

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Dexamethasone Formulation

Version
4.0

Revision Date:
2025/06/17

SDS Number:
1842875-00017

Date of last issue: 2025/04/14
Date of first issue: 2017/07/20

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone Formulation

Other means of identification : DEXAFORT AQUEOUS SUSPENSION OF DEXAMETHASONE AS MIXED ESTERS (37231)

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 : suspension
Colour : white to off-white

May cause an allergic skin reaction. May damage the unborn child. Harmful to aquatic life with long lasting effects.

GHS Classification

Skin sensitisation : Category 1

Reproductive toxicity : Category 1B

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



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Signal word	:	Danger
Hazard statements	:	H317 May cause an allergic skin reaction. H360D May damage the unborn child. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P203 Obtain, read and follow all safety instructions before use. P261 Avoid breathing mist or vapours. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. Response: P318 If exposed or concerned, get medical advice. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P333 + P317 If skin irritation or rash occurs: Get medical help. P362 + P364 Take off contaminated clothing and wash it before reuse. Storage: P405 Store locked up. Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

May cause an allergic skin reaction. May damage the unborn child.

Environmental hazards

Harmful to aquatic life with long lasting effects.

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)
Benzyl alcohol	100-51-6	>= 1 -< 10
Dexamethasone	50-02-2	>= 0.3 -< 1

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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 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 | : May cause an allergic skin reaction.
May damage the unborn child. |
| 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 ₂)
Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire-fighting | : Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon oxides
Metal 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 | : In the event of fire, wear self-contained breathing apparatus. |

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for firefighters

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : 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 : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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. Avoid breathing mist or vapours. 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. Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

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Storage

- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
dexamethasone	50-02-2	TWA	10 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm ²	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

- 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.
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. 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 work-

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ing place.
When using do not eat, drink or smoke.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	white to off-white
Odour Threshold	:	No data available
pH	:	7.0 - 7.8
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
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

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Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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
	:	Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity

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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:

Benzyl alcohol:

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:

Benzyl alcohol:

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

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans

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Result	:	positive
Assessment	:	Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl alcohol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

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.

Components:

Benzyl alcohol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

Reproductive toxicity

May damage the unborn child.

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Components:

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
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: >= 0.062 mg/kg body weight
Result: Specific developmental abnormalities

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight
Result: Skeletal and visceral variations, Fetal growth retardation

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

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Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Benzyl alcohol:

Species	:	Rat
NOAEL	:	1.072 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

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	:	Dog
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:

Benzyl alcohol:

- | | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211 |

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 |

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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:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

dexamethasone:

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

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

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

Mobility in soil

No data available

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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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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
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 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 : no

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

Not applicable for product as supplied.

National Regulations

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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 catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

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 and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

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

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import : Not listed
and Export

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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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

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 Con-

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centration 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