

Ribavirin Liquid Formulation

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

 4.10
 30.09.2023
 406963-00020
 Date of first issue: 10.12.2015

SECTION 1. IDENTIFICATION

Product name : Ribavirin Liquid 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

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Blood)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H341 Suspected of causing genetic defects.

H360Df May damage the unborn child. Suspected of damaging

fertility.

H373 May cause damage to organs (Blood) through prolonged

or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.



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P260 Do not breathe mist or vapors.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

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)	
Sucrose	57-50-1	>= 30 -< 50	
Glycerine	56-81-5	>= 20 -< 30	
Ribavirin	36791-04-5	>= 1 -< 5	

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. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water. Suspected of causing genetic defects.

Most important symptoms

and effects, both acute and

delayed

May damage the unborn child. Suspected of damaging fertili-

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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



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> 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

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon 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

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).

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



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Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapors.

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

assessment

Keep container tightly closed.

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 locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

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	
Sucrose	57-50-1	CMP	10 mg/m ³	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen				
		TWA	10 mg/m ³	ACGIH	
Glycerine	56-81-5	CMP (Mist)	10 mg/m ³	AR OEL	
Ribavirin	36791-04-5	Wipe limit	400 μg/100 cm ²	Internal	
		TWA	40 μg/m3 (OEB 3)	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.



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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.

Combined particulates and organic vapor type

Filter type

Material

Hand protection

: 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.

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 : clear

Odor : No data available

Odor Threshold : No data available

pH : 4,8 - 5,5

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



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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

No data available Density

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.

Particle size Not applicable

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-

tions

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



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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Components:

Sucrose:

Acute oral toxicity : LD50 (Rat): 29.700 mg/kg

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

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

Ribavirin:

Acute oral toxicity : LD50 (Rat): 4.116 - 5.584 mg/kg

LD50 (Mouse): > 10.000 mg/kg

LD50 (Dog): >= 1.500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of:

administration)

LD50 (Rat): 1.554 - 1.758 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 1.268 mg/kg Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:

Glycerine:

Species : Rabbit

Result : No skin irritation

Ribavirin:

Remarks : No data available

May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.



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Components:

Glycerine:

Species : Rabbit

Result : No eye irritation

Ribavirin:

Remarks : No data available

May irritate eyes.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Ribavirin:

Remarks : No data available

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Sucrose:

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

Result: negative

Glycerine:

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

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

thesis in mammalian cells (in vitro)

Result: negative

Ribavirin:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Rodent cell line

Result: positive



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Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test

Species: Rat Result: negative

Test Type: Mouse Lymphoma

Species: Mouse Result: positive

Test Type: Micronucleus test

Species: Mouse Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell

mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Glycerine:

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

Ribavirin:

Species : Mouse
Application Route : Oral
Exposure time : 6 Months

LOAEL : 75 mg/kg body weight

Result : negative Target Organs : Blood, Testes

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

mans.

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

NOAEL : 10 mg/kg body weight

Result : negative

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

mans.

Species : Mouse
Application Route : Oral
Exposure time : 18 Months
Result : negative

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



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mans.

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

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

Species: Rat

Application Route: Ingestion

Result: negative

Ribavirin:

Effects on fertility : Test Type: Fertility

Species: Rat, male

Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight

Symptoms: Reduced fertility

Result: positive

Test Type: Fertility Species: Mouse, male Application Route: Oral

Fertility: LOAEL: 35 mg/kg body weight

Symptoms: Reduced fertility

Result: positive

Test Type: Fertility Species: Rat, females Application Route: Oral

Fertility: NOAEL: 10 mg/kg body weight

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

Test Type: Fertility Species: Rat, male Application Route: Oral

Fertility: NOAEL: 160 mg/kg body weight

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

Effects on fetal development : Test Type: Development

Species: Rat, female Application Route: Oral

Developmental Toxicity: LOAEL: <= 1 mg/kg body weight Symptoms: Reduced body weight, Reduced number of viable

fetuses., Skeletal malformations.

Result: Embryotoxic effects and adverse effects on the

offspring were detected.



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Test Type: Development Species: Rabbit, female Application Route: Oral

General Toxicity Maternal: LOAEL: 1 mg/kg body weight Developmental Toxicity: LOAEL: 1 mg/kg body weight Symptoms: Reduced body weight, Skeletal malformations. Result: Embryotoxic effects and adverse effects on the

offspring were detected.

Test Type: Development Species: Hamster Application Route: Oral

Developmental Toxicity: LOAEL: 2,5 mg/kg body weight Symptoms: Skeletal and visceral variations ., Total Resorp-

tions / resorption rate.

Result: Embryotoxic effects and adverse effects on the

offspring were detected.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 0,3 mg/kg body weight

Embryo-fetal toxicity.: LOAEL: 1 mg/kg body weight

Symptoms: Skeletal malformations.

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of

adverse effects on development, based on animal

experiments.

STOT-single exposure

Not classified based on available information.

Components:

Ribavirin:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.

Components:

Ribavirin:

Routes of exposure : Ingestion Target Organs : Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.



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Repeated dose toxicity

Components:

Glycerine:

Species : Rat

NOAEL : 0,167 mg/l LOAEL : 0,622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Species : Rat

NOAEL : 8.000 - 10.000 mg/kg

Application Route : Ingestion Exposure time : 2 y

Species : Rabbit
NOAEL : 5.040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

Ribavirin:

Species : Monkey LOAEL : 30 mg/kg Exposure time : 10 d

Target Organs : Blood, Gastrointestinal tract

Species: RatNOAEL: 7,6 mg/kgApplication Route: InhalationExposure time: 90 d

Target Organs : Blood, Lungs

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 1 y

Target Organs : Blood, Gastrointestinal tract

Species : Mouse
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 18 Months

Target Organs : Blood, Cardio-vascular system

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ribavirin:

Inhalation : Symptoms: Headache, Dizziness



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Remarks: Based on Human Evidence

Skin contact : Remarks: May cause eye irritation.

Based on Human Evidence

Eye contact : Remarks: May cause eye irritation.

Based on Human Evidence

Ingestion : Symptoms: blood effects, immune system effects, anorexia,

Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver

function change, Gastrointestinal disturbance

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1.955 mg/l

Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10.000 mg/l

Exposure time: 16 h

Method: DIN 38 412 Part 8

Ribavirin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 117 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 119

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 6,9

ma/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Glycerine:



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Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1,75

Ribavirin:

Partition coefficient: n-

octanol/water

log Pow: 0,971

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



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SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable Not applicable

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

AICS not determined

DSL not determined

IECSC not determined

SECTION 16. OTHER INFORMATION

Revision Date 30.09.2023 dd.mm.yyyy Date format

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

ACGIH USA. ACGIH Threshold Limit Values (TLV) AR OEL Argentina. Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average AR OEL / CMP TLV (Threshold Limit Value)

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;



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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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