SECTION 1. IDENTIFICATION

Substance name : PREZCOBIX® PED tablets for oral suspension 600 mg darunavir, 90 mg cobicistat
Rezolsta
GLIDE

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
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 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)

Hazards for the product as supplied

Not a hazardous substance or mixture.

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
DARUNAVIR ETHANOLATE	635728-49-3*	>= 50 - < 70	-
COBICISTAT	1004316-88-4*	>= 10 - < 20	-
cellulose	9004-34-6*	>= 10 - < 20	-
Cellulose	9004-34-6*	>= 5 - < 10	-
Octadecanoic acid, magnesium salt	557-04-0*	>= 1 - < 5	-
colloidal anhydrous silica	112945-52-5*	>= 1 - < 5	-
titandioxide	13463-67-7*	>= 0.1 - < 1	-
acetic acid	64-19-7*	< 0.1	-
VANILLIN	121-33-5*	< 0.1	-

* Indicates that the identifier is a CAS No.
Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : Health injuries are not known or expected under normal use.
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	:	Abdominal pain Diarrhoea headache Liver disorders nausea Vomiting 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 hazardous combustion products are known
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	:	Evacuate personnel to safe areas. 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.
Environmental precautions	:	Should not be released into the environment.
Methods and materials for containment and cleaning up	:	Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal.Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. 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	:	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. Store at room temperature.
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.			
colloidal anhydrous silica	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
COBICISTAT	1004316-88-4	TWA	0.030 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	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 2.			
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
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
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.			
COBICISTAT	1004316-88-4	TWA	0.030 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	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 2.			
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
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
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
colloidal anhydrous silica	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL
		ST	15 ppm 37 mg/m3	NIOSH REL
		TWA	10 ppm 25 mg/m3	OSHA Z-1
		TWA	10 ppm 25 mg/m3	OSHA P0
VANILLIN	121-33-5	TWA	10 mg/m3	US WEEL

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, Coated
Colour	:	purple, to, red
Odour	:	No data available
pH	:	No data available
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	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
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, 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: 4,905 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

COBICISTAT:

Acute oral toxicity : (Rat): Remarks: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

cellulose:

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

colloidal anhydrous silica:

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

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

acetic acid:

Acute oral toxicity : LD50 (Rat): 3,310 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44 mg/l
Exposure time: 4 h
Test atmosphere: vapour

VANILLIN:

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): 5,010 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Components:

DARUNAVIR ETHANOLATE:

Result : No skin irritation
Remarks : Based on Animal Evidence

COBICISTAT:

Species : Rabbit
Remarks : Substance caused a mild irritation of eyes and skin in animal experiments.

cellulose:

Species : Rabbit
Remarks : No skin irritation

colloidal anhydrous silica:

Species : Rabbit
Result : No skin irritation

acetic acid:

Result : Causes severe burns.

Serious eye damage/eye irritation

Components:

DARUNAVIR ETHANOLATE:

Remarks : May irritate eyes.

COBICISTAT:

Remarks : No data available

cellulose:

Species : Rabbit
Remarks : No eye irritation

colloidal anhydrous silica:

Species : Rabbit
Result : No eye irritation

acetic acid:

Result : Corrosive to eyes

VANILLIN:

Species : Rabbit
Result : Irritating to eyes.
Exposure time : 72 h

Result : Eye irritation

Respiratory or skin sensitisation

Components:

DARUNAVIR ETHANOLATE:

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

COBICISTAT:

Remarks	:	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.

COBICISTAT:

Genotoxicity in vitro	:	Remarks: No data available
Germ cell mutagenicity - Assessment	:	Did not show mutagenic effects in animal experiments.

acetic acid:

Germ cell mutagenicity - Assessment	:	Not mutagenic in Ames Test

Carcinogenicity

Components:

DARUNAVIR ETHANOLATE:

Carcinogenicity - Assessment	:	No information available.

COBICISTAT:

Species	:	Mouse
Exposure time	:	2 years
Result	:	No evidence of carcinogenicity in animal studies.

