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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Substance name : RILPIVIRINE HYDROCHLORIDE

CAS-No. : 700361-47-3

Reference number : JNJ-16150108-AAC
R314585
T002605

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

Use of the Sub-
stance/Mixture : Active Pharmaceutical Ingredient

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium

Telephone : +3214602111

Telefax : +3214602841

E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Acute toxicity, Category 4 H302: Harmful if swallowed.

Eye irritation, Category 2 H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms : 

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection/ face protection.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

No information available.
None known.
Warning! May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name : RILPIVIRINE HYDROCHLORIDE
Chemical nature : Solid

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (%)
RILPIVIRINE HYDROCHLORIDE	700361-47-3	<= 100

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : If breathed in, move person into fresh air.

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- If symptoms persist, call a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
If symptoms persist, call a physician.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 15 minutes.
Remove contact lenses.
Consult a physician.
- If swallowed : If swallowed, rinse mouth with water (only if the person is con-
scious).
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Irritating to eyes.
depression
- Abdominal pain
Dizziness
headache
insomnia
Rash

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water mist
Dry powder
Foam
Carbon dioxide (CO₂)
Sand
Aqueous film forming foam (AFFF).
- Unsuitable extinguishing media : Water spray jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Heating can release hazardous gases.
Risk of dust explosion.
- Hazardous combustion products : No hazardous combustion products are known

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5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Firefighters must wear fire resistant personal protective equipment.

Further information : In the event of fire, cool tanks with water spray. Avoid dust formation.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Evacuate personnel to safe areas.
Avoid dust formation.
Keep away from open flames, hot surfaces and sources of ignition.
Avoid breathing dust.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in properly labelled containers.
Keep in suitable, closed containers for disposal.
Treat recovered material as described in the section "Disposal considerations".
Sweep up and shovel into suitable containers for disposal.
Pick up and arrange disposal without creating dust.

6.4 Reference to other sections

For disposal information, see section 13, Refer to protective measures listed in sections 7 and 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations.
To avoid thermal decomposition, do not overheat.
Keep away from heat and sources of ignition.
Avoid formation of dust and aerosols.
Use personal protective equipment as required.

Advice on protection against fire and explosion : Keep away from heat and sources of ignition. Avoid dust formation.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

Dust explosion class : St1

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition.

Recommended storage temperature : 15 - 25 °C

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
RILPIVIRINE HYDROCHLORIDE	700361-47-3	TWA	0,180 mg/m ³	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
Further information	J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B.			

8.2 Exposure controls

Engineering measures

Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection
Material : Neoprene
Nitrile rubber

Remarks : Impervious gloves Take note of the information given by the

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- producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
- Skin and body protection : closed work clothing
Long sleeved clothing
- Respiratory protection : Respirator with a particle filter (EN 143)
Use only respiratory protection that conforms to international/national standards.
Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
- Filter type : P2
- Wear a self-contained breathing apparatus in all circumstances when the mask and cartridge do not give adequate protection (e.g. : medium confinement/insufficient oxygen/in case of large uncontrolled emissions).
- Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : powder
- Colour : white
- Odour : No data available
- Odour Threshold : No data available
- Melting point/range : 315 °C
- Boiling point/boiling range : No data available
- Flash point : No data available
- Burning number : 2, 20 °C, Air
2, 100 °C, Air

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Upper explosion limit : No data available

Lower explosion limit : No data available

Relative vapour density : No data available

Density : No data available

Solubility(ies)
Water solubility : 0,01 g/l

Partition coefficient: n-
octanol/water : log Pow: 4,86

Auto-ignition temperature : > 565 °C
Method: M.I.T. Dust Cloud BAM METHOD

Decomposition temperature : 325 °C
Relevant T

240 °C
Minimum T

Explosive properties : No data available

Oxidizing properties : No data available

9.2 Other information

Impact sensitivity : Not impact sensitive.
39 J

Molecular weight : 402,89 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Risk of dust explosion.

10.4 Conditions to avoid

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Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

Carbon monoxide, Nitrogen oxides (NOx), Hydrogen chloride gas

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat): > 800 mg/kg
Remarks: May be harmful if swallowed.
LD50 (Dog): > 80 mg/kg

Acute inhalation toxicity : Remarks: May be harmful if inhaled.

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

Product:

Method: In vitro BCOP (Bovine Corneal Opacity and Permeability) assay
Result: Eye irritation

Respiratory or skin sensitisation

Product:

Method: Local Lymph Node Assay (LLNA) in mice
Result: Not a sensitizer

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Test Type: Ames test
Result: negative
: Test Type: Chromosome aberration test in vitro
Result: negative

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Genotoxicity in vivo : Test Type: in vivo assay
Cell type: Bone marrow
Method: Mutagenicity (micronucleus test)
Result: negative

Carcinogenicity

Product:

Remarks: No data available

Reproductive toxicity

Product:

Effects on fertility : Dose: 160 - 1600
Remarks: negative

Effects on foetal development : Dose: 160 - 1600 mg/kg
Remarks: negative

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

12.2 Persistence and degradability

Product:

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Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Product:

Mobility : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : No information available..

12.6 Other adverse effects

Product:

Additional ecological information : Remarks: No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.
In accordance with National, Federal, State and Local regulations.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

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14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012-12-31
Numbers:	123456,78	as	123 456,78

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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