

Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Atropine Sulfate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6	Acute toxicity (Oral), Category 4 Acute toxicity (Inhala- tion), Category 4 Eye irritation, Category 2A	>= 1 -< 5
Sodium chloride	7647-14-5	Acute toxicity (Oral), Category 5	>= 1 -< 5
Atropine Sulfate	5908-99-6	Acute toxicity (Oral), Category 4	>= 0,1 -< 1



Atropine Sulfate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 7665458-00007 Date of first issue: 14.12.2020 2.5

Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Inhalation) (Eye, Central nervous system), Category 1

SECTION 4. FIRST AID MEASURES

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. In case of eye contact Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

None known.

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

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

Notes to physician Treat symptomatically and supportively.

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

Exposure to combustion products may be a hazard to health.

fighting

Hazardous combustion prod-

ucts

Carbon oxides Metal oxides

Chlorine compounds

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.



Atropine Sulfate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 7665458-00007 Date of first issue: 14.12.2020 2.5

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 emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment. **Environmental precautions**

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 Use only with adequate ventilation. Avoid inhalation of vapor or mist. Advice on safe handling

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

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

assessment

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

environment.

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

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



Atropine Sulfate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.5
 30.09.2023
 7665458-00007
 Date of first issue: 14.12.2020

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 labeled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Atropine Sulfate	5908-99-6	TWA	2 μg/m3 (OEB 4)		
	Further information: Eye				
		Wipe limit	20 μg/100 cm ²		

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not

exist, handle over lined trays or benchtops.

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

Combined particulates and organic vapor 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.

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.



Atropine Sulfate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.5
 30.09.2023
 7665458-00007
 Date of first issue: 14.12.2020

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : Translucent-colorless to pale yellow

Odor : No data available

Odor Threshold : No data available

pH : 3,0 - 6,5

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

Relative density : No data available

Density : 0,900 - 1,100 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

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.



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Molecular weight : No data available

Particle size : Not applicable

SECTION 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 : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation exposure 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

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Sodium chloride:

Acute oral toxicity : LD50 (Rat): 3.550 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Atropine Sulfate:

Acute oral toxicity : LD50 (Rat): 500 mg/kg

LD50 (Mouse): 75 mg/kg

LD50 (Rabbit): 600 mg/kg

LD50 (Guinea pig): 1.100 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Sodium chloride:

Species : Rabbit

Result : No 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

Sodium chloride:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Benzyl alcohol:

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



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Method : OECD Test Guideline 406

Result : negative

Sodium chloride:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse Result : negative

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

Sodium chloride:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay

(in vitro) Result: positive

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: positive

Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Application Route: Intraperitoneal injection

Result: positive

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Atropine Sulfate:

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

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

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

Sodium chloride:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Atropine Sulfate:

Species : Rat

Application Route : Intraperitoneal injection

Exposure time : 28 month(s)
NOAEL : 2,5 mg/kg bw/day

Result : negative

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

Not classified based on available information.

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



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

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

Species: Mouse

Application Route: Ingestion

Result: negative

Atropine Sulfate:

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

Species: Rat, male

Application Route: Ingestion

General Toxicity Parent: LOAEL: 62,5 mg/kg body weight

Result: Reduced fertility

Test Type: Fertility/early embryonic development

Species: Rat, female

Application Route: Intraperitoneal injection

General Toxicity Parent: LOAEL: 1 mg/kg body weight

Result: Effect on estrous cycle

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

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: Abnormalities of the musculosketal system.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, and/or on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Atropine Sulfate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:

Atropine Sulfate:

Routes of exposure : Inhalation

Target Organs : Eye, Central nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations of 50 ppmV/6h/d or less.

Repeated dose toxicity

Components:

Benzyl alcohol:



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Species : Rat

NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Sodium chloride:

Species : Rat

LOAEL : 2.533 mg/kg
Application Route : Ingestion
Exposure time : 2 y

Atropine Sulfate:

Species : Rabbit LOAEL : 59 mg/kg Application Route : Subcutaneous

Exposure time : 100 d

Target Organs : Central nervous system

Symptoms : Convulsions, respiratory depression

Species : Rat

LOAEL : 0,5 mg/kg
Application Route : Inhalation
Exposure time : 21 d
Target Organs : Eye

Symptoms : Dilatation of the pupil

Species : Dog
LOAEL : 0,5 mg/kg
Application Route : Inhalation
Exposure time : 21 d
Target Organs : Eye

Symptoms : Dilatation of the pupil

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Atropine Sulfate:

General Information : Target Organs: Central nervous system

Symptoms: dry mouth, Blurred vision, tachycardia, constipation, central nervous system effects, restlessness, Fatigue,

delirium, mental depression

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:



Atropine Sulfate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 7665458-00007 Date of first issue: 14.12.2020 2.5

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Sodium chloride:

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l Toxicity to fish

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4.136 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50: > 2.000 mg/l

Exposure time: 96 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 252 mg/l

Exposure time: 33 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia pulex (Water flea)): 314 mg/l

Exposure time: 21 d

Toxicity to microorganisms

EC10: > 1.000 mg/l

Atropine Sulfate:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 356 mg/l

Exposure time: 48 h

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d



Atropine Sulfate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.5
 30.09.2023
 7665458-00007
 Date of first issue: 14.12.2020

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

Atropine Sulfate:

Partition coefficient: n-

octanol/water

log Pow: 1,83

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.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)



Atropine Sulfate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.5 30.09.2023 7665458-00007 Date of first issue: 14.12.2020

Brazil. List of chemicals controlled by the Federal : Not applicable

Police

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

DSL : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023 Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety

Data Sheet

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

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 Svstem; 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 Sub-



Atropine Sulfate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.5
 30.09.2023
 7665458-00007
 Date of first issue: 14.12.2020

stances 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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