RILPIVIRINE

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SECTION 1. IDENTIFICATION

Product name : RILPIVIRINE

Substance name : EDURANT® PED (rilpivirine) tablets, for oral suspension
RILPIVIRINE Pediatric 2.5-mg tablet
JNJ-16150108-AAC eq. 2.5-mg tablet
TMC278 Edurant Pediatric

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Pharmacotherapeutic group: Antivirals for systemic use
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation : Category 2A

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 - < 50
RILPIVIRINE HYDROCHLORIDE	700361-47-3	>= 5 - < 10
DODECYL SODIUM SULPHATE	151-21-3	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult 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 conscious).
Call a physician immediately.

Most important symptoms and effects, both acute and : depression
headache

delayed		insomnia Rash
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	:	No information available.
Further information	:	No information available.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Avoid dust formation. Avoid breathing dust. Evacuate personnel to safe areas.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	No data available
Advice on safe handling	:	Do not break, crush or spill this Finished Pharmaceutical Product. To avoid thermal decomposition, do not overheat. Use personal protective equipment as required. Keep away from heat and sources of ignition.

Avoid inhalation, ingestion and contact with skin and eyes.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep container tightly closed in a dry and well-ventilated place.
Keep away from heat and sources of ignition.
Store at room temperature.
Protect against light.

Recommended storage temperature : 59 - 86 °F / 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
RILPIVIRINE HYDROCHLORIDE	700361-47-3	TWA	0.180 mg/m3	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.			
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m3	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., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Colour : white

Odour : No data available

pH : No data available

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available

Solubility(ies)

Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available

Viscosity

Viscosity, kinematic	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 150 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

RILPIVIRINE HYDROCHLORIDE:

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.

DODECYL SODIUM SULPHATE:

Acute oral toxicity : LD50 Oral (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Components:

Cellulose:

Species : Rabbit
Remarks : No skin irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

Serious eye damage/eye irritation

Components:

Cellulose:

Species : Rabbit
Remarks : No eye irritation

RILPIVIRINE HYDROCHLORIDE:

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

DODECYL SODIUM SULPHATE:

Species : Rabbit
Result : Corrosive to eyes
Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Components:

Cellulose:

Species : Guinea pig
Remarks : Did not cause sensitisation on laboratory animals.

RILPIVIRINE HYDROCHLORIDE:

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

DODECYL SODIUM SULPHATE:

Result : Not a sensitizer

Germ cell mutagenicity

Components:

RILPIVIRINE HYDROCHLORIDE:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay

Cell type: Bone marrow
Method: Mutagenicity (micronucleus test)
Result: negative

DODECYL SODIUM SULPHATE:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negative

Carcinogenicity

Components:

RILPIVIRINE HYDROCHLORIDE:

Remarks : No data available

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:

RILPIVIRINE HYDROCHLORIDE:

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

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

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

STOT - single exposure

Components:

DODECYL SODIUM SULPHATE:

Exposure routes : Inhalation
Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure

No data available

Repeated dose toxicity
No data available

Aspiration toxicity
No data available

Experience with human exposure
No data available

Toxicology, Metabolism, Distribution
No data available

Neurological effects
No data available

Further information
No data available

Other health hazards
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish	:	Remarks: No data available

RILPIVIRINE HYDROCHLORIDE:

Toxicity to fish	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	:	Remarks: No data available
Toxicity to algae/aquatic plants	:	Remarks: No data available

DODECYL SODIUM SULPHATE:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 29 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l Exposure time: 48 h Test Type: flow-through test
Toxicity to algae/aquatic plants	:	EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l Exposure time: 72 h
Toxicity to fish (Chronic	:	

toxicity)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1 mg/l

Persistence and degradability

Components:

RILPIVIRINE HYDROCHLORIDE:

Biodegradability : Remarks: No data available

DODECYL SODIUM SULPHATE:

Biodegradability : Result: Readily biodegradable.

Biochemical Oxygen Demand (BOD) : > 60 %(m)

Dissolved organic carbon (DOC) : > 70 %(m)

Bioaccumulative potential

Components:

RILPIVIRINE HYDROCHLORIDE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 4.86

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 0.83 (68 °F / 20 °C)

Mobility in soil

Components:

RILPIVIRINE HYDROCHLORIDE:

Mobility : Remarks: No data available

DODECYL SODIUM SULPHATE:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

RILPIVIRINE HYDROCHLORIDE:

Results of PBT and vPvB assessment	:	No information available.
Additional ecological information	:	No data available

DODECYL SODIUM SULPHATE:

Environmental fate and pathways	:	No data available
Results of PBT and vPvB assessment	:	Substance is not persistent, bioaccumulative, and toxic (PBT).
Additional ecological information	:	No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	In accordance with National, Federal, State and Local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6

Pennsylvania Right To Know

Cellulose	9004-34-6
Mannitol	87-78-5
RILPIVIRINE HYDROCHLORIDE	700361-47-3

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6

Other regulations

Restricted to professional users.
Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

For research use only.

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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

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