

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue:
9.5	2024/09/04	100000014540	2024/06/25
			Date of first issue: 2018/04/25

### SECTION 1. IDENTIFICATION

Product name : XARELTO  
Substance name : XARELTO 15 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 (Blood)  
- repeated exposure (Oral)

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic : Category 3

# SAFETY DATA SHEET



## XARELTO

Version 9.5      Revision Date: 2024/09/04      SDS Number: 100000014540      Date of last issue: 2024/06/25  
Date of first issue: 2018/04/25

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 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	>= 30 - < 50
RIVAROXABAN	366789-02-8	>= 10 - < 20
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	>= 1 - < 5
TITANDIOXIDE	13463-67-7	>= 0.1 - < 1
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
DODECYL SODIUM SULPHATE	151-21-3	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

- 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.

# SAFETY DATA SHEET



## XARELTO

Version 9.5      Revision Date: 2024/09/04      SDS Number: 100000014540      Date of last issue: 2024/06/25  
Date of first issue: 2018/04/25

Special protective equipment : In the event of fire, wear self-contained breathing apparatus for firefighters

### 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

# SAFETY DATA SHEET



## XARELTO

Version 9.5      Revision Date: 2024/09/04      SDS Number: 100000014540      Date of last issue: 2024/06/25  
Date of first issue: 2018/04/25

		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
		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
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.				
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m <sup>3</sup>	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
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

# SAFETY DATA SHEET



## XARELTO

Version 9.5      Revision Date: 2024/09/04      SDS Number: 100000014540      Date of last issue: 2024/06/25  
Date of first issue: 2018/04/25

				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).

### 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

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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.

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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



# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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

**XARELTO**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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

**XARELTO**

Version 9.5	Revision Date: 2024/09/04	SDS Number: 100000014540	Date of last issue: 2024/06/25 Date of first issue: 2018/04/25
----------------	------------------------------	-----------------------------	---

**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

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

- NOEC (Pimephales promelas (fathead minnow)):  $\geq$  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:

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue:
9.5	2024/09/04	100000014540	2024/06/25
			Date of first issue: 2018/04/25

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

#### TITANDIOXIDE:

Partition coefficient: n-octanol/water : 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)

**XARELTO**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

**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

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

### 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



# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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
--------------	------------

### 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](http://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

**XARELTO**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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

# SAFETY DATA SHEET



## XARELTO

Version	Revision Date:	SDS Number:	Date of last issue: 2024/06/25
9.5	2024/09/04	100000014540	Date of first issue: 2018/04/25

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