according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Posaconazole Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 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 : Pharmaceutical Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : Aqueous solution Colour : Colorless to pale yellow

Odour : odourless

May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

GHS Classification

Skin sensitisation : Category 1

Specific target organ toxicity - : Category 2

repeated exposure

Short-term (acute) aquatic

: Category 3

hazard

Long-term (chronic) aquatic

Category 3

hazard

GHS label elements

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Hazard pictograms :





Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

H373 May cause damage to organs through prolonged or re-

peated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

P260 Do not breathe 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.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P314 Get medical advice/ attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

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 cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Harmful to aquatic life. 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)	
.betaCyclodextrin, sulfobutyl ethers, sodium	182410-00-0	>= 30 -< 50	
salts			

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Posaconazole | 171228-49-2 | >= 1 -< 2.5

4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

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.
: Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

In case of eye contact

delayed

Diarrhoea Fever Headache

Nausea Vomiting

May cause an allergic skin reaction.

May cause damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

uete

ucts

Sulphur oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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

Take care to prevent spills, waste and minimize release to the

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

environment.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Posaconazole	171228-49-2	TWA	300 μg/m3 (OEB 2)	Internal

Engineering measures: Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

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

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection

Hand protection Material Work uniform or laboratory coat.

: Chemical-resistant gloves

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

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : Colorless to pale yellow

Odour : odourless

Odour Threshold : No data available

pH : 2.6

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.15 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

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 : Not applicable

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition

products

Oxidizing agents

: 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.

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Acute oral toxicity : LD50 (Rat): > 8,800 mg/kg

Posaconazole:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

LD50 (Mouse): > 3,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Components:

Posaconazole:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Posaconazole:

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:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Assessment : Probability or evidence of skin sensitisation in humans

Posaconazole:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Posaconazole:

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

Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Intravenous

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Posaconazole:

Species : Rat
Application Route : oral (feed)
Exposure time : 2 Years
Result : positive

Remarks : The mechanism or mode of action is not relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : positive

Remarks : The mechanism or mode of action is not relevant in humans.

Reproductive toxicity

Not classified based on available information.

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Intravenous injection

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Result: negative

Posaconazole:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male

General Toxicity - Parent: NOAEL: 180 mg/kg body weight

Symptoms: No effects on mating performance

Result: negative

Test Type: Fertility/early embryonic development

Species: Rat, female

General Toxicity - Parent: NOAEL: 45 mg/kg body weight

Symptoms: No effects on mating performance

Result: negative

Effects on foetal develop- : Test Type: Embryo-foetal development

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

ment Species: Rat, female

Application Route: Oral

Developmental Toxicity: LOAEL: 29 mg/kg body weight Result: Fetotoxicity, Malformations were observed.

Test Type: Embryo-foetal development

Species: Rabbit, female

Developmental Toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Posaconazole:

Exposure routes : Ingestion

Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive

organs, Nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Posaconazole:

Species : Rat, female LOAEL : 5 mg/kg
Application Route : Oral Exposure time : 6 Months

Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species: DogLOAEL: 3 mg/kgApplication Route: OralExposure time: 392 Days

Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal

cord, lymphoid tissue

Species : Monkey LOAEL : 15 mg/kg Application Route : Oral Exposure time : 1 Months

Target Organs : Bone marrow, Adrenal gland, Lymph nodes, Blood

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Species Dog LOAEL 3 mg/kg Application Route Oral Exposure time 56 Weeks

Target Organs Adrenal gland, Bone marrow, Kidney, Nervous system,

spleen, thymus gland, Testis, lymphoid tissue

Species Monkey LOAEL 180 mg/kg Application Route Oral Exposure time 12 Months

Target Organs Blood, Gastrointestinal tract, spleen

Species Monkey LOAEL 8 mg/kg Intravenous Application Route Exposure time 1 Months

Target Organs Cardio-vascular system, Lungs, Adrenal gland, Blood

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Posaconazole:

Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver Ingestion

effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia,

electrolyte imbalance

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 220 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 96 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l

Exposure time: 72 h

Posaconazole:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.276 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): >

0.509 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.244 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

: 1

Toxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Posaconazole:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 28 h

Method: OECD Test Guideline 314

Stability in water : Degradation half life (DT50): > 30 d

Method: OECD Test Guideline 111

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

Bioaccumulative potential

Components:

Posaconazole:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 20 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.15

Mobility in soil

Components:

Posaconazole:

Distribution among environ-

mental compartments

log Koc: 5.52

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Dispose of in accordance with local regulations.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
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 : Not applicable

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

aircraft)

Packing instruction (passen:

ger aircraft)

Not applicable

IMDG-Code

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

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

Not applicable

Not applicable for product as supplied.

National Regulations

GB 6944/12268

Marine pollutant

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

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Yangtze River Protection Law

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2023/09/26

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 6.7 2023/09/26 22497-00022 Date of first issue: 2014/10/16

compile the Safety Data eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

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 Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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