



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **VIRAZOLE® (ribavirin for inhalation solution)**

Synonyms • Ribavirin

Product Code • 301870007145; NDC 0187-0007-14

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finished Pharmaceutical Product; Virazole is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus (RSV).

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS

- Eye Irritation 2A
- Acute Toxicity Oral 4
- Carcinogenicity 2
- Reproductive Toxicity 1B
- Specific Target Organ Toxicity Single Exposure 2
- Specific Target Organ Toxicity Repeated Exposure 2

Label elements

UN GHS

DANGER



- Hazard statements**
- Causes serious eye irritation
 - Suspected of causing cancer.
 - May damage fertility or the unborn child.

Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
 - Wash thoroughly after handling.
 - Use personal protective equipment as required.
- Response**
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - If eye irritation persists: Get medical advice/attention.
 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.
 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS**
- No data available

Section 3 - Composition/Information on Ingredients

Substances

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Ribavirin	CAS:36791-04-5	100%	UN GHS: Eye Irrit 2A, Acute Tox. Oral 4, Carc.2, Repro. 1B, STOT SE 2, STOT RE 2

Mixtures

- Material does not meet the criteria of a mixture according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Provide symptomatic or supportive care as necessary.
- Skin**
- After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of (to be specified by manufacturer). If irritation develops and persists, get medical attention.
- Eye**
- If eye contact occurs, rinse eyes under gently running water for at least 15 minutes. Use sufficient force to open eyelids and roll eyes while flushing. Seek medical attention if irritation persists or signs of toxicity occur. Provide symptomatic or supportive care as necessary.
- Ingestion**
- Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Provide symptomatic or supportive care as necessary. If signs/symptoms develop, get medical attention.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed**Notes to Physician**

- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are provided on the product packaging and/or in the product insert.

Section 5: Fire-Fighting Measures**Extinguishing media**

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Firefighting Procedures • As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and appropriate protective clothing.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • No data available

Hazardous Combustion Products • During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Environmental precautions

- LARGE SPILLS: Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers. Prevent runoff from entering drains, sewers, and streams.

Other Information

- In the event of a release of bulk material, the user should determine if the release qualifies as reportable according to local, state, and federal regulations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use of impervious gloves is recommended if there is a potential for skin contact.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- No regulatory limits for ribavirin have been established. Good industrial hygiene practices should be followed to reduce exposures as much as possible.

Exposure controls

Engineering Measures/Controls

- Use chemical fume hood, process enclosures, local exhaust ventilation or other engineering controls to minimize airborne levels.

Personal Protective Equipment

Respiratory

- In case of insufficient ventilation, wear suitable respiratory equipment. Use NIOSH approved respiratory protection (US requirements)

Eye/Face

- Wear eye/face protection , .

Hands

- Wear protective gloves .

Skin/Body

- Avoid contact with skin.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Glass vial containing lyophilized ribavirin as a white powder.
Color	White to off-white.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point	165 to 176 C(329 to 348.8 F)
Decomposition Temperature	> 245 C(> 473 F)	pH	Not relevant
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble 142 g/L @ 25 C(77 F)
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Heat of Combustion (ΔHc)	Not relevant
Flammability (solid, gas)	Not relevant		

Environmental			
Octanol/Water Partition coefficient	Not relevant	Biochemical Oxygen Demand BOD/BOD5	Not relevant

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- No data available

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Avoid exposure to extreme heat or cold.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

		Components
Ribavirin (100%)	36791-04-5	<p>Acute Toxicity: Ingestion/Oral-Rat LD50 • 2700 mg/kg; Tumorigenic:Active as anti-cancer agent; Ingestion/Oral-Mouse LDLo • 4 g/kg; Tumorigenic:Active as anti-cancer agent;</p> <p>Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 5220 mg/kg 29 Day(s)-Intermittent; Behavioral:Food intake (animal); Blood:Normocytic anemia; Blood:Leukopenia; Ingestion/Oral-Rat TDLo • 1680 mg/kg 14 Day(s)-Intermittent; Blood:Changes in leucocyte (WBC) count;</p> <p>Reproductive: Ingestion/Oral-Mouse TDLo • 3150 mg/kg (90D male); Reproductive Effects:Paternal Effects:Spermatogenesis; Ingestion/Oral-Mouse TDLo • 9 g/kg (60D male); Reproductive Effects:Paternal Effects:Testes, epididymis, sperm duct; Ingestion/Oral-Rat TDLo • 25 mg/kg (9D preg); Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system; Intravenous-Hamster TDLo • 5 mg/kg (8D preg); Reproductive Effects:Specific Developmental Abnormalities:Central nervous system; Reproductive Effects:Specific Developmental Abnormalities:Eye, ear; Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system</p>

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Oral 4
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 2
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Specific Target Organ Toxicity Repeated Exposure 2 - Reversible with discontinuation of exposure.

STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 2
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 1B
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - No data available

Skin

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - No data available.

Eye

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - No data available

Ingestion

- Acute (Immediate)**
 - Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
 - No data available

Carcinogenic Effects

- Ribavirin increased the incidence of cell transformations and mutations in mouse Balb/c 3T3 (fibroblasts) and L5178Y (lymphoma) cells at concentrations of 0.015 mg/mL, respectively (without metabolic activation). Modest increases in mutation rates (3-4X) were observed at concentrations between 3.75-10.0 mg/mL in L5178Y cells in vitro with the addition of a metabolic activation fraction. In the mouse micronucleus assay, ribavirin was clastogenic at intravenous doses of 20-200 mg/kg when administered for 5 days (estimated human equivalent of 7.14-28.6 mg/kg, based on body surface area adjustment). In vivo carcinogenicity studies with ribavirin are incomplete. However, results of a chronic feeding study with ribavirin in rats, at doses of 16-100 mg/kg/day (estimated human equivalent of 2.3-14.3 mg/kg/day, based on body surface area adjustment for the adult), suggest that ribavirin may induce benign mammary, pancreatic, pituitary and adrenal tumors.

Reproductive Effects

- Pregnancy: Category X. Although clinical studies have not been performed, ribavirin may cause fetal harm in humans. Ribavirin has demonstrated significant teratogenic and or embryocidal potential in all animal species in which adequate studies have been conducted. Teratogenic effects were evident after single oral doses of 2.5 mg/kg or greater in the hamster, and after daily oral doses of 0.3 and 1.0 mg/kg in the rabbit and rat, respectively (estimated human equivalent doses of 0.12 and 0.14 mg/kg, based on body surface area adjustment for the adult). Malformations of the skull, palate, eye, jaw, limbs, skeleton, and gastrointestinal tract were noted. The incidence and severity of teratogenic effects increased with escalation of the drug dose. Survival of fetuses and offspring was reduced. Ribavirin has been shown to produce testicular lesions in rodents. In the mouse, administration of ribavirin at doses between 35-150 mg/kg/day (estimated human equivalent from 2.92-12.5 mg/kg/day, based on body surface area adjustment for the adult) resulted in significant seminiferous tubule atrophy, decreased sperm concentrations, and increased numbers of sperm with abnormal morphology. Partial recovery of sperm production was apparent 3-6 months following dose cessation.

Other information

- Studies of environmental exposure to aerosolized Virazole in health care workers administering care to patients receiving the drug have not detected adverse signs or symptoms related to exposure. However, 152 health care workers have reported experiencing adverse events through post-marketing surveillance. The most common signs and symptoms were headache (51%), conjunctivitis (32%), and rhinitis, nausea, rash, dizziness, pharyngitis, or lacrimation (10-20% each). Refer to the product insert and/or prescribing information for additional acute and/or chronic health effects.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

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

- No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ribavirin	36791-04-5	No	No	No

Canada

Labor**Canada - WHMIS - Classifications of Substances**

• Ribavirin	36791-04-5	Not Listed
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Canada - WHMIS - Ingredient Disclosure List

• Ribavirin	36791-04-5	Not Listed
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United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Ribavirin	36791-04-5	Not Listed
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United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Ribavirin	36791-04-5	Not Listed
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U.S. - California - Proposition 65 - Developmental Toxicity

• Ribavirin	36791-04-5	developmental toxicity, initial date 4/1/90
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U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

• Ribavirin	36791-04-5	Not Listed
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U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Ribavirin	36791-04-5	Not Listed
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U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Ribavirin	36791-04-5	male reproductive toxicity, initial date 2/27/01
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Section 16 - Other Information**Last Revision Date**

- 05/May/2015

Preparation Date

- 05/May/2015

Disclaimer/Statement of Liability

- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.