

**Dexamethasone (with Ethanol) Formulation**

Version 3.0      Revision Date: 2023/04/04      SDS Number: 752034-00016      Date of last issue: 2022/10/01  
Date of first issue: 2016/06/14

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Dexamethasone (with Ethanol) Formulation

**Manufacturer or supplier's details**

Company : MSD  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone number : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

|| No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

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

Vapours may form explosive mixture with air.

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	< 10
Dexamethasone	50-02-2	>= 0.025 -< 0.25

# Voluntarily-disclosed substance

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**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

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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.

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### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : 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).

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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 : 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.

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### 7. HANDLING AND STORAGE

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.

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

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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
Ethanol	64-17-5	PSD	1,000 ppm	ID OEL
	Further information: Confirmed animal carcinogen.			
		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.

Filter type : Combined particulates and organic vapour type

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.

Eye 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).

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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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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
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

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|| 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**

Information on likely routes of exposure : Inhalation  
Skin contact  
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

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### 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

### 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
Genotoxicity in vivo	: 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)
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	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.

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

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.



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### 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  
 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

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### 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

## 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

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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 Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Ethanol:**

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

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

#### Components:

##### **Ethanol:**

Partition coefficient: n-octanol/water	:	log Pow: -0.35
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##### **Dexamethasone:**

Partition coefficient: n-octanol/water	:	log Pow: 1.83
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##### **Mobility in soil**

No data available

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

No data available

## 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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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

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

##### 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 aircraft) : Not applicable  
Packing instruction (passenger 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 : Not applicable

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

Not applicable for product as supplied.

#### Special precautions for user

Not applicable

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### 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

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**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Ethanol

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### 16. OTHER INFORMATION

Revision Date : 2023/04/04

**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/>

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)

ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / STEL : Short-term exposure limit

ID OEL / PSD : Short term exposure limit

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AIIIC - 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; TECl - 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

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.

ID / EN