1. Identification

Product identifier: Ribavirin

Other means of identification:
- Catalog number: 1602706
- Chemical name: 1H-1,2,4-Triazole-3-carboxamide, 1-beta-D-ribofuranosyl-
- Synonym(s): Tribavirin

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Reproductive toxicity Category 1

OSHA hazard(s): Not classified.

Label elements:
- Signal word: Danger
- Hazard statement: May damage fertility or the unborn child.
- Precautionary statement:
  - Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
  - Response: If exposed or concerned: Get medical advice/attention.
  - Storage: Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition/information on ingredients

Substance: Ribavirin

Hazardous components:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ribavirin</td>
<td>Tribavirin</td>
<td>36791-04-5</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Liver damage.

Most important symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures
Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures
Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage
Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection
Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines
No exposure standards allocated.

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Individual protection measures, such as personal protective equipment
Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection

Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other
For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene
Considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White crystalline powder.

Physical state
Solid.

Form
Powder.

Odor
Odorless.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
345.2 - 348.8 °F (174 - 176 °C) / 330.8 - 334.4 °F (166 - 168 °C)

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
< 0.0000001 kPa at 25 °C

Vapor density
Not available.

Relative density
Not available.

Solubility in water
Freely soluble.

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information
Chemical family
Synthetic triazole nucleoside.

Molecular formula
C8-H12-N4-O5

Molecular weight
244.21 g/mol

pH in aqueous solution
4 - 6.5 (in 2% solution)

Solubility (other)
Slightly soluble in dehydrated alcohol.

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Stable at normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials

Hazardous decomposition products
NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Based on available data, the classification criteria are not met.

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure
Anemia. Hypocalcemia.

Medical conditions aggravated by exposure

Acute toxicity
Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ribavirin (CAS 36791-04-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>2700 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 - 200 mg/kg Dominant lethal assay in rats</td>
<td>Result: Negative.</td>
<td></td>
</tr>
<tr>
<td>Test Duration: 5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In vitro mouse lymphoma assay</td>
<td>Result: Positive.</td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>This material is not considered to be a carcinogen by IARC, NTP, or OSHA.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 - 100 mg/kg/day Carcinogenicity study in p53 (+/-) mice</td>
<td>Result: Not oncogenic.</td>
<td></td>
</tr>
<tr>
<td>0 - 60 mg/kg/day Carcinogenicity study in rats</td>
<td>Result: Not oncogenic.</td>
<td></td>
</tr>
<tr>
<td>Test Duration: 2 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>May damage fertility or the unborn child.</td>
<td></td>
</tr>
<tr>
<td>Studies in animals have shown significant adverse effects on the fetus, including fetal death, in nearly all species tested. Because it is unknown whether ribavirin is contained in the sperm and whether birth defects may be induced, male and female patients receiving ribavirin therapy are advised to use two reliable methods of contraception during and for six months following therapy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
</tbody>
</table>

12. Ecological information

Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.
Bioaccumulative potential  Not available.
Mobility in soil  Not available.
Other adverse effects  Not available.

13. Disposal considerations

Disposal instructions  Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations  Not available.
Hazardous waste code  Not available.
Waste from residues / unused products  Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging  Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT  Not regulated as a hazardous material by DOT.
IATA  Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code  No information available.

15. Regulatory information

US federal regulations  CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories  Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No
SARA 302 Extremely hazardous substance  No
SARA 311/312 Hazardous chemical  No

Other federal regulations  Safe Drinking Water Act (SDWA)  Not regulated.
Food and Drug Administration (FDA)  Not regulated.

US state regulations  WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDLS)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
</tbody>
</table>
Country(s) or region | Inventory name | On inventory (yes/no)*
---------------------|---------------|------------------
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

- **Issue date**: 02-24-2006
- **Revision date**: 08-07-2014
- **Version #**: 02
- **Further information**: Not available.

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**Revision Information**
This document has undergone significant changes and should be reviewed in its entirety.