

SAFETY DATA SHEET



Dihydrostreptomycin Sulfate Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
5918691-00014

Date of last issue: 11.02.2025
Date of first issue: 20.05.2020

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

1.1 Product identifier

Trade name : Dihydrostreptomycin Sulfate 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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 : H319: Causes serious eye irritation.

Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.
H372 Causes damage to organs through prolonged or repeated exposure.

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Precautionary statements

Prevention:

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection/ face protection.

Response:

P314 Get medical advice/ attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Dihydrostreptomycin sulphate

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)
Dihydrostreptomycin sulphate	5490-27-7 226-823-7	STOT RE 1; H372 (ear, Kidney, inner ear)	>= 30 - < 50
Sodium metabisulphite	7681-57-4 231-673-0 016-063-00-2	Acute Tox. 4; H302 Eye Dam. 1; H318	>= 1 - < 3

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.
Get medical attention if symptoms occur.

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In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

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.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.
Causes damage to organs through prolonged or repeated exposure.

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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Sulphur oxides
Metal 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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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 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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
Do not breathe decomposition products.

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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 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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m ³ (OEB 1)	
	Further information: OTO			
Sodium metabisulphite	7681-57-4	OEL-RL	10 mg/m ³	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sulphur dioxide	7446-09-5	OEL- RL STEL/C	0,5 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		TWA	0,5 ppm 1,3 mg/m ³	2017/164/EU
		STEL	1 ppm 2,7 mg/m ³	2017/164/EU

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

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Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium metabisulphite	Workers	Inhalation	Long-term systemic effects	225 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	66 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	8,6 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Sodium metabisulphite	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Sewage treatment plant	75,4 mg/l

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.

Laboratory operations do not require special containment.

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.

Filter type : Combined particulates and inorganic gas/vapour type (B-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : No data available

Colour : No data available

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

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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	: 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	: 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

Molecular weight	: No data available
Particle size	: Not applicable

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 : Can react with strong oxidizing agents.
Hazardous decomposition products will be formed at elevated

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temperatures.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

Thermal decomposition : Sulphur dioxide

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:

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

Components:

Dihydrostreptomycin sulphate:

||| Acute oral toxicity : LD50 (Rat): 9.000 - 25.000 mg/kg
LD50 Oral (Mouse): 30.000 mg/kg

Sodium metabisulphite:

||| Acute oral toxicity : LD50 (Rat): 1.540 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5,5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation

||| Not classified based on available information.

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Components:**Sodium metabisulphite:**

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Serious eye damage/eye irritation

||| Causes serious eye irritation.

Components:**Sodium metabisulphite:**

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irreversible effects on the eye

Respiratory or skin sensitisation**Skin sensitisation**

||| Not classified based on available information.

Respiratory sensitisation

||| Not classified based on available information.

Components:**Sodium metabisulphite:**

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative

Germ cell mutagenicity

||| Not classified based on available information.

Components:**Dihydrostreptomycin sulphate:**

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Result: negative
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Sodium metabisulphite:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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Species: Mouse
Application Route: Subcutaneous
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:**Dihydrostreptomycin sulphate:**

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 5 mg/kg body weight
Result : negative

Sodium metabisulphite:

Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
Result : negative
Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:**Dihydrostreptomycin sulphate:**

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-foetal development
Species: Guinea pig
Application Route: Intramuscular
General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.

Sodium metabisulphite:

Effects on fertility : Test Type: Three-generation study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit

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Application Route: Ingestion
Result: negative

STOT - single exposure

||| Not classified based on available information.

STOT - repeated exposure

||| Causes damage to organs through prolonged or repeated exposure.

Components:

Dihydrostreptomycin sulphate:

||| Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Dihydrostreptomycin sulphate:

||| Species : Guinea pig
||| LOAEL : 40 mg/kg
||| Application Route : Oral
||| Exposure time : 90 d
||| Target Organs : ear
||| Symptoms : hearing loss

||| Species : Cat
||| LOAEL : 100 mg/kg
||| Application Route : Oral
||| Exposure time : 60 d
||| Target Organs : ear
||| Symptoms : ataxia, hearing loss, Reduced body weight

||| Species : Cat
||| LOAEL : 300 mg/kg
||| Application Route : Oral
||| Exposure time : 21 d
||| Target Organs : ear
||| Symptoms : ataxia, hearing loss, Reduced body weight

Sodium metabisulphite:

||| Species : Rat
||| NOAEL : 110 mg/kg
||| LOAEL : 220 mg/kg
||| Application Route : Ingestion
||| Exposure time : 104 Weeks

Aspiration toxicity

||| Not classified based on available information.

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General Information	: Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension
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SECTION 12: Ecological information**12.1 Toxicity****Components:****Sodium metabisulphite:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 89 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): 43,8 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 33,3 mg/l Exposure time: 72 h
Toxicity to microorganisms	: EC10 (Pseudomonas putida): 30,8 mg/l Exposure time: 17 h
Toxicity to fish (Chronic toxicity)	: NOEC: >= 316 mg/l Exposure time: 34 d Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: >= 10 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

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
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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**

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

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

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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 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:

DSL : not determined

AICS : 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

H302 : Harmful if swallowed.

H318 : Causes serious eye damage.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Eye Dam. : Serious eye damage

STOT RE : Specific target organ toxicity - repeated exposure

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2017/164/EU	:	Europe. Commission Directive 2017/164/EU establishing a fourth list of indicative occupational exposure limit values
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
2017/164/EU / STEL	:	Short term exposure limit
2017/164/EU / TWA	:	Limit Value - eight hours
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
ZA OEL / OEL- RL STEL/C	:	Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

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:

Eye Irrit. 2	H319
STOT RE 1	H372

Classification procedure:

Calculation method
Calculation method

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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.

ZA / EN