Johnson & Johnson

PREZISTA

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3.9	2025/09/10	100000009116	Date of first issue: 2013/12/17

SECTION 1. IDENTIFICATION

Product name : PREZISTA
Substance name : Prezista, 100 mg/ml oral suspension
Darunavir ethanolate

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 SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is not 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)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
DARUNAVIR ETHANOLATE	635728-49-3	>= 10 - < 20
PROPYLENE GLYCOL	57-55-6	>= 0.1 - < 1
cellulose	9004-34-6	< 0.1

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 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

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 delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Abdominal pain
Diarrhoea
headache
Liver disorders
nausea
Vomiting
Rash
anorexia

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during : No information available.

firefighting

Hazardous combustion products	:	No information available. No hazardous combustion products are known
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. Evacuate personnel to safe areas. Do not break, crush or spill this Finished Pharmaceutical Product.
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	:	Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. 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 safe handling	:	To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Use personal protective equipment as required.
Conditions for safe storage	:	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. Keep locked up.
Recommended storage temperature	:	59 - 77 °F / 15 - 25 °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
DARUNAVIR ETHANOLATE	635728-49-3	TWA	1.6 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 A	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 1A.			
PROPYLENE GLYCOL	57-55-6	TWA	10 mg/m3	US WEEL
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

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	:	suspension
Colour	:	white, off-white, opaque
Odour	:	No data available
pH	:	6.5 (68 °F / 20 °C)
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	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 density	:	No data available
Density	:	No data available

Solubility(ies)

Water solubility	:	No data available

Viscosity

Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal 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
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

Components:

DARUNAVIR ETHANOLATE:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Dog): > 320 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

PROPYLENE GLYCOL:

Acute oral toxicity : LD50 (Rat): > 10,400 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): > 317,042 mg/l
Exposure time: 2 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 20,800 mg/kg

cellulose:

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

Skin corrosion/irritation

Components:

DARUNAVIR ETHANOLATE:

Result : No skin irritation
Remarks : Based on Animal Evidence

cellulose:

Species : Rabbit
Remarks : No skin irritation

Serious eye damage/eye irritation

Components:

DARUNAVIR ETHANOLATE:

Remarks : May irritate eyes.

cellulose:

Species : Rabbit
Remarks : No eye irritation

Respiratory or skin sensitisation

Components:

DARUNAVIR ETHANOLATE:

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

cellulose:

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

Germ cell mutagenicity

Components:

DARUNAVIR ETHANOLATE:

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)

Germ cell mutagenicity - Assessment : Did not show mutagenic effects in animal experiments.

Carcinogenicity

Components:

DARUNAVIR ETHANOLATE:

Carcinogenicity - Assessment : No information 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:

DARUNAVIR ETHANOLATE:

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

STOT - single exposure

Components:

DARUNAVIR ETHANOLATE:

Assessment : No information available.

STOT - repeated exposure

Components:

DARUNAVIR ETHANOLATE:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

DARUNAVIR ETHANOLATE:

Species : Rat
NOAEL : 19 mg/kg
Exposure time : 6 months

Species : Dog
NOAEL : 30 mg/kg
Exposure time : 12 months

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:

DARUNAVIR ETHANOLATE:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 38 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility NOEC (Oncorhynchus mykiss (rainbow trout)): 38 mg/l Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 44 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility NOEC (Daphnia magna (Water flea)): 2.6 mg/l Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: FDA 4.01 Remarks: No toxicity at the limit of solubility NOECr (Pseudokirchneriella subcapitata (green algae)): 43 mg/l Test Type: Growth inhibition Method: FDA 4.01

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 43 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test
Method: FDA 4.01
Remarks: No toxicity at the limit of solubility

NOECb (Pseudokirchneriella subcapitata (green algae)): 43 mg/l
Test Type: Cell multiplication inhibition test
Method: FDA 4.01

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 9.4 mg/l
Method: OECD Test Guideline 210

LOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 19 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

LOEC (Daphnia magna (Water flea)): 38 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

EC50 (Daphnia magna (Water flea)): > 38 mg/l
Method: OECD Test Guideline 211

NOEC (Midge emergence (Chironomus riparius)): 80 mg/kg
Method: OECD Test Guideline 218

LOEC (Midge emergence (Chironomus riparius)): > 80 mg/kg
Method: OECD Test Guideline 218

EC50 (Midge emergence (Chironomus riparius)): > 80 mg/kg
Exposure time: 28 d
Method: OECD Test Guideline 218

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

PROPYLENE GLYCOL:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 51,600 mg/l
Exposure time: 96 h
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 43,500 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : NOEC: > 100 mg/l

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	(Daphnia sp. (water flea)): 13,020 mg/l Exposure time: 7 d

cellulose:

Toxicity to fish	:	Remarks: No data available

Persistence and degradability

Components:

DARUNAVIR ETHANOLATE:

Biodegradability	:	Result: Not readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301B

PROPYLENE GLYCOL:

Biodegradability	:	Biodegradation: 81 % Exposure time: 28 d

Bioaccumulative potential

Components:

PROPYLENE GLYCOL:

Bioaccumulation	:	Bioconcentration factor (BCF): < 100 Remarks: No data available
Partition coefficient: n-octanol/water	:	log Pow: -0.92

Mobility in soil

Components:

DARUNAVIR ETHANOLATE:

Distribution among environmental compartments	:	Adsorption/Soil Koc: > 265 Method: OECD Test Guideline 106 Adsorption/Soil Koc: < 993 Method: OECD Test Guideline 106

PROPYLENE GLYCOL:

Distribution among environmental compartments	:	Remarks: No data available

Other adverse effects

Components:

PROPYLENE GLYCOL:

Results of PBT and vPvB assessment	:	No information available.
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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5
DARUNAVIR ETHANOLATE	635728-49-3

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

New York City Hazardous Substances

ethyl butyrate	105-54-4
acetic acid	64-19-7
ethyl acetate	141-78-6

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
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
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
US WEEL / TWA	:	8-hr TWA

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

Revision Date : 2025/09/10

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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