Ribavirin



Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Ribavirin

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

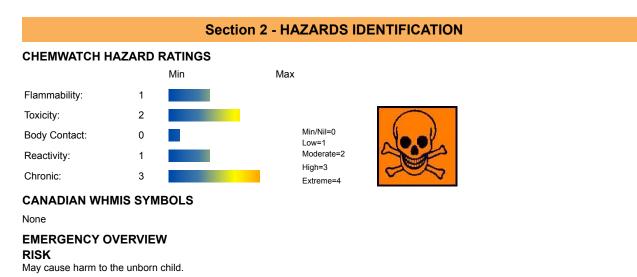


SUPPLIER

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SYNONYMS

C8-H12-N4-O5, "1-[3, 4-dihydroxy-5-hydroxymethyl)oxolan-2-yl]-1, 2, 4-triazol-3-", carboxamide, "1, 2, 4-triazole-3-carboxamide, 1beta-D-ribofurnosyl-", "1beta-D-ribofuranosyl-1, 2, 4-triazole-3-carboxamide", Icn-1229, Copegus, Rebetol, RTCA, Ribamidyl, Ribasphere, Vilona, Viramid, Virazole, Ribavirine, Ribavirine, Tribavirin, "antiviral agent/ viricide", "AIDS/ influenza/ hepatitis C agent"



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POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual.

■ Limited evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

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SKIN

• The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

• Open cuts, abraded or irritated skin should not be exposed to this material.

• Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

■ Inhalation of aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.

■ Limited evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.

CHRONIC HEALTH EFFECTS

• Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

Ample evidence from experiments exists that there is a suspicionthis material directly reduces fertility.

Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of

appropriate studies with similar materials using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

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Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Administration, in the mouse, of doses between 35-150 mg/kg/day (estimated human equivalent of 2.92-12.5 mg/kg/day, based on body surface area adjustment) resulted in significant seminiferous tubule atrophy, decreased sperm counts and increased number of sperm with abnormal morphology.

Partial recovery of sperm production was apparent 3-6 months after dose cessation. In several additional toxicology studies, ribavirin has been shown to produce testicular lesions (tubular atrophy) in adult rats at oral dose levels as low as 16 mg/kg/day (estimated human equivalent of 2.29 mg/kg/day, based on body surface area adjustment).

Ribavirin has ben reported to produce teratogenic effects in some animals.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS					
NAME	CAS	S RN	%		
ribavirin	367	791-04-5	>98		

Section 4 - FIRST AID MEASURES

SWALLOWED

 \cdot If swallowed do NOT induce vomiting. \cdot If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE

• If this product comes in contact with the eyes: • Wash out immediately with fresh running water. • Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin or hair contact occurs: · Flush skin and hair with running water (and soap if available). · Seek medical attention in event of irritation. **INHALED**

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

Treat symptomatically.

About 45% of an ingested dose is absorbed in the the gastrointestinal tract probably with the assistance of nucleoside transporters. It is then widely distributed in tissues including the CSF and brain. About one-third of the absorbed dose is excreted unchanged in the urine. The rest is extracted in the urine as the de-ribosylated base.

Section 5 - FIRE FIGHTING MEASURES					
Vapour Pressure (mmHG):	Negligible				
Upper Explosive Limit (%):	Not Available				
Specific Gravity (water=1):	Not Available				
Lower Explosive Limit (%):	Not Available				

EXTINGUISHING MEDIA

· Water spray or fog.

· Foam.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.

· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

 \cdot Combustible solid which burns but propagates flame with difficulty.

• Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

FIRE INCOMPATIBILITY

Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses: Chemical goggles. Gloves: Respirator: Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- · Clean up waste regularly and abnormal spills immediately.
- · Avoid breathing dust and contact with skin and eyes.
- · Wear protective clothing, gloves, safety glasses and dust respirator.
- · Use dry clean up procedures and avoid generating dust.
- · Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- · Dampen with water to prevent dusting before sweeping.
- \cdot Place in suitable containers for disposal.
- MAJOR SPILLS
- Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

 \cdot Avoid all personal contact, including inhalation.

· Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

· Do NOT cut, drill, grind or weld such containers.

· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

Glass container.

- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.
- STORAGE REQUIREMENTS

Store in original containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• ribavirin: CAS:36791-04-5

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

When handling very small quantities of the material eye protection may not be required.

- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
- · Chemical goggles
- · Face shield. Full face shield may be required for supplementary but never for primary protection of eyes

• Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- · dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

• When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- · Double gloving should be considered.
- · PVC gloves.
- · Protective shoe covers.
- · Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- \cdot polychloroprene
- · nitrile rubber
- · butyl rubber
- · fluorocaoutchouc
- · polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.

· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.

- · For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- · Eye wash unit.
- · Ensure there is ready access to an emergency shower.
- · For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Divided Solid	Molecular Weight	244.21
330.8- 334.4; 174-176	Viscosity	Not Applicable
Not Applicable	Solubility in water (g/L)	Miscible
Not Available	pH (1% solution)	Not Applicable
Not Available	pH (as supplied)	Not Applicable
Not Available	Vapour Pressure (mmHG)	Negligible
Not Available	Specific Gravity (water=1)	Not Available
Not Available	Relative Vapor Density (air=1)	Not Applicable
Negligible	Evaporation Rate	Not Applicable
	330.8- 334.4; 174-176 Not Applicable Not Available Not Available Not Available Not Available Not Available	330.8- 334.4; 174-176ViscosityNot ApplicableSolubility in water (g/L)Not AvailablepH (1% solution)Not AvailablepH (as supplied)Not AvailableVapour Pressure (mmHG)Not AvailableSpecific Gravity (water=1)Not AvailableRelative Vapor Density (air=1)

APPEARANCE

White to off-wite crystalline powder; mixes with water. Exists in two polymorphic forms: mp 166-168 C - mp 174-176 C.

log Kow -1.85 (computed)

Material

Value

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.

· Product is considered stable.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

RIBAVIRIN

TOXICITY AND IRRITATION

RIBAVIRIN:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY IRRITATION

Oral (Rat) LD50: 2700 mg/kg

Intraperitoneal (Mouse) LD50: 1300 mg/kg

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Tumourigenic (active as anti-cancer agent), diarrhoea, bladder changes,

haemorrhage, normocytic anaemia, leukopenia, changes in blood marrow, chages in

platelet count, metabolic chanes in calcium, degenerative changes in brain /

coverings, changes in teeth and supporting structures, specific developmental

abnormalitues (musculoskeletal system, central nervous system, eye/ ear, skin/

appendages), paternal effects, reproductive effects

Section 12 - ECOLOGICAL INFORMATION

No data				
Ecotoxicity	,			
Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
ribavirin	LOW		LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- · Reduction
- · Reuse
- · Recycling

· Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

· Recycle wherever possible.

· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

ribavirin (CAS: 36791-04-5) is found on the following regulatory lists;

"US - California Air Toxics ""Hot Spots"" List (Assembly Bill 2588) Substances for which production, use or other presence must be reported","US - California Occupational Safety and Health Regulations (CAL/OSHA) - Hazardous Substances List","US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "US - California Proposition 65 -Reproductive Toxicity","US - Maine Chemicals of High Concern List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation and/or ingestion may produce health damage*.
- Exposure may produce irreversible effects*.
- * (limited evidence).

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Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references.

The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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