Species	:	Rat, males
Exposure time	:	2 years
NOAEL	:	50
Remarks	:	Did not show carcinogenic effects in animal experiments.

Species	:	Rat, females
Exposure time	:	2 years
NOAEL	:	30
Remarks	:	Did not show carcinogenic effects in animal experiments.

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.

COBICISTAT:

Effects on fertility	:	Species: Rat General Toxicity - Parent: NOAEL: 100 mg/kg Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.
Effects on foetal development	:	Species: Rat Teratogenicity: NOAEL: 50 mg/kg Remarks: Did not show teratogenic effects in animal experiments. Species: Rabbit Teratogenicity: NOAEL: 100 mg/kg Remarks: Did not show teratogenic effects in animal experiments.

STOT - single exposure

Components:

DARUNAVIR ETHANOLATE:

Assessment : No information available.

COBICISTAT:

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

VANILLIN:

Remarks : No data available

STOT - repeated exposure

Components:

DARUNAVIR ETHANOLATE:

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

COBICISTAT:

Remarks : No data available

VANILLIN:

Remarks : No data available

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

COBICISTAT:

Species : Rat
Target Organs : Liver
Remarks : No adverse effect has been observed in chronic toxicity tests.

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

Endocrine disrupting properties

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

COBICISTAT:

Toxicity to fish : NOEC (Daphnia magna (Water flea)): 17.5 mg/l

NOEC (Pimephales promelas (fathead minnow)): 4.84 mg/l

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

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 29.3 mg/l

Toxicity to microorganisms : NOEC (activated sludge): > 1,000 mg/l

cellulose:

Toxicity to fish : Remarks: No data available

colloidal anhydrous silica:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

acetic acid:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 47 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

DARUNAVIR ETHANOLATE:

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

COBICISTAT:

Biodegradability : Concentration: 1.0 mg/l
Result: Not readily biodegradable.
Exposure time: 28 d
Kinetic:
: 35.5 %
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Concentration: 4.5 mg/l
Result: Not readily biodegradable.
Exposure time: 28 d
Kinetic:
: 8 %

Stability in water : Degradation half life (DT50): 171 - 241 Days
Remarks: total system 1

colloidal anhydrous silica:

Biodegradability : Remarks: No data available

VANILLIN:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

COBICISTAT:

Bioaccumulation	:	Species: Fish Bioconcentration factor (BCF): 2 Remarks: Does not bioaccumulate.
Partition coefficient: n-octanol/water	:	log Pow: 4.2 Remarks: No data available

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water	:	Remarks: No data available

colloidal anhydrous silica:

Bioaccumulation	:	Remarks: No data available
Partition coefficient: n-octanol/water	:	Remarks: No data available

titandioxide:

Partition coefficient: n-octanol/water	:	Remarks: No data available

VANILLIN:

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	Pow: 1.23 (72 °F / 22 °C)

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

COBICISTAT:

Distribution among environmental compartments	:	Medium: Soil Koc: 3.624 - 9.012
Stability in soil	:	Dissipation time: 171 - 241 d

Percentage dissipation: > 10 % (DT50)

colloidal anhydrous silica:

Distribution among environmental compartments : Remarks: No data available

VANILLIN:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

colloidal anhydrous silica:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

VANILLIN:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

Endocrine disrupting properties

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

Environmentally hazardous : no

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 IMO instruments
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

cellulose	9004-34-6
Cellulose	9004-34-6

Pennsylvania Right To Know

DARUNAVIR ETHANOLATE	635728-49-3
COBICISTAT	1004316-88-4
mannitol	87-78-5
cellulose	9004-34-6
Cellulose	9004-34-6
acetic acid	64-19-7

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

acetic acid	64-19-7
isobutyric acid	79-31-2

California Permissible Exposure Limits for Chemical Contaminants

cellulose	9004-34-6
Cellulose	9004-34-6
Octadecanoic acid, magnesium salt	557-04-0
colloidal anhydrous silica	112945-52-5

Other regulations
Restricted to professional users.

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
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
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
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
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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

This SDS received a major version update triggered by a change in Section 1.

Revision Date : 2026/05/28

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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