XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014541	Date of first issue: 2018/04/25

SECTION 1. IDENTIFICATION

Product name : XARELTO
Substance name : XARELTO 20 mg tablets
rivaroxaban

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: Antithrombotic agents
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)

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood)

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic : Category 3

hazard

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H373 May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P260 Do not breathe dust.
P273 Avoid release to the environment.

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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 accidently leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
microcrystalline cellulose	9004-34-6	>= 30 - < 50
RIVAROXABAN	366789-02-8	>= 20 - < 30
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
DODECYL SODIUM SULPHATE	151-21-3	>= 0.1 - < 1
TITANDIOXIDE	13463-67-7	>= 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	:	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. aplastic anemia bleeding constipation Diarrhoea Vomiting Fever Oedema Dizziness headache pruritis hypotension Rash nausea Fatigue Pneumonia respiratory tract irritation Cough Shortness of breath May cause damage to organs through prolonged or repeated exposure if swallowed.
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.
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.
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	:	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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
microcrystalline 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
RIVAROXABAN	366789-02-8	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.			
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
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.			
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0

		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Colour : red

Odour : No data available

Odour Threshold : 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

Evaporation rate	:	No data available
Flammability (solid, gas)	:	No information 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 density	:	No data available
Density	:	No data available

Solubility(ies)

Water solubility	:	No data available
Solubility in other solvents	:	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
Oxidizing 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

Components:

RIVAROXABAN:

Acute oral toxicity : LD0 (Rat): > 500 mg/kg
Method: Acute oral toxicity

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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:

RIVAROXABAN:

Remarks : No data available

DODECYL SODIUM SULPHATE:

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

Serious eye damage/eye irritation

Components:

RIVAROXABAN:

Remarks : No data available

DODECYL SODIUM SULPHATE:

Species : Rabbit

Result : Corrosive to eyes
Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Components:

RIVAROXABAN:

Remarks : No data available

DODECYL SODIUM SULPHATE:

Result : Not a sensitizer

Germ cell mutagenicity

Components:

RIVAROXABAN:

Genotoxicity in vitro : Test Type: in vitro assay
Test system: Chinese hamster V79 cells
Method: In vitro Mammalian Chromosome Aberration Test
Result: negative

Test Type: Ames test
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.

DODECYL SODIUM SULPHATE:

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

Carcinogenicity

Components:

RIVAROXABAN:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
Dose : 60 mg/kg body weight
Frequency of Treatment : daily
NOAEL : 60 mg/kg
Method : OECD Test Guideline 451
GLP : yes

Species	:	Mouse, male and female
Application Route	:	Oral
Exposure time	:	2 Years
Dose	:	60 mg/kg body weight
Frequency of Treatment	:	daily
NOAEL	:	60 mg/kg
Method	:	OECD Test Guideline 451
GLP	:	yes

Carcinogenicity - Assessment : No evidence of carcinogenicity.

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.

IARC Group 2B: Possibly carcinogenic to humans
13463-67-7 TITANDIOXIDE

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

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.

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:

RIVAROXABAN:

Effects on fertility : Species: Rat
Application Route: Oral
Fertility: NOAEL: > 200 mg/kg body weight
Early Embryonic Development: NOAEL: 50 mg/kg body weight
Method: Study of Fertility and Early Embryonic Development to Implantation
Result: Not classified

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: < 10
Method: Developmental Toxicity
Result: Not classified

Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: < 2.5

Method: Developmental Toxicity
Result: Not classified

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility., No evidence of reprotoxicity.

Teratogenicity - Assessment : No evidence of adverse effects on development., No effects on or via lactation

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

STOT - single exposure

Components:

RIVAROXABAN:

Remarks : Not classified

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

Components:

RIVAROXABAN:

Exposure routes : Oral
Target Organs : Blood
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

RIVAROXABAN:

Species : Rat
NOAEL : 2.5 mg/kg
Application Route : Oral
Exposure time : 26 weeks
Target Organs : Blood

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 52 weeks
Target Organs : Blood

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:

RIVAROXABAN:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 3.4 mg/l End point: Immobilization Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	NOEC (Desmodesmus subspicatus (green algae)): 0.52 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 ErC50 (Desmodesmus subspicatus (green algae)): > 2.12 mg/l End point: Growth rate Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 0.086 mg/l Exposure time: 36 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility LOEC (Danio rerio (zebra fish)): > 0.086 mg/l Exposure time: 36 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility

NOEC (Pimephales promelas (fathead minnow)): >= 0.086 mg/l
Exposure time: 28 d
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.5 mg/l
Exposure time: 21 d
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211

LOEC (Daphnia magna (Water flea)): 3.9 mg/l
Exposure time: 21 d
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (activated sludge): 19.4 mg/l
Exposure time: 0.5 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC (activated sludge): 4 mg/l
Exposure time: 0.5 h
Method: OECD Test Guideline 209

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : 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:

RIVAROXABAN:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Stability in water : Degradation half life (DT50): 235 Days (25 °C) pH: 9
Remarks: total system 1

Hydrolysis: 0 %

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

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:

RIVAROXABAN:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 1.5
Method: OECD Test Guideline 107

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Bioaccumulation : Remarks: No data available

Octadecanoic acid, magnesium salt:

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

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

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

TITANDIOXIDE:

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

Mobility in soil

Components:

RIVAROXABAN:

Distribution among environmental compartments : Remarks: No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among environmental compartments : Remarks: No data available

DODECYL SODIUM SULPHATE:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

RIVAROXABAN:

Additional ecological information : No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

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

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

Massachusetts Right To Know

microcrystalline cellulose	9004-34-6

Pennsylvania Right To Know

Cellulose	9004-34-6
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1

RIVAROXABAN	366789-02-8
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3 74811-65-7

Pennsylvania Right To Know

microcrystalline cellulose	9004-34-6
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
RIVAROXABAN	366789-02-8
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3 74811-65-7

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 Jersey Right To Know

Cellulose	9004-34-6
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
RIVAROXABAN	366789-02-8
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3 74811-65-7

New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

New York City Hazardous Substances

TITANDIOXIDE	13463-67-7
diiron trioxide	1309-37-1

California Prop. 65

WARNING: This product can expose you to chemicals including TITANDIOXIDE, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6

California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose	9004-34-6

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.

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
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

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 : 2024/09/04

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