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SECTION 1. IDENTIFICATION

Substance name : OPSUMIT 10 mg FC tablets
macitentan

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
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)**

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

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Hazard statements : H360D May damage the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1	>= 50 - < 70
cellulose	9004-34-6	>= 20 - < 30
MACITENTAN	441798-33-0	>= 10 - < 20
titandioxide	13463-67-7	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
polysorbate 80#	9005-65-6	>= 0.1 - < 1

Voluntarily-disclosed non-hazardous substance
Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

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- 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 : anemia
nasopharyngitis
pharyngitis
headache
bronchitis
urinary tract infection
flu-like symptoms
- Notes to physician : Treat symptomatically.

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.
- 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.
- 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

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- Advice on protection against fire and explosion : No data available
- Advice on safe handling : 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. Do not break, crush or spill this Finished Pharmaceutical Product.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place.
- Recommended storage temperature : 68 - 77 °F / 20 - 25 °C

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-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1	PBOEL-HHC	1 A	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 1A. This means that the OEL is estimated to be from 1000 to 3000 µg/m3				
cellulose	9004-34-6	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
MACITENTAN	441798-33-0	TWA	0.0043 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J

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				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 3B., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 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.

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 : Coated, tablet

Colour : white

Odour : No data available

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Odour Threshold : No data available

pH : 6
Concentration: 0.02 g/l

Melting point/ range : 273 °F / 134 °C

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : 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 : 0.0001 g/l

Solubility in other solvents : 4.7 g/l
Solvent: Methanol

> 100 g/l
Solvent: Dimethyl sulfoxide

> 60 g/l
Solvent: Acetone

Partition coefficient: n-octanol/water : Pow: 2.9pH: 7.4

Pow: 3.9pH: 4.2

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : No data available

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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.
Heat, flames and sparks.
Exposure to moisture
Exposure to light.

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 inhalation toxicity : Acute toxicity estimate: 182.29 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

MACITENTAN:

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

polysorbate 80:

Acute toxicity (other routes of administration) : LD50 (Rat): 6,804 mg/kg
Application Route: oral administration

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Skin corrosion/irritation**Components:****cellulose:**

Species : Rabbit
Remarks : No skin irritation

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

Species : Rabbit
Remarks : No eye irritation

Respiratory or skin sensitisation**Components:****cellulose:**

Species : Guinea pig
Remarks : Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity**Components:****MACITENTAN:**

Genotoxicity in vitro : Test Type: Ames test
Method: Bacterial Reverse Mutation Test
Result: negative

Test Type: A mouse lymphoma test
Result: negative

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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Result: negative

Germ cell mutagenicity -
Assessment : No evidence of mutagenicity based on in vitro and in vivo
studies and expert judgment.

Carcinogenicity**Components:****MACITENTAN:**

Carcinogenicity -
Assessment : Did not show carcinogenic effects in animal experiments.

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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:

MACITENTAN:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Dose: 25 mg/kg bw/day
Symptoms: Fetotoxicity

Test Type: Embryo-foetal development
Species: Rabbit
Dose: 25 mg/kg bw/day
Symptoms: Fetotoxicity

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

MACITENTAN:

Species : Dog
NOAEL : 5 mg/kg
Exposure time : 39 w

Species : Rat
NOAEL : 10 mg/kg
Exposure time : 26 w

Aspiration toxicity

No data available

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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:****cellulose:**

Toxicity to fish : Remarks: No data available

MACITENTAN:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Persistence and degradability**Components:****MACITENTAN:**

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1):**

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

MACITENTAN:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n- : Pow: 2.9

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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 311/312 Hazards : Reproductive toxicity

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

cellulose 9004-34-6

Pennsylvania Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) 5989-81-1
cellulose 9004-34-6
MACITENTAN 441798-33-0
sodium starch glycolate 9063-38-1

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 List of Hazardous Substances

crospovidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

cellulose 9004-34-6

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.

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)

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values)
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1
Limits for Air Contaminants
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

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

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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

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Numbers: 123456,78 as 123,456.78

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