

Desloratadine Solid Formulation

Version 2.3 Revision Date: 09/13/2019 SDS Number: 49990-00012 Date of last issue: 15.05.2019
 Date of first issue: 23.01.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Desloratadine Solid Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : MSD
 117 16th Road
 07033 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

Telefax : 908-735-1496

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)**

Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :  

Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
 H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
 H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 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.

Storage:
 P405 Store locked up.

Hazardous components which must be listed on the label:
 Desloratadine

2.3 Other hazards

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)
Desloratadine	100643-71-8	Acute Tox.4; H302 Eye Dam.1; H318 Repr.2; H361fd Aquatic Chronic2; H411	>= 3 - < 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 : 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.

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- Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
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.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes serious eye damage.
Suspected of damaging fertility. Suspected of damaging the unborn child.
- Contact with dust can cause mechanical irritation or drying of the skin.

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
Metal oxides
Oxides of phosphorus

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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 and personal protective equipment recommendations.

6.2 Environmental precautions

- Environmental precautions : Discharge into the environment must be avoided. 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.
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- Advice on safe handling : Do not breathe dust.
 Do not swallow.
 Do not get in eyes.
 Avoid prolonged or repeated contact with skin.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 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.

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

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**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m ³	ZA OEL
Further information	Recommended Limit			
		TWA OEL-RL (inhalable dust)	10 mg/m ³	ZA OEL
Further information	Recommended Limit			
		STEL OEL-RL (Dust)	20 mg/m ³	ZA OEL
Further information	Recommended Limit			
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
Talc	14807-96-6	TWA OEL-RL (Respirable dust)	1 mg/m ³	ZA OEL
Further information	Recommended Limit			

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		TWA OEL-RL (inhalable dust)	10 mg/m ³	ZA OEL
Further information	Recommended Limit			
Titanium dioxide	13463-67-7	TWA OEL-RL (Respirable dust)	5 mg/m ³	ZA OEL
Further information	Recommended Limit			
		TWA OEL-RL (inhalable dust)	10 mg/m ³	ZA OEL
Further information	Recommended Limit			

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Titanium dioxide	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	700 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Titanium dioxide	Fresh water	0,184 mg/l
	Marine water	0,0184 mg/l
	Intermittent use/release	0,193 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	1000 mg/kg
	Marine sediment	100 mg/kg
	Soil	100 mg/kg

8.2 Exposure controls**Engineering measures**

Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Eye protection : Wear the following personal protective equipment:
 Chemical resistant goggles must be worn.
 If splashes are likely to occur, wear:
 Face-shield

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

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Skin and body protection	:	end of workday. Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
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	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
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)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

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Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : 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

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 toxicological effects**

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

Acute toxicity

Not classified based on available information.

Product:

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Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:**Desloratadine:**

Acute oral toxicity : LD50 (Rat): > 549 mg/kg
LD50 (Mouse): 353 mg/kg
LD50 (Monkey): > 250 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.

Skin corrosion/irritation

Not classified based on available information.

Components:**Desloratadine:**

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**Desloratadine:**

Species : Rabbit
Remarks : Severe eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Desloratadine:**

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**Desloratadine:**

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Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Desloratadine:**

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : Oral
LOAEL : 10 mg/kg body weight
Result : equivocal
Target Organs : Liver
Remarks : Based on data from similar materials
The mechanism or mode of action may not be relevant in humans.

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:**Desloratadine:**

Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 12 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility
Species: Rat, female
Fertility: NOAEL: 3 mg/kg body weight
Symptoms: No effects on fertility
Result: negative

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Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 30 mg/kg body weight
 Result: No teratogenic effects

Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 9 mg/kg body weight
 Symptoms: Preimplantation loss, Reduced body weight
 Result: Specific developmental abnormalities
 Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 18 mg/kg body weight
 Result: No adverse effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Desloratadine:**

Species : Rat
 LOAEL : 30 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Kidney
 Remarks : Significant toxicity observed in testing
 The mechanism or mode of action may not be relevant in humans.

Species : Monkey
 NOAEL : 6 mg/kg
 LOAEL : 12 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Central nervous system
 Symptoms : Gastrointestinal disturbance

Species : Monkey

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NOAEL : 40 mg/kg
 Application Route : Oral
 Exposure time : 17 Months
 Remarks : No significant adverse effects were reported

Species : Monkey
 NOAEL : 6 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Symptoms : Gastrointestinal disturbance, Fatigue

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Desloratadine:**

Inhalation : Remarks: May cause respiratory tract irritation.
 Eye contact : Symptoms: Eye irritation
 Ingestion : Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

SECTION 12: Ecological information**12.1 Toxicity****Components:****Desloratadine:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 9,2 mg/l
 Exposure time: 96 h
 Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,6 mg/l
 Exposure time: 48 h
 Method: FDA 4.08

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 1,6 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,36 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Natural microorganism): 53,7 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

NOEC (Natural microorganism): 12 mg/l

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Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,12 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,48 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability**Components:****Desloratadine:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 67,4 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: FDA 3.11

Stability in water : Hydrolysis: < 10 % at 50 °C(5 d)
Method: FDA 3.09

12.3 Bioaccumulative potential**Components:****Desloratadine:**

Partition coefficient: n-octanol/water : log Pow: 1,24
Method: OECD Test Guideline 107

12.4 Mobility in soil**Components:****Desloratadine:**

Distribution among environmental compartments : log Koc: 3,00
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

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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.
- 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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

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.

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:

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

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are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302 : Harmful if swallowed.
 H318 : Causes serious eye damage.
 H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.
 H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
 Aquatic Chronic : Long-term (chronic) aquatic hazard
 Eye Dam. : Serious eye damage
 Repr. : Reproductive toxicity
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
 ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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; KECI - 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; 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

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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:

Eye Dam. 1	H318
Repr. 2	H361fd
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method
Calculation method

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.

ZA / EN