

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
6.9	2024/09/03	100000014451	Date of first issue: 2018/04/06

### SECTION 1. IDENTIFICATION

Product name : XARELTO  
Substance name : XARELTO 2.5 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 : Category 2  
- repeated exposure  
Short-term (acute) aquatic hazard : Category 3  
Long-term (chronic) aquatic : Category 3

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hazard

### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H373 May cause damage to organs through prolonged or repeated exposure.  
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 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)
microcrystalline cellulose	9004-34-6	$\geq 30 - < 50$
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	$\geq 1 - < 5$
RIVAROXABAN	366789-02-8	$\geq 1 - < 5$
Octadecanoic acid, magnesium salt	557-04-0	$\geq 0.1 - < 1$
DODECYL SODIUM SULPHATE	151-21-3	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

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- If inhaled : Health injuries are not known or expected under normal use. 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.  
anemia  
Gastrointestinal discomfort  
Abdominal pain  
constipation  
Diarrhoea  
nausea  
Vomiting  
Fever  
headache  
Dizziness  
hypotension  
Rash  
May cause damage to organs through prolonged or repeated exposure.
- 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

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- 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.
- 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.

### 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/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1

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		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m <sup>3</sup>	ACGIH
RIVAROXABAN	366789-02-8	TWA	0.030 mg/m <sup>3</sup>	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.				
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.				

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

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**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 : film, Coated, tablet

Colour : light yellow

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

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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

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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



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**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.

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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:

##### **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

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### 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

#### Product:

Assessment : May cause damage to organs through prolonged or 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

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**Other health hazards**

No data available

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Toxicity to fish : Remarks: No data available

**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

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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

**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:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Biodegradability : Remarks: No data available

**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 %

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### **DODECYL SODIUM SULPHATE:**

Biodegradability : Result: Readily biodegradable.

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

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

### **Bioaccumulative potential**

#### **Components:**

#### **HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Bioaccumulation : Remarks: No data available

#### **RIVAROXABAN:**

Bioaccumulation : Remarks: No data available

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

#### **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)

### **Mobility in soil**

#### **Components:**

#### **HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Distribution among environmental compartments : Remarks: No data available

#### **RIVAROXABAN:**

Distribution among environmental compartments : Remarks: No data available

### **DODECYL SODIUM SULPHATE:**

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

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### Other adverse effects

#### Components:

##### **HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

##### **RIVAROXABAN:**

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

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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.

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## 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

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**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****49 CFR**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION****US State Regulations****Massachusetts Right To Know**

microcrystalline cellulose 9004-34-6

**Pennsylvania Right To Know**

microcrystalline cellulose 9004-34-6

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, 5989-81-1

hydrate (1:1)

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 York City Hazardous Substances**

TITANDIOXIDE 13463-67-7

**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.



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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
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

AIIIC - 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

# SAFETY DATA SHEET



## XARELTO

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Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;  
vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2024/09/03

### Date and Number Formats

This document uses the following notation for printing dates and numbers:

<b>Date:</b>	Dec 31th, 2012	as	2012/12/31
<b>Numbers:</b>	123456,78	as	123,456.78

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