according to GB/T 16483 and GB/T 17519



## **Dihydrostreptomycin Sulfate Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 5918677-00010 Date of first issue: 2020/05/20

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dihydrostreptomycin Sulfate Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

Appearance:No data availableColour:No data availableOdour:No data available

Causes serious eye irritation. Causes damage to organs through prolonged or repeated expo-

sure.

tation

**GHS Classification** 

Serious eye damage/eye irri-

11-

: Category 2A

Specific target organ toxicity - :

0 .

repeated exposure

**GHS** label elements

Hazard pictograms



Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.

according to GB/T 16483 and GB/T 17519



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H372 Causes damage to organs through prolonged or repeated

exposure.

Precautionary statements : **Prevention:** 

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P314 Get medical advice/ attention if you feel unwell.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### **Health hazards**

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

### **Environmental hazards**

Not classified based on available information.

#### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Dihydrostreptomycin sulphate	5490-27-7	>= 30 -< 50
Sodium metabisulphite	7681-57-4	>= 1 -< 2.5

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

according to GB/T 16483 and GB/T 17519



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Get medical attention if symptoms occur.

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, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Causes serious eye irritation.

Causes damage to organs through prolonged or repeated

exposure.

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).

Notes to physician : Treat symptomatically and supportively.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides Sulphur oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

according to GB/T 16483 and GB/T 17519



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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.

Methods and materials for containment and 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 absor-

bent.

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-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. 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 as-

sessment

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.

Avoidance of contact : Oxidizing agents

**Storage** 

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

according to GB/T 16483 and GB/T 17519



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Dihydrostreptomycin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)		
	Further information: OTO				
		Wipe limit	Not required		
Sodium metabisulphite	7681-57-4	TWA	5 mg/m3	ACGIH	

### Occupational exposure limits of decomposition products

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Sulphur dioxide	7446-09-5	PC-TWA	5 mg/m3	CN OEL
		PC-STEL	10 mg/m3	CN OEL
		STEL	0.25 ppm	ACGIH

**Engineering measures** 

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to pre-

vent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems

are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and inorganic gas/vapour type 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.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

according to GB/T 16483 and GB/T 17519



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Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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.

### 9. 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

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

according to GB/T 16483 and GB/T 17519



## **Dihydrostreptomycin Sulfate Formulation**

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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.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Hazardous decomposition products will be formed at elevated

temperatures.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition products

Thermal decomposition : Sulphur dioxide

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

according to GB/T 16483 and GB/T 17519



## **Dihydrostreptomycin Sulfate Formulation**

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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.

### **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

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

### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### **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

### Sodium metabisulphite:

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

Result: negative

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) 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

according to GB/T 16483 and GB/T 17519



## **Dihydrostreptomycin Sulfate Formulation**

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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 develop- : Test Type: Embryo-foetal development

ment 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 develop-

Lifects off foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

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.

according to GB/T 16483 and GB/T 17519



## **Dihydrostreptomycin Sulfate Formulation**

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### 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.

### **Experience with human exposure**

### **Components:**

### Dihydrostreptomycin sulphate:

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting,

Headache, hypotension

### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

#### Sodium metabisulphite:

according to GB/T 16483 and GB/T 17519



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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 fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): >= 316 mg/l

Exposure time: 34 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): >= 10 mg/l

Exposure time: 21 d

Toxicity to microorganisms : EC10 (Pseudomonas putida): 30.8 mg/l

Exposure time: 17 h

### Persistence and degradability

No data available

### Bioaccumulative potential

No data available

### Mobility in soil

No data available

### Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

#### **International Regulations**

**UNRTDG** 

UN number : Not applicable

according to GB/T 16483 and GB/T 17519



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Proper shipping name : Not applicable Class : Not applicable Subsidiary risk : Not applicable Packing group : Not applicable Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

**IMDG-Code** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable

Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **National Regulations**

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Marine pollutant : no

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

**Regulations on Safety Management of Hazardous Chemicals** 

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

according to GB/T 16483 and GB/T 17519



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> logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import Not listed

and Export

**Regulation on the Administration of Precursor Chemicals** 

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

DSL not determined

**AICS** not determined

**IECSC** not determined

16. OTHER INFORMATION

**Revision Date** 2024/09/28

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 Agen-

cy, 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.

Date format : yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

according to GB/T 16483 and GB/T 17519



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CN OEL : Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

CN OEL / PC-TWA : Permissible concentration - time weighted average CN OEL / PC-STEL : Permissible concentration - short term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

#### **Disclaimer**

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.

CN / EN