05.2021

---

NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 59 Weeks
Target Organs	: Central nervous system
Symptoms	: ataxia, Convulsions, Coma, Loss of reflexes, Tremors

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Amprolium:

Inhalation	: Target Organs: Skin Symptoms: Allergic reactions
Eye contact	: Target Organs: Lungs Symptoms: Allergic reactions, Asthma
Ingestion	: Target Organs: Central nervous system Symptoms: Neurological disorders

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Amprolium:

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 110 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### Amprolium:

Partition coefficient: n-octanol/water	: log Pow: -1,12 pH: 7
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### 12.4 Mobility in soil

No data available

**Amprolium Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
8633863-00009Date of last issue: 06.07.2024  
Date of first issue: 21.05.2021**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 Other adverse effects****Product:**

Endocrine disrupting potential

: 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.

**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**

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA</b>	: Not regulated as a dangerous good

**14.2 UN proper shipping name**

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA</b>	: Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 8633863-00009 Date of last issue: 06.07.2024 Date of first issue: 21.05.2021

---

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.4 Packing group

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA (Cargo)</b>	:	Not regulated as a dangerous good
<b>IATA (Passenger)</b>	:	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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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

<b>AICS</b>	:	not determined
<b>DSL</b>	:	not determined
<b>IECSC</b>	:	not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## 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

<b>H361</b>	:	Suspected of damaging fertility or the unborn child.
<b>H372</b>	:	Causes damage to organs through prolonged or repeated

# SAFETY DATA SHEET



## Amprolium Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 8633863-00009	Date of last issue: 06.07.2024 Date of first issue: 21.05.2021
----------------	------------------------------	------------------------------	---

H412 : exposure if swallowed.  
Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Chronic	: Long-term (chronic) aquatic hazard
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (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 - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International 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; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 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/>

### Classification of the mixture:

Skin Corr. 1	H314
Eye Dam. 1	H318
Repr. 2	H361
STOT RE 1	H372

### Classification procedure:

Based on product data or assessment
Based on product data or assessment
Calculation method
Calculation method

# SAFETY DATA SHEET



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---

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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