

PREZISTA

Version	Revision Date:	SDS Number:	Date of last issue: 2025/08/19
9.2	2025/09/10	100000014480	Date of first issue: 2018/04/12

SECTION 1. IDENTIFICATION

Product name : PREZISTA
Substance name : PREZISTA 600 mg oral tablet
darunavir

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 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

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
44.8252 %

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Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
DARUNAVIR ETHANOLATE	635728-49-3	$\geq 50 - < 70$
cellulose	9004-34-6	$\geq 30 - < 50$
colloidal anhydrous silica	112945-52-5	$\geq 1 - < 5$
titandioxide	13463-67-7	$\geq 1 - < 5$
Octadecanoic acid, magnesium salt	557-04-0	$\geq 0.1 - < 1$

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 : Remove contact lenses.
Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
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
anorexia
Diarrhoea
headache
Liver disorders
nausea
Rash
Vomiting
- Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information

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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.
- 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 : Avoid dust formation.
Avoid breathing dust.
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.
- Environmental precautions : Should not be released into the environment.
- Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
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.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Avoid inhalation, ingestion and contact with skin and eyes.
Keep away from heat and sources of ignition.
To avoid thermal decomposition, do not overheat.
Do not break, crush or spill this Finished Pharmaceutical Product.
Use personal protective equipment as required.
- Conditions for safe storage : Keep away from heat and sources of ignition.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep locked up.

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Store in original container.
To maintain product quality, do not store in heat or direct sunlight.

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/m ³	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.			
cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
colloidal anhydrous silica	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m ³ / %SiO ₂ (Silica)	OSHA Z-3
		TWA	6 mg/m ³ (Silica)	NIOSH REL
titandioxide	13463-67-7	TWA	2.4 mg/m ³	J&J OEL/PBOEL HHC
		TWA	10 mg/m ³	ACGIH
Octadecanoic acid,	557-04-0	TWA	10 mg/m ³	ACGIH

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magnesium salt		(Inhalable particulate matter)		
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

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 : No data available

Odour : No data available

pH : No data available

Melting point/ range : No data available

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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)		
<u>Water solubility</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
<u>Viscosity, dynamic</u>	:	Not applicable
<u>Viscosity, kinematic</u>	:	Not applicable
Explosive properties	:	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	:	Heat, flames and sparks. To avoid thermal decomposition, do not overheat.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

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SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity
Product:

Acute oral toxicity : Acute toxicity estimate: 4,813 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
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

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

Skin corrosion/irritation
Components:
DARUNAVIR ETHANOLATE:

Result : No skin irritation
Remarks : Based on Animal Evidence

cellulose:

Species : Rabbit
Remarks : No skin irritation

colloidal anhydrous silica:

Species : Rabbit
Result : No skin irritation

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Serious eye damage/eye irritation**Components:****DARUNAVIR ETHANOLATE:**

Remarks : May irritate eyes.

cellulose:Species : Rabbit
Remarks : No eye irritation**colloidal anhydrous silica:**Species : Rabbit
Result : 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: negativeTest Type: Chromosome aberration test in vitro
Result: negativeGenotoxicity 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.

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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

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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

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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

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

Persistence and degradability
Components:
DARUNAVIR ETHANOLATE:

Biodegradability : Result: Not readily biodegradable.

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Exposure time: 28 d
Method: OECD Test Guideline 301B

colloidal anhydrous silica:

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****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

Octadecanoic acid, magnesium salt:

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

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

colloidal anhydrous silica:

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

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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

cellulose	9004-34-6
titandioxide	13463-67-7

Massachusetts Right To Know

cellulose	9004-34-6
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Pennsylvania Right To Know

DARUNAVIR ETHANOLATE	635728-49-3
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cellulose	9004-34-6
titandioxide	13463-67-7

Pennsylvania Right To Know

DARUNAVIR ETHANOLATE	635728-49-3
cellulose	9004-34-6

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 Jersey Right To Know

DARUNAVIR ETHANOLATE	635728-49-3
cellulose	9004-34-6
crospovidone	9003-39-8
colloidal anhydrous silica	112945-52-5
titandioxide	13463-67-7

New York City Hazardous Substances

titandioxide	13463-67-7
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California List of Hazardous Substances

crospovidone	9003-39-8
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California List of Hazardous Substances

crospovidone	9003-39-8
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California Permissible Exposure Limits for Chemical Contaminants

cellulose	9004-34-6
colloidal anhydrous silica	112945-52-5
titandioxide	13463-67-7

California Permissible Exposure Limits for Chemical Contaminants

cellulose	9004-34-6
colloidal anhydrous silica	112945-52-5

The components of this product are reported in the following inventories:

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

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.

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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
ACGIH / TWA	:	Time weighted average
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
OSHA Z-3 / 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

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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

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.

US / EN