

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

SECTION 1. IDENTIFICATION

Substance name : XARELTO (rivaroxaban) Granule for Oral Suspension
1mg/mL
rivaroxaban
rivaroxaban granules 2%

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)**

Not a hazardous substance or mixture.

GHS label elements

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

Other hazards

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

SAFETY DATA SHEET



| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------------------------|-------------|-----------------------|
| microcrystalline cellulose | 9004-34-6 | $\geq 10 - < 20$ |
| Benzoic acid, sodium salt (1:1) | 532-32-1 | $\geq 1 - < 5$ |
| hydroxypropylmethylcellulose | 9004-65-3 | $\geq 1 - < 5$ |
| citric acid | 77-92-9 | $\geq 1 - < 5$ |
| RIVAROXABAN | 366789-02-8 | $\geq 1 - < 5$ |
| PROPYLENE GLYCOL | 57-55-6 | $\geq 0.1 - < 1$ |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- If inhaled : 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 : 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



| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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.
Avoid dust formation.
Avoid breathing dust.
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 or vacuum with HEPA filter 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 : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.

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 cool, well-ventilated place.
Keep away from heat and sources of ignition.
Store at room temperature.

Recommended storage temperature : 68 - 77 °F / 20 - 25 °C

Further information on storage stability : Do not freeze.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

SAFETY DATA SHEET



Version
7.1

Revision Date:
2025/09/10

SDS Number:
100000016864

Date of last issue: 2025/03/07
Date of first issue: 2021/11/12

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------------|--|---------------------------------------|---|-------------------------|
| microcrystalline 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 |
| Benzoic acid, sodium salt (1:1) | 532-32-1 | TWA (Inhalable particulate matter) | 2.5 mg/m ³ | ACGIH |
| hydroxypropylmethylcellulose | 9004-65-3 | TWA | 10 mg/m ³ | ACGIH |
| RIVAROXABAN | 366789-02-8 | TWA | 0.030 mg/m ³ | 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. | | | |
| PROPYLENE GLYCOL | 57-55-6 | TWA | 10 mg/m ³ | US WEEL |

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

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

SAFETY DATA SHEET

**Johnson
&Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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 : granules

Colour : white, to, off-white

Odour : No data available

Odour Threshold : No data available

pH : 4 - 4.8
Concentration: 1,000 mg/l
(aqueous suspension)

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data 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 vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

SAFETY DATA SHEET

**Johnson
&Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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

Viscosity

Viscosity, dynamic : No data available

Explosive properties : No data available

Oxidizing 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 : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Benzoic acid, sodium salt (1:1):

Acute oral toxicity : LD50 (Rat): 3,140 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

citric acid:

Acute oral toxicity : LD50 (Rat): 3,000 mg/kg
Symptoms: Pain, Bloody vomiting

SAFETY DATA SHEET

**Johnson
& Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

LD50 (Mouse): 5,400 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

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

PROPYLENE GLYCOL:

Acute oral toxicity : LD50 (Rat): > 10,400 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): > 317,042 mg/l
Exposure time: 2 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 20,800 mg/kg

Skin corrosion/irritation

Components:

Benzoic acid, sodium salt (1:1):

Remarks : No data available

RIVAROXABAN:

Remarks : No data available

Serious eye damage/eye irritation

Components:

Benzoic acid, sodium salt (1:1):

Result : Eye irritation

citric acid:

Result : Eye irritation

RIVAROXABAN:

Remarks : No data available

| | | | |
|----------------|------------------------------|-----------------------------|---|
| Version 7.1 | Revision Date: 2025/09/10 | SDS Number: 100000016864 | Date of last issue: 2025/03/07 Date of first issue: 2021/11/12 |
|----------------|------------------------------|-----------------------------|---|

Respiratory or skin sensitisation

Components:

Benzoic acid, sodium salt (1:1):

Remarks : No data available

citric acid:

Remarks : No data available

RIVAROXABAN:

Remarks : No data available

Germ cell mutagenicity

Components:

Benzoic acid, sodium salt (1:1):

Germ cell mutagenicity - Assessment : No information available.

citric acid:

Genotoxicity in vitro : Method: Ames test
Result: negative

Germ cell mutagenicity - Assessment : Did not show mutagenic effects in animal experiments.

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.

Carcinogenicity

Components:

Benzoic acid, sodium salt (1:1):

Carcinogenicity - Assessment : No information available.

