

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
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SECTION 1. IDENTIFICATION

Substance name : TRACLEER/STAYVEER/BOSENTAN 62,5 & 125 mg FC tablets
Bosentan monohydrate

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)

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic : Category 3

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

hazard

GHS label elements

Hazard pictograms



Signal word

: Warning

Hazard statements

: H317 May cause an allergic skin reaction