

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone (with Ethanol) 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

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

<b>Appearance</b>	: liquid
<b>Colour</b>	: clear
<b>Odour</b>	: No data available

Combustible liquid.

#### GHS Classification

Flammable liquids : Category 4

#### GHS label elements

Hazard pictograms : None

Signal word : Warning

Hazard statements : H227 Combustible liquid.

Precautionary statements :

#### Prevention:

P210 Keep away from heat/ sparks/ open flames/ hot surfaces.  
No smoking.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

### Physical and chemical hazards

Combustible liquid.

### Health hazards

Not classified based on available information.

### Environmental hazards

Not classified based on available information.

### Other hazards which do not result in classification

Vapours may form explosive mixture with air.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	$\geq 1$ -< 10
Dexamethasone	50-02-2	$\geq 0.1$ -< 0.25

# Voluntarily-disclosed non-hazardous substance

## 4. 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.
- If inhaled : If inhaled, remove to fresh air.  
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 : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : None known.
- 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

Unsuitable extinguishing media	:	Carbon dioxide (CO <sub>2</sub> ) Dry chemical High volume water jet
Specific hazards during fire-fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

### 7. HANDLING AND STORAGE

#### 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 vapours or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

#### Storage

- Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
Dexamethasone	50-02-2	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/03/23
2.10	2020/10/10	752031-00012	Date of first issue: 2016/06/14

---

Filter type	:	Combined particulates and organic vapour type
Eye/face protection	:	Wear the following personal protective equipment: Safety glasses
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Wear the following personal protective equipment: If assessment demonstrates that there is a risk of explosive atmospheres or flash fires, use flame retardant antistatic protective clothing. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
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. Take note that the product is flammable, which may impact the selection of hand protection. Wash hands before breaks and at the end of workday.
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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	4.9
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	68 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

Flammability (liquids) : Not applicable

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

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

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 size : No data available

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Combustible liquid.  
Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### Ethanol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

#### Dexamethasone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 14 mg/kg  
Application Route: Subcutaneous

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Ethanol:

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

#### Dexamethasone:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Ethanol:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

#### Dexamethasone:

Species : Rabbit  
Result : Mild eye irritation

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Ethanol:

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

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Ethanol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

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

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: equivocal

##### Dexamethasone:

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

Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

### Components:

#### **Ethanol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

#### **Dexamethasone:**

Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 6 mg/kg body weight  
Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 0.025 mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL:  $\geq$  0.062 mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL:  $\geq$  0.02 mg/kg body weight  
Result: Skeletal and visceral variations, Retardations

Reproductive toxicity - Assessment : May damage the unborn child.

#### **STOT - single exposure**

Not classified based on available information.

#### **STOT - repeated exposure**

Not classified based on available information.

### Components:

#### **Dexamethasone:**

Exposure routes : Oral  
Target Organs : Adrenal gland, Immune system, thymus gland  
Assessment : May cause damage to organs through prolonged or repeated exposure.

#### **Repeated dose toxicity**

### Components:

#### **Ethanol:**

Species : Rat  
NOAEL : 1,280 mg/kg

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

LOAEL : 3,156 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### Dexamethasone:

Species : Rat  
NOAEL : 0.0015 mg/kg  
Application Route : Oral  
Exposure time : 7 d  
Target Organs : Liver  
Remarks : Significant toxicity observed in testing

Species : Rat  
LOAEL : 0.003 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Target Organs : Blood, Adrenal gland, thymus gland  
Remarks : Significant toxicity observed in testing

Species : Rat  
LOAEL : 0.125 mg/kg  
Application Route : Oral  
Exposure time : 6 Weeks  
Target Organs : Adrenal gland  
Remarks : Significant toxicity observed in testing

Species : Rat  
LOAEL : 0.4 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing

Species : Dog  
LOAEL : 8 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Dexamethasone:

Ingestion : Target Organs: Immune system  
Target Organs: Adrenal gland  
Target Organs: Bone  
Symptoms: muscle weakness

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Ethanol:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
Exposure time: 72 h
- EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
Exposure time: 72 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 9 d
- Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l  
Exposure time: 16 h

##### **Dexamethasone:**

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 56 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- M-Factor (Chronic aquatic toxicity) : 1
- Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- NOEC: 1,000 mg/l  
Exposure time: 3 h

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version 2.10      Revision Date: 2020/10/10      SDS Number: 752031-00012      Date of last issue: 2020/03/23  
Date of first issue: 2016/06/14

---

Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

##### **Dexamethasone:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 3.54 d  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

##### **Ethanol:**

Partition coefficient: n-octanol/water : log Pow: -0.35

##### **Dexamethasone:**

Partition coefficient: n-octanol/water : log Pow: 1.83

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Empty containers retain residue and can be dangerous.  
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.  
If not otherwise specified: Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG

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# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/03/23
2.10	2020/10/10	752031-00012	Date of first issue: 2016/06/14

Not regulated as a dangerous good

### IATA-DGR

Not regulated as a dangerous good

### IMDG-Code

Not regulated as a dangerous good

### 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

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 16. OTHER INFORMATION

### 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/>

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / STEL : Short-term exposure limit

AllC - 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 Sys-

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Dexamethasone (with Ethanol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/03/23
2.10	2020/10/10	752031-00012	Date of first issue: 2016/06/14

---

tem; 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; 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.

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