

SAFETY DATA SHEET



SPORANOX

Version 8.4	Revision Date: 2025/09/10	SDS Number: 100000014438	Date of last issue: 2025/08/19 Date of first issue: 2018/04/23
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SECTION 1. IDENTIFICATION

Product name	:	SPORANOX
Substance name	:	SPORANOX 100 mg oral capsules USA itraconazole

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: Antimycotics for systemic use This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component. This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).
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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. Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate

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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)
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 30 - < 50
hydroxypropylmethylcellulose	9004-65-3	>= 20 - < 30
ITRACONAZOLE	84625-61-6	>= 10 - < 20
starch	9005-25-8	>= 5 - < 10
poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-ethane-1,2-diol, ethoxylated	25322-68-3	>= 1 - < 5
titandioxide	13463-67-7	>= 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 : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Abdominal pain
headache
nausea

Notes to physician : Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

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Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous combustion products : No hazardous combustion products are known

Further information : Avoid dust formation.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid dust formation. Evacuate personnel to safe areas. In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations". Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations. To avoid thermal decomposition, do not overheat. Keep away from heat and sources of ignition. 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 container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up.

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&Johnson**

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	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
hydroxypropylmethylcellulose	9004-65-3	TWA	10 mg/m3	ACGIH
ITRACONAZOLE	84625-61-6	TWA	0.360 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 OTOTOXIC: has the potential to cause hearing impairment or balance problems		
starch	9005-25-8	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
poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.- hydroxy-ethane-1,2-diol, ethoxylated	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL

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titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH

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

Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally required.
Hand protection	
Remarks	: Disposable gloves
Eye protection	: No special precautions required.
Skin and body protection	: closed work clothing
Protective measures	: The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: pellets
Colour	: No data available
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

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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 vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
<u>Water solubility</u>	: No data available
Partition coefficient: n-octanol/water	: No data available
Decomposition temperature	: No data available
Viscosity	
<u>Viscosity, dynamic</u>	: Not applicable
<u>Viscosity, kinematic</u>	: Not applicable
Explosive properties	: No data available
Oxidizing properties	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under normal conditions.
Conditions to avoid	: To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	: None known.
Hazardous decomposition products	: None known.

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate: 2,779 mg/kg
Method: Calculation method

Components:**ITRACONAZOLE:**

Acute oral toxicity : LD50 (Rat): > 320 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.
LD50 (Mouse): > 320 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 40 - 46 mg/kg
Application Route: intravenous injection
LD50 (Mouse): 46 mg/kg
Application Route: intravenous injection

Skin corrosion/irritation**Components:****ITRACONAZOLE:**

Remarks : No data available

Serious eye damage/eye irritation**Components:****ITRACONAZOLE:**

Remarks : No data available

Respiratory or skin sensitisation**Components:****ITRACONAZOLE:**

Remarks : No data available

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Germ cell mutagenicity

Components:

ITRACONAZOLE:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

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

Carcinogenicity

Components:

ITRACONAZOLE:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

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:

ITRACONAZOLE:

Reproductive toxicity - Assessment : In animal testing, risk of impaired fertility was shown only after administration of very high doses of this substance.

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted in maternal and foetal toxicity.

STOT - single exposure

Components:

ITRACONAZOLE:

Remarks : No data available

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STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

ITRACONAZOLE:

Species : Rat
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 3 m

Species : Rat
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 3 m
Subsequent observation period : 1 m

Species : Dog
NOAEL : 2.5 mg/kg
Application Route : Oral
Exposure time : 3 m

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 3 m
Subsequent observation period : 1 m

Species : Rat
NOAEL : < 7 mg/kg
Application Route : Oral
Exposure time : 6m

Species : Rat
NOAEL : < 3 mg/kg
Application Route : Oral
Exposure time : 12 m

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 12 m

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

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Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

hydroxypropylmethylcellulose:

Toxicity to fish : Remarks: No data available

ITRACONAZOLE:

Toxicity to fish : EC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,000 mg/l
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : (Scenedesmus capricornutum (fresh water algae)): > 1,000 mg/l
Test Type: Growth inhibition
Method: OECD Test Guideline 201

(microcystis aeruginosa (blue green algae)): > 1,000 mg/l
Test Type: Growth inhibition
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (activated sludge): >= 2,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

EC50 (activated sludge): > 2,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

hydroxypropylmethylcellulose:

Biodegradability : Remarks: No data available

ITRACONAZOLE:

Biodegradability : Remarks: No data available

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Bioaccumulative potential

Components:

hydroxypropylmethylcellulose:

Bioaccumulation : Remarks: No data available

ITRACONAZOLE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Pow: 5.18

starch:

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

titandioxide:

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

Mobility in soil

Components:

hydroxypropylmethylcellulose:

Distribution among environmental compartments : Remarks: No data available

ITRACONAZOLE:

Distribution among environmental compartments : log Koc: 15.3
Method: OECD Test Guideline 121
Remarks: immobile

Other adverse effects

Components:

hydroxypropylmethylcellulose:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

ITRACONAZOLE:

Additional ecological information : No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl starch	57-50-1 9005-25-8
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Pennsylvania Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl hydroxypropylmethylcellulose	57-50-1 9004-65-3
ITRACONAZOLE	84625-61-6
starch	9005-25-8
poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-ethane-1,2-diol, ethoxylated	25322-68-3

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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

alpha-D-Glucopyranoside, beta-D-fructofuranosyl starch	57-50-1
	9005-25-8

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.

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
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
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 -

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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.

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