SPORANOX

Version	Revision Date:	SDS Number:	Date of last issue: 2018-04-10
1.74	2018-04-17	100000009856	Date of first issue: 2013-12-18

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : SPORANOX
Substance name : SPORANOX oral solution, 10 mg/ml
Itraconazole

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : 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.
A safety data sheet is not required for this product under Article 31 of REACH. This SDS has been created on a voluntary basis (to pass on relevant information required under Article 32). Since an SDS is not required, this document may not contain all of the information that is required for substance and mixture SDS's under REACH.

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium
Telephone : +3214602111

Telefax : +3214602841

E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Supplemental Hazard Statements : Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Additional Labelling:

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment:
EUH210 Safety data sheet available on request.
The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 40 %

2.3 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 the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
ITRACONAZOLE	84625-61-6	Acute Tox. 4; H302	< 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : 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

4.3 Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating can release hazardous gases.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

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

Further information : Avoid dust formation.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : 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.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for 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".

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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.

Advice on common storage : Do not freeze.

Recommended storage temperature : < 25 °C

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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.			
hydrochloric acid	7647-01-0	TWA	5 ppm 8 mg/m3	2000/39/EC
Further information	Indicative			
		STEL	10 ppm 15 mg/m3	2000/39/EC
Further information	Indicative			
		TLV 8 hr	5 ppm 8 mg/m3	BE OEL
		TLV 15 min	10 ppm 15 mg/m3	BE OEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

PROPYLENE GLYCOL : End Use: Workers
Exposure routes: Inhalation
Potential health effects: Long-term systemic effects
Value: 168 mg/m3
End Use: Workers
Exposure routes: Inhalation
Potential health effects: Long-term local effects
Value: 10 mg/m3
End Use: Consumers
Exposure routes: Inhalation
Potential health effects: Long-term systemic effects
Value: 50 mg/m3
End Use: Consumers
Exposure routes: Inhalation
Potential health effects: Long-term local effects

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		Value: 10 mg/m3
SORBITOL 70% NIET KRIST.	:	End Use: Workers Exposure routes: Skin contact Potential health effects: Long-term systemic effects Value: 2000 mg/kg End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 5 mg/m3 End Use: Consumer use Exposure routes: Skin contact Potential health effects: Long-term systemic effects Value: 2000 mg/kg End Use: Consumer use Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 0,89 mg/m3 End Use: Consumer use Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 200 mg/kg
hydrochloric acid	:	End Use: Workers Exposure routes: Inhalation Potential health effects: Acute local effects Value: 15 mg/m3 End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 8 mg/m3

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

ITRACONAZOLE	:	Fresh water Value: 1 mg/l
PROPYLENE GLYCOL	:	Fresh water Value: 260 mg/l Marine water Value: 26 mg/l Fresh water sediment Value: 572 mg/kg Marine water Value: 57,2 mg/kg Soil Value: 50 mg/kg aqua (intermittent releases) Value: 183 mg/l STP Value: 20000 mg/l
SORBITOL 70% NIET KRIST.	:	Water Value: 0,973 mg/l Marine water Value: 0,0973 mg/l aqua (intermittent releases) Value: 9,73 mg/l

		Sewage treatment plant Value: 66,7 mg/l Fresh water sediment Value: 3,63 mg/kg Marine sediment Value: 0,363 mg/kg Soil Value: 0,15 mg/kg
hydrochloric acid	:	Fresh water Value: 0,036 mg/l aqua (intermittent releases) Value: 0,045 mg/l Marine water Value: 0,036 mg/l STP Value: 0,036 mg/l

8.2 Exposure controls

Engineering measures

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Eye protection	:	No special precautions required.
Hand protection Remarks	:	No special precautions required.
Skin and body protection	:	No special precautions required.
Respiratory protection	:	No personal respiratory protective equipment normally required. Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
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.

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.
Upper explosion limit	:	No data available
Lower explosion 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
Partition coefficient: n-octanol/water	:	No data available
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

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.

10.5 Incompatible materials

Materials to avoid : None known.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 2 000 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

Germ cell mutagenicity

Components:

ITRACONAZOLE:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
	:	Test Type: Chromosome aberration test in vitro Species: 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.

Reproductive toxicity

Components:

ITRACONAZOLE:

Reproductive toxicity -	:	In animal testing, risk of impaired fertility was shown only after

Assessment 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

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

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	:	(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 bacteria	:	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

12.2 Persistence and degradability

Components:

ITRACONAZOLE:

Biodegradability	:	Remarks: No data available

12.3 Bioaccumulative potential

Components:

ITRACONAZOLE:

Bioaccumulation	:	Remarks: No data available
Partition coefficient: n-	:	Pow: 5,18

octanol/water

12.4 Mobility in soil

Components:

ITRACONAZOLE:

Distribution among environmental compartments : log Koc: 15,3
Method: OECD Test Guideline 121
Remarks: immobile

12.5 Results of PBT and vPvB assessment

Components:

ITRACONAZOLE:

Assessment : No information available..

12.6 Other adverse effects

Components:

ITRACONAZOLE:

Additional ecological information : Remarks: No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : 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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations : Restricted to professional users.

According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Full text of H-Statements

H302 : Harmful if swallowed.

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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