



MATERIAL SAFETY DATA SHEET

I. PRODUCT IDENTIFICATION

TRADE NAME (as labeled): VIRAZOLE® (ribavirin for inhalation solution)
MANUFACTURER'S NAME: ICN PHARMACEUTICALS, INC.
Address (complete mailing address): 3300 Hyland Avenue
 Costa Mesa, CA 92626
Phone number for additional information: (714) 545-0100
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II. HAZARDOUS INGREDIENTS

CAS Number: 36791-04-S.
Chemical Name: 1-β-D-ribofuranosyl-1H-1,2,4-triazole-3-carboxamide.
Clinical Indication: Severe lower respiratory tract infections due to Respiratory Syncytial Virus.
Biological Activity or Toxicological Class: Antiviral agent.
Environmental Hazard/ Caution: N/A.
Emergency Hazard Symbol:

HEALTH	0
FLAMMABILITY	0
REACTIVITY	0
PERSONAL PROTECTION	*

*Not a required category.

III. PHYSICAL PROPERTIES

Appearance: White solid.
Melting Point: 165°-176°C (329°-349°F).
 NOTE: Amorphous lyophilized material may fuse and/or melt at lower temperature.
Vapor Pressure: Negligible.
Evaporation Rate (n-butyl acetate = 1): Negligible.
Volatile Fraction by Weight: Negligible.
Specific Gravity (H₂O = 1): N/A.
Solubility in Water (by weight): Freely soluble, ~0.35 g/mL.

N/D = NOT DETERMINED <= LESS THAN >= GREATER THAN N/A = NOT APPLICABLE



IV. FIRE AND EXPLOSION

Flash Point, °F: N/A.
 Auto Ignition Temperature, °F: N/A.
 Flammable Limits in Air, Volume %: N/A lower (LEL) _____ upper (UEL) _____

Fire Extinguishing Materials:

water spray carbon dioxide other: CO₂
 foam dry chemical

Special Fire Fighting Procedures: N/A.

Unusual Fire and Explosion Hazards: Fire or excessive heat may produce hazardous decomposition products.

V. HEALTH HAZARD INFORMATION

Primary Routes of Entry: Ribavirin exposure can occur through swallowing and inhalation.
 Animal Toxicity: Oral LD₅₀ in rats was 400–6000 mg/kg/day. Anemia was the most consistent finding in subchronic and chronic studies. Teratogenicity was produced in several rodent species. The threshold for teratogenicity was in the range of 1–2 mg/kg in the hamster, the most sensitive species. Ribavirin was not teratogenic in baboons at doses up to 120 mg/kg/day during critical periods of gestation. Embryo lethality was observed in rabbits at 1 mg/kg/day.
 Exposure Effects: No overdosage with ribavirin by inhalation has been reported in humans.
 Exposure Limits: Typical occupational exposure to ribavirin in environmental air, without recommended protective measures, are reported to result in undetectable or barely detectable body burdens, approximately 0.1–1.0% of levels reported to be toxic to laboratory animals (Linn et al.: *Arch. Environ. Health*. 1995;50(6):445–451).

To date, no teratogenic events have been reported with ribavirin exposure at therapeutic or environmental levels in humans. Due to teratogenic effects found in rodents, however, pregnant women should avoid exposure to the drug.

FIRST AID: EMERGENCY PROCEDURES

Treat symptomatically. If signs of skin or eye irritation or other symptoms are present, seek medical attention.

SUSPECTED CANCER AGENT?

NO: This product's ingredients are not found in the lists below:

YES: Federal OSHA NTP IARC

California employers using Cal/OSHA — Regulated carcinogens must register with Cal/OSHA. The Cal/OSHA and Federal OSHA carcinogen lists are similar.

Listed as a potential teratogen in California's Proposition 65.

VENTILATION AND PERSONAL PROTECTION

Ventilation: Use in well-ventilated area.

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Personal Protection:

Levels of ribavirin in the environment are expected to be very low relative to therapeutic levels during proper administration of the drug. A well-ventilated hospital setting will minimize incidental exposure while ribavirin is being administered. Of the isolated complaints received to date, headache, conjunctivitis, and rhinitis are the most commonly reported events. However, these are the signs and symptoms of Respiratory Syncytial Virus (RSV) infection in the adult patient (*Principal and Practice of Infectious Diseases*. Bannett, Mandell and Douglas. 2nd Ed. 1988, Chapter 109) Since aerosolized ribavirin is used to treat RSV (a highly-contagious viral pathogen), hospital staff responsible for aerosol delivery should consider using coverings (eyes, nose, and mouth), as a standard recommendation for infection control. Such procedures should also serve to reduce incidental exposure to ribavirin. See Section V, Health Hazard Information.

VI. REACTIVITY DATA

Stability:	Stable, but can decompose above 245°C. Avoid temperatures above 145°C.
Conditions to Avoid:	None.
Incompatibility:	Strong oxidizers.
Hazardous Decomposition Products:	Combustion will produce CO ₂ and probably CO. Oxides of nitrogen may also be present.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	None.

VII. SPILL, LEAK, AND DISPOSAL PROCEDURES

For small solid or liquid spills, wipe up with wet paper towels. Rinse with water.

For large spills of solid materials, sweep up material and package for safe feed to an incinerator.

Dispose of according to hospital disposal policies.

Discharge, treatment, or disposal may be subject to federal, state, or local laws.

VIII. SPECIAL HANDLING INFORMATION

Keep from contact with strong oxidizing materials. Keep aerosol from sources of ignition.

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