

# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

**SECTION 1: IDENTIFICATION** 

Product name : Posaconazole Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd

Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Skin sensitisation : Category 1

Specific target organ toxicity - : repeated exposure (Oral)

Category 2 (Adrenal gland, Bone marrow, Kidney, Liver, Nerv-

ous system, Reproductive organs)

**GHS label elements** 

Hazard pictograms

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

H373 May cause damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:

P260 Do not breathe mist or vapours.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves.

Response:



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

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.

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

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
.betaCyclodextrin, sulfobutyl ethers, sodium	182410-00-0	>= 30 -< 60
salts		
Posaconazole	171228-49-2	>= 1 -< 3

## **SECTION 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

Fever Headache Nausea Vomiting

Diarrhoea

May cause an allergic skin reaction.

May cause damage to organs through prolonged or repeated

exposure if swallowed.



## **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

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.

### **SECTION 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-

ucts

Carbon oxides Sulphur oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### **SECTION 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.



## **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : 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

environment.

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.

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

use of administrative controls.

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

#### SECTION 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



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

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

Hand protection Material

: Chemical-resistant gloves

Eye 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 : Work uniform or laboratory coat.

**SECTION 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



# Posaconazole Injection Formulation

Version **Revision Date:** SDS Number: Date of last issue: 26.09.2023 22485-00024 7.5 06.04.2024 Date of first issue: 16.10.2014

Relative vapour density No data available

Relative density No data available

Density 1.15 g/cm<sup>3</sup>

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

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Not applicable Particle size

#### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Stable under normal conditions. Chemical stability Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

## **SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.



## **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

### 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.

**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



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

#### **Chronic toxicity**

## 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

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



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

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-

ment

Test Type: Embryo-foetal development

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 (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

### **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



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 6 Months

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

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure 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

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
Application Route : Intravenous
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:

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

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

electrolyte imbalance



## **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

#### **SECTION 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

Toxicity to daphnia and other :

aquatic invertebrates

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

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

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

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

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209



## Posaconazole Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 22485-00024 7.5 06.04.2024 Date of first issue: 16.10.2014

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

Bioaccumulative potential

**Components:** 

Posaconazole:

Species: Lepomis macrochirus (Bluegill sunfish) Bioaccumulation

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

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

**International Regulations** 

**UNRTDG** 

**UN** number Not applicable Proper shipping name Not applicable



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

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 : Not applicable

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 Not applicable Labels **EmS Code** Not applicable Not applicable Marine pollutant

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

Not applicable for product as supplied.

## **National Regulations**

**ADG** 

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

Special precautions for user

Not applicable

### **SECTION 15. REGULATORY INFORMATION**

Safety, health and environmental regulations/legislation specific for the substance or mix-

Therapeutic Goods (Poisons:

Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition,



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

#### **Further information**

Sheet

Revision Date : 06.04.2024

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Date format : dd.mm.yyyy

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 Tem-



# **Posaconazole Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.5 06.04.2024 22485-00024 Date of first issue: 16.10.2014

perature; 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

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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