

## **Timolol / Dorzolamide Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.13 30.09.2023 28787-00021 Date of first issue: 06.11.2014

#### **SECTION 1. IDENTIFICATION**

Product name : Timolol / Dorzolamide Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor

Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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** 

Specific target organ toxicity - :

repeated exposure

Category 1 (Cardio-vascular system, Central nervous system,

Gastrointestinal tract, Lungs)

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Cardio-vascular system, Cen-

tral nervous system, Gastrointestinal tract, Lungs) through pro-

longed or repeated exposure.

Precautionary Statements : Prevention:

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste



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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)
Dorzolamide	130693-82-2	>= 1 -< 5
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-	26921-17-5	>= 0,1 -< 1
morpholino-1,2,5-thiadiazole monomaleate		

#### **SECTION 4. FIRST AID MEASURES**

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

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. Flush eyes with water as a precaution.

In case of eye contact

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

Causes 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).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING 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



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ucts Nitrogen oxides (NOx)

Sulfur oxides Hydrogen chloride

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 fire-fighters

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

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec: :

tive equipment and emer-

gency 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 diking or other appropriate

containment to keep material from spreading. If diked 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.

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

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 breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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

assessment



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

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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Dorzolamide	130693-82-2	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Eye				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	
(S)-3-[3-(tert-butylamino)-2- hydroxypropoxy]-4- morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Eye, Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of

the compound to uncontrolled areas (e.g., open-face

containment devices). Minimize open handling.

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 Hand protection

: Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.



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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.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 5,6

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

Vapor pressure : No data available

Relative vapor density : No data available



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Relative density : 1,02

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

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

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

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

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:** 

Dorzolamide:



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Acute oral toxicity : LD50 (Rat): 1.927 mg/kg

LD50 (Mouse): 1.320 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Acute oral toxicity : LD50 (Rat): 1.000 mg/kg

LD50 (Mouse): 1.140 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 300 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 800 mg/kg

Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Dorzolamide:

Species : Monkey

Result : Mild eye irritation

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rabbit

Result : Mild eye irritation

Species : Dog

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.



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#### **Components:**

Dorzolamide:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : Weak sensitizer

### Germ cell mutagenicity

Not classified based on available information.

Components:

Dorzolamide:

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: negative

Test Type: Alkaline elution assay Test system: rat hepatocytes

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster fibroblasts

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay

Species: Mouse Result: negative

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

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

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Method: OECD Test Guideline 474

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Dorzolamide:

Species : Rat, male
Application Route : Oral
Exposure time : 2 Years

20 mg/kg body weight

Result : negative

Remarks : The mechanism or mode of action may not be relevant in hu-



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mans.

Species : Mouse Application Route : Oral

Exposure time : 21 month(s)
Result : negative

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

LOAEL : 300 mg/kg body weight

Result : negative Target Organs : Adrenal gland

Remarks : The significance of these findings for humans is not certain.

Species : Mouse, female

Application Route : Oral Exposure time : 18 Months

LOAEL : 500 mg/kg body weight

Result : negative

Target Organs : Lungs, Mammary gland, Uterus (including cervix)

Remarks : The significance of these findings for humans is not certain.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

#### Reproductive toxicity

Not classified based on available information.

#### **Components:**

### **Dorzolamide:**

Effects on fertility : Test Type: Fertility

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 7,5 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 1 mg/kg body weight Result: Embryotoxic effects and adverse effects on the

offspring were detected only at high maternally toxic doses

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 2,5 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:



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

Species: Rat

Application Route: Oral

Fertility: NOAEL Mating/Fertility: 150 mg/kg body weight Early Embryonic Development: NOAEL F1: 150 mg/kg body

weight

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rabbit

Developmental Toxicity: LOAEL F1: 50 mg/kg body weight Result: Some evidence of adverse effects on development,

based on animal experiments.

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

Causes damage to organs (Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs) through prolonged or repeated exposure.

**Product:** 

Target Organs : Cardio-vascular system, Central nervous system, Gastrointes-

tinal tract, Lungs

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### **Components:**

Dorzolamide:

Target Organs : Central nervous system, Gastrointestinal tract, Bone, Blood,

Bladder

Assessment : May cause damage to organs through prolonged or repeated

exposure.

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Target Organs : Lungs, Cardio-vascular system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

#### **Components:**

Dorzolamide:

Species : Rat NOAEL : 0,05 mg/kg

Application Route : Oral

Target Organs : Bladder, Kidney

Species : Dog



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NOAEL : 0,05 mg/kg
LOAEL : 2 mg/kg
Application Route : Oral
Exposure time : 1 y

Target Organs : Gastrointestinal tract, Bone, Blood

Species : Monkey NOAEL : 0,05 mg/kg

Exposure time : 1 y

Target Organs : Gastrointestinal tract, Bone, Blood

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 67 Weeks

Species : Dog
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 54 Weeks
Target Organs : Kidney

#### **Aspiration toxicity**

Not classified based on available information.

#### Experience with human exposure

**Product:** 

Eye contact : Symptoms: The most common side effects are:, bitter taste,

burning or stinging of the eye, Blurred vision, Abdominal pain, Dizziness, digestive disorder, eye pain, Headache, hyperten-

sion, Nausea, upper respiratory tract infection

**Components:** 

Dorzolamide:

Eye contact : Symptoms: burning or stinging of the eye, Blurred vision, tear-

ing, asthenia, bitter taste, Nausea, dry mouth, Headache

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Eye contact : Symptoms: burning or stinging of the eye, dryness of the

eyes, Headache, Nausea, Dizziness, dry mouth, changes in

libido, hair loss, Allergic reactions

Ingestion : Symptoms: Headache, Fatigue, Respiratory disorders, Gas-

trointestinal discomfort, Allergic reactions, Rash, hair loss,

altered mental status, Dizziness, changes in libido

### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Dorzolamide:



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Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 699 mg/l

Exposure time: 48 h

Toxicity to microorganisms : EC50 (Natural microorganism): > 800 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 411 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 161 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50: > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

EC50 (Photobacterium phosphoreum): > 1.800 mg/l

Persistence and degradability

Components:

Dorzolamide:

Biodegradability : Result: not rapidly degradable

Biodegradation: 5 % Exposure time: 28 d

Method: OECD Test Guideline 314

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 30 d

Stability in water : Hydrolysis: 0 %(61 d)

Method: FDA 3.09

**Bioaccumulative potential** 

Components:

Dorzolamide:

Partition coefficient: n-

log Pow: 0,292

octanol/water

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Partition coefficient: n- : log Pow: 1,48



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octanol/water

Mobility in soil

No data available

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.

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.

#### **SECTION 14. TRANSPORT INFORMATION**

### **International Regulations**

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

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

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

AICS : not determined

DSL : not determined

IECSC : not determined



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#### **SECTION 16. OTHER INFORMATION**

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**Further information** 

Sources of key data used to compile the Material Safety

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

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

#### 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

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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