SAFETY DATA SHEET

**Johnson
&Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

citric acid:

Carcinogenicity - Assessment : No information available.

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.

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:

Benzoic acid, sodium salt (1:1):

Teratogenicity - Assessment : No information available.

citric acid:

Teratogenicity - Assessment : No information available.

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

SAFETY DATA SHEET



| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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

STOT - single exposure

Components:

Benzoic acid, sodium salt (1:1):

Remarks : No data available

citric acid:

Assessment

: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

RIVAROXABAN:

Remarks : Not classified

STOT - repeated exposure

Components:

RIVAROXABAN:

Exposure routes

: Oral

Target Organs

: Blood

Assessment

: May cause damage to organs through prolonged or repeated exposure.

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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:****Benzoic acid, sodium salt (1:1):**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

hydroxypropylmethylcellulose:

Toxicity to fish : Remarks: No data available

citric acid:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): ca. 600 mg/l
Exposure time: 96 h

SAFETY DATA SHEET

**Johnson
& Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 48 h

EC50 (Daphnia magna (Water flea)): 120 mg/l
Exposure time: 72 h

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): 640 mg/l
Exposure time: 7 d

(microcystis aeruginosa (blue green algae)): 80 mg/l
Exposure time: 8 d

Toxicity to microorganisms : (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h

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

SAFETY DATA SHEET

**Johnson
& Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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

PROPYLENE GLYCOL:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 51,600 mg/l
Exposure time: 96 h
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 43,500 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : NOEC: > 100 mg/l

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : (Daphnia sp. (water flea)): 13,020 mg/l
Exposure time: 7 d

Persistence and degradability

Components:

Benzoic acid, sodium salt (1:1):

Biodegradability : Remarks: No data available

hydroxypropylmethylcellulose:

Biodegradability : Remarks: No data available

citric acid:

Biodegradability : Result: Biodegradable
Biodegradation: 98 %
Exposure time: 2 d
Method: OECD Test Guideline 302

Biochemical Oxygen Demand (BOD) : 526 mg/g
Incubation time: 5 d

Chemical Oxygen Demand (COD) : 728 mg/g

SAFETY DATA SHEET

**Johnson
& Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

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 %

PROPYLENE GLYCOL:

Biodegradability : Biodegradation: 81 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Benzoic acid, sodium salt (1:1):

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -2.27

hydroxypropylmethylcellulose:

Bioaccumulation : Remarks: No data available

citric acid:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.8 - -0.2 (68 °F / 20 °C)
Method: OECD Test Guideline 117

RIVAROXABAN:

Bioaccumulation : Remarks: No data available

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

PROPYLENE GLYCOL:

Bioaccumulation : Bioconcentration factor (BCF): < 100
Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.92

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

Mobility in soil**Components:****Benzoic acid, sodium salt (1:1):**

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

hydroxypropylmethylcellulose:

Distribution among environmental compartments : Remarks: No data available

citric acid:

Distribution among environmental compartments : Remarks: No data available

RIVAROXABAN:

Distribution among environmental compartments : Remarks: No data available

PROPYLENE GLYCOL:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Components:****Benzoic acid, sodium salt (1:1):**

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

hydroxypropylmethylcellulose:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

citric acid:

Results of PBT and vPvB assessment : No information available.

SAFETY DATA SHEET



| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

Additional ecological information : No data available

RIVAROXABAN:

Additional ecological information : No data available

PROPYLENE GLYCOL:

Results of PBT and vPvB assessment : No information available.

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

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

microcrystalline cellulose 9004-34-6

Pennsylvania Right To Know

mannitol 87-78-5
microcrystalline cellulose 9004-34-6
Benzoic acid, sodium salt (1:1) 532-32-1
carboxy methyl cellulose, sodium salt 9004-32-4

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

California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose 9004-34-6

Other regulations

Restricted to professional users.

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

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

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 |
| US WEEL | : | USA. Workplace Environmental Exposure Levels (WEEL) |
| 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 |

SAFETY DATA SHEET

**Johnson
& Johnson**

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

OSHA Z-1 / TWA : 8-hour time weighted average
US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally 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 : 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.

SAFETY DATA SHEET



| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/03/07 |
| 7.1 | 2025/09/10 | 100000016864 | Date of first issue: 2021/11/12 |

US / EN