

**Dexamethasone (with Ethanol) Formulation**

Version 4.1      Revision Date: 2023/04/04      SDS Number: 752037-00016      Date of last issue: 2022/10/01  
Date of first issue: 2016/06/14

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Dexamethasone (with Ethanol) Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

**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 of chemical product**

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

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

Important symptoms and outlines of the emergency assumed : 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)	ENCS No.
Ethanol#	64-17-5	>= 1 - < 10	2-202
Dexamethasone	50-02-2	>= 0.1 - < 0.25	

# Voluntarily-disclosed 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  
 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 prod- : Carbon oxides

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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.

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### 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

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- 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  
 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.
- 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

#### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / 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.
- Filter type : Combined particulates and organic vapour type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Choose gloves to protect hands against chemicals depending

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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).

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : clear

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Up- : No data available  
per flammability limit

Lower explosion limit /  
Lower flammability limit : No data available

Flash point : 68 °C

Decomposition temperature : No data available

pH : 4.9

Evaporation rate : No data available



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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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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**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.

**Components:****Ethanol:**

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

**Dexamethasone:**



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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  
 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

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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

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
 Exposure time: 96 h

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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  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

#### **Ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %

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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

**Hazardous to the ozone layer**

Not applicable

**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.  
Do not dispose of waste into sewer.

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**

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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.

### National Regulations

Refer to section 15 for specific national regulation.

### Special precautions for user

Not applicable

**ERG Code** : 128

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Designated Flammable Substances, Flammable liquid, (2 cubic metre)

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

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### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Ethanol	>=1 - <10	-

### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Ethanol	-

### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

### Ordinance on Prevention of Lead Poisoning

Not applicable

### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

### Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

### Poisonous and Deleterious Substances Control Law

Not applicable

### Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

#### Until March 31st, 2023

Not applicable

#### From April 1st, 2023

Not applicable

### High Pressure Gas Safety Act

Not applicable

### Explosive Control Law

Not applicable

### Vessel Safety Law

Not regulated as a dangerous good

### Aviation Law

Not regulated as a dangerous good

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**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)  
Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable  
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

**Waste Disposal and Public Cleansing Law**

Specially Controlled Industrial Waste

**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****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

AIC - 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); EC<sub>x</sub> - Concentration associated with x% response; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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; NZoC - New

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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.

JP / EN