

**SPORANOX**

Version	Revision Date:	SDS Number:	Date of last issue:
1.7	2019/01/15	100000014438	2018/12/11
			Date of first issue: 2018/04/23

**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 Pharmaceutica NV

Address : Turnhoutseweg 30  
Beerse 2340  
Belgium

Telephone : +3214602111  
Telefax : +3214602841

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

**Emergency telephone number** : **CHEMTREC US: 1-800-424-9300**  
**CHEMTREC International: +1 703-527-3887**

**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).

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

**Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:  
6.906 %

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 6.906 %

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**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 accidentally leaking, broken or crushed.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

Chemical nature : Solid

Substance name : SPORANOX 100 mg oral capsules USA

**Hazardous components**

Chemical name	CAS-No.	Concentration (% w/w)
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 30 - < 50
METHYLCELLULOSE	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

**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 con-  
scious).  
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.

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**SECTION 5. FIREFIGHTING MEASURES**

- 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

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place.  
Keep away from heat and sources of ignition.  
Keep locked up.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
METHYLCELLULOSE	9004-65-3	TWA	10 mg/m <sup>3</sup>	ACGIH
ITRACONAZOLE	84625-61-6	TWA	0.360 mg/m <sup>3</sup>	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.				
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.- hydroxy-Ethane-1,2-diol, eth- oxylated	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	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
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3 (Titanium dioxide)	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 Maxxam Analytics ([www.maxxamlabs.com](http://www.maxxamlabs.com)) or the Laboratory of Occupational and Environmental Hygiene ([www.lamh.be](http://www.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

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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	:	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	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

**SECTION 10. STABILITY AND REACTIVITY**

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

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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:****METHYLCELLULOSE:**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**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:****METHYLCELLULOSE:**

Remarks: No data available

**ITRACONAZOLE:**

Remarks: No data available

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

Remarks: No data available

**ITRACONAZOLE:**

Remarks: No data available

**Starch:**

Remarks: Contact with eyes may cause irritation.

**Respiratory or skin sensitisation****Components:****METHYLCELLULOSE:**

Remarks: No data available

**ITRACONAZOLE:**

Remarks: No data available

**Germ cell mutagenicity****Components:****METHYLCELLULOSE:**

Genotoxicity in vitro : Remarks: No data available

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

**Carcinogenicity****Components:****METHYLCELLULOSE:**

Remarks: No data available



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**ITRACONAZOLE:**

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

**IARC**

Group 2B: Possibly carcinogenic to humans

TITANDIOXIDE 13463-67-7

Group 2B: Possibly carcinogenic to humans

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity****Components:****METHYLCELLULOSE:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**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:****METHYLCELLULOSE:**

Remarks: No data available

**ITRACONAZOLE:**

Remarks: No data available

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**STOT - repeated exposure****Components:****METHYLCELLULOSE:**

Remarks: 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

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**Further information****Components:****METHYLCELLULOSE:**

Remarks: No data available

**Starch:**

Remarks: Health injuries are not known or expected under normal use.

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:****Components:****METHYLCELLULOSE:**

Toxicity to fish : Remarks: No data available

**ITRACONAZOLE:**Toxicity to fish : EC50 (*Lepomis macrochirus* (Bluegill sunfish)): > 1,000 mg/l  
Method: OECD Test Guideline 203Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): > 1,000 mg/l  
aquatic invertebrates Method: OECD Test Guideline 202Toxicity 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 201Toxicity to microorganisms : NOEC (activated sludge): >= 2,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209EC50 (activated sludge): > 2,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209**Persistence and degradability****Components:****METHYLCELLULOSE:**

Biodegradability : Remarks: No data available

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**ITRACONAZOLE:**

Biodegradability : Remarks: No data available

**Starch:**

Biodegradability : Result: Readily biodegradable.

**Bioaccumulative potential****Components:****METHYLCELLULOSE:**

Bioaccumulation : Remarks: No data available

**ITRACONAZOLE:**

Bioaccumulation : Remarks: No data available

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

**TITANDIOXIDE:**

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

**Mobility in soil****Components:****METHYLCELLULOSE:**

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****Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).**Components:****METHYLCELLULOSE:**

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Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

**ITRACONAZOLE:**

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

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

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**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.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489):

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.- hydroxy-Ethane-1,2-diol, ethoxylated	25322-68-3	3.24 %
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**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations****Massachusetts Right To Know**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl Starch	57-50-1 9005-25-8
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**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	57-50-1
METHYLCELLULOSE	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

**Pennsylvania Right To Know**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
METHYLCELLULOSE	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

**New Jersey Right To Know**

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alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
METHYLCELLULOSE	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

**New York City Hazardous Substances**

TITANDIOXIDE	13463-67-7
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**New York City Hazardous Substances**

TITANDIOXIDE	13463-67-7
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**California Prop 65**

, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

TITANDIOXIDE	13463-67-7
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WARNING! This product contains a chemical known to the State of California to cause cancer.

TITANDIOXIDE	13463-67-7
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**Other regulations**

: Restricted to professional users.

**California Permissible Exposure Limits for Chemical Contaminants**

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

**California Permissible Exposure Limits for Chemical Contaminants**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
Starch	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.

**TSCA list**

Not relevant

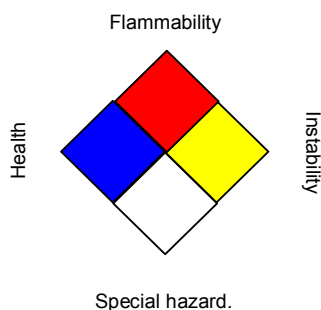
**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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

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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; 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

**Further information****NFPA:****HMIS® IV:**

<b>HEALTH</b>	<input type="text"/>	<input type="text"/>
<b>FLAMMABILITY</b>	<input type="text"/>	<input type="text"/>
<b>PHYSICAL HAZARD</b>	<input type="text"/>	<input type="text"/>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Revision Date : 2019/01/15

**Date and Number Formats**

This document uses the following notation for printing dates and numbers:

<b>Date:</b>	Dec 31th, 2012	as	2012/12/31
<b>Numbers:</b>	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



# SAFETY DATA SHEET

## SPORANOX



Version	Revision Date:	SDS Number:	Date of last issue: 2018/12/11
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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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