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SECTION 1. IDENTIFICATION

Substance name : UPTRAVI® (selexipag) tablets, for oral use, 100 mcg tablets
ACT-293987
selexipag

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)

Hazards for the product as supplied

Not a hazardous substance or mixture.

Other hazards

Warning! May form combustible dust concentrations in air.

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GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
starch	9005-25-8*	$\geq 30 - < 50$	-
Octadecanoic acid, magnesium salt	557-04-0*	$\geq 1 - < 5$	-
SELEXIPAG	475086-01-2*	$\geq 0.1 - < 1$	-

* Indicates that the identifier is a CAS No.

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.
- 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 : Headache
Diarrhoea
jaw pain
Nausea
Vomiting
flushing
pain in extremity
muscle pain
- Notes to physician : Treat symptomatically.

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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 fire-fighting : 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

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Avoid inhalation, ingestion and contact with skin and eyes.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.

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Store in original container.
Keep away from heat and sources of ignition.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Store at room temperature.

Recommended storage temperature : 59 - 86 °F / 15 - 30 °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
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
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
SELEXIPAG	475086-01-2	TWA	0.0028 mg/m3	J&J OEL/PBOEL HHC
		STV	0,028 mg/100cm ²	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 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 3B., Notation SKIN: has the potential for absorption via the skin.				

Engineering measures : All personal protective equipment should be based on a risk

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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 : yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Upper explosion limit / Upper : No data available

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flammability limit

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 : No data available

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

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

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.

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Components:****SELEXIPAG:**

Acute oral toxicity : mortality (Rat): \geq 500 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Skin corrosion/irritation**Components:****SELEXIPAG:**

Method : in vitro skin corrosion test
Result : negative

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

Species : Bovine cornea
Result : Eye irritation
Method : In vitro BCOP (Bovine Corneal Opacity and Permeability) assay

Respiratory or skin sensitisation**Components:****SELEXIPAG:**

Test Type : In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)
Result : negative

Test Type : KeratinoSens assay
Result : positive

Test Type : Maximisation Test
Exposure routes : Intradermal
Species : Guinea pig
Result : Not a skin sensitizer.
Remarks : Not classified

Germ cell mutagenicity**Components:****SELEXIPAG:**

Germ cell mutagenicity - : No evidence of mutagenicity based on weight of evidence.

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Assessment

Carcinogenicity

Components:

SELEXIPAG:

Species : Rat
 Exposure time : 2 y
 Dose : 100 mg/kg
 Result : No evidence of carcinogenicity in animal studies.

Species : Mouse
 Exposure time : 2 y
 Dose : 500 mg/kg
 Result : No evidence of carcinogenicity in animal studies.

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:

SELEXIPAG:

Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Oral
 Fertility: NOEL: 60 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Dose: 2, 6, 20 mg/kg/day
 Result: Not classified

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral
 Dose: 3, 10, 30 mg/kg
 Result: No adverse effects

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

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Teratogenicity - Assessment : Did not show teratogenic effects in animal experiments.

STOT - single exposure

No data available

STOT - repeated exposure

Components:

SELEXIPAG:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

SELEXIPAG:

Species : Rat
NOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 26 weeks

Species : Dog
Application Route : Oral
Target Organs : Bone, Bone marrow, intestinal tract

Species : Dog
NOEL : 2 mg/kg
Exposure time : 39 weeks

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

Endocrine disrupting properties

No data available

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****starch:**Partition coefficient: n- : Remarks: No data available
octanol/water**Octadecanoic acid, magnesium salt:**Partition coefficient: n- : Remarks: No data available
octanol/water**SELEXIPAG:**Partition coefficient: n- : Pow: 2.2
octanol/water**Mobility in soil**

No data available

Other adverse effects

No data available

Endocrine disrupting properties

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**

Environmentally hazardous : no

UNRTDG

Not regulated as a dangerous good

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IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

Special precautions for user

Not applicable

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

starch

9005-25-8

Pennsylvania Right To Know

D-Mannitol

69-65-8

starch

9005-25-8

hydroxypropylcellulose

9004-64-2

UNKNOWN COMP

Not Assigned

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

starch

9005-25-8

Octadecanoic acid, magnesium salt

557-04-0

Other regulations

Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

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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
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
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

AICC - 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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

This SDS received a major version update triggered by a change in Section 1.

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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

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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