

SPORANOX

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SECTION 1. IDENTIFICATION

Product name : SPORANOX
Substance name : SPORANOX oral solution, 10 mg/ml
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 not 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. 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 : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
PROPYLENE GLYCOL	57-55-6	$\geq 10 - < 20$
ITRACONAZOLE	84625-61-6	$\geq 1 - < 5$
hydrochloric acid	7647-01-0	$\geq 0.1 - < 1$

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 : Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.
Abdominal pain
headache
nausea
Dizziness
Cough
Diarrhoea
Vomiting
Fever
Shortness of breath
Rash
- Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.

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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Specific hazards during firefighting : Heating can release hazardous gases.
- 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 : 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. Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
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 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.
- Materials to avoid : Do not freeze.
- Recommended storage : < 77 °F / < 25 °C

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temperature

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
PROPYLENE GLYCOL	57-55-6	TWA	10 mg/m3	US WEEL
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			
hydrochloric acid	7647-01-0	C	2 ppm	ACGIH
		C	5 ppm 7 mg/m3	NIOSH REL
		C	5 ppm 7 mg/m3	OSHA Z-1
		C	5 ppm 7 mg/m3	OSHA P0

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 : Disposable gloves

Eye protection : No special precautions required.

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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	:	liquid, solution
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No information available.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative 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

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Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : 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 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.

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

Components:**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

ITRACONAZOLE:

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

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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 injectionLD50 (Mouse): 46 mg/kg
Application Route: intravenous injection**hydrochloric acid:**Acute inhalation toxicity : LC50 (Mouse): 20.487 mg/m3/5M
Test atmosphere: vapourLC50 (Mouse): 3.940 mg/m3/30M
Test atmosphere: vapourLC50 (Mouse): 8.300 mg/m3/30M
Test atmosphere: vapourLC50 (Rat): 45.000 - 60.938 mg/m3/5M
Test atmosphere: vapourLC50 (Rat): 7.400 - 8.300 mg/m3/30M
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,010 mg/kg

Acute toxicity (other routes of administration) : Remarks: No data available

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

Remarks : No data available

hydrochloric acid:

Result : Corrosive to skin

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

Remarks : No data available

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hydrochloric acid:

Result : Corrosive to eyes

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

Remarks : No data available

hydrochloric acid:

Remarks : No data available

Germ cell mutagenicity**Components:****ITRACONAZOLE:**Genotoxicity in vitro : Test Type: Ames test
Result: negativeTest Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negativeGenotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

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

hydrochloric acid:

Germ cell mutagenicity - Assessment : No information available.

Carcinogenicity**Components:****ITRACONAZOLE:**

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

hydrochloric acid:

Carcinogenicity - Assessment : No information available.

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.

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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.

hydrochloric acid:

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

STOT - single exposure**Components:****ITRACONAZOLE:**

Remarks : No data available

hydrochloric acid:

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

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 : 1 m

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period

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	: 1 m

period

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

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****PROPYLENE GLYCOL:**

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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

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

hydrochloric acid:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 862 mg/l
Exposure time: 48 h

EC50 (Scenedesmus capricornutum (fresh water algae)): 8.5 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 71 mg/l
Exposure time: 24 h

Toxicity to algae/aquatic plants : EC50: 25.5 mg/l
Exposure time: 120 h
Method: OECD Test Guideline 201

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Persistence and degradability**Components:****PROPYLENE GLYCOL:**

Biodegradability : Biodegradation: 81 %
Exposure time: 28 d

ITRACONAZOLE:

Biodegradability : Remarks: No data available

hydrochloric acid:

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****PROPYLENE GLYCOL:**

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

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

ITRACONAZOLE:

Bioaccumulation : Remarks: No data available

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

hydrochloric acid:

Bioaccumulation : Remarks: No data available

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

Mobility in soil**Components:****PROPYLENE GLYCOL:**

Distribution among environmental compartments : Remarks: No data available

ITRACONAZOLE:

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

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Other adverse effects**Components:****PROPYLENE GLYCOL:**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

ITRACONAZOLE:

Additional ecological information : No data available

hydrochloric acid:

Environmental fate and pathways : No data available

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

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49 CFR

Not regulated as a dangerous good

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

hydrochloric acid	7647-01-0
1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	128-44-9

Pennsylvania Right To Know

HYDROXYPROPYL-BETA-CYCLODEXTRIN	128446-35-5
water	7732-18-5
syrups, corn, hydrogenated	68425-17-2
PROPYLENE GLYCOL	57-55-6
hydrochloric acid	7647-01-0
1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	128-44-9

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

hydrochloric acid	7647-01-0
benzaldehyde	100-52-7
ethanol	64-17-5
ethyl butyrate	105-54-4
isopentyl acetate	123-92-2
2-furaldehyde	98-01-1
acetic acid	64-19-7

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.

This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

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	:	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 / C	:	Ceiling limit
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / C	:	Ceiling value not be exceeded at any time.
OSHA P0 / C	:	Ceiling limit
OSHA Z-1 / C	:	Ceiling
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

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

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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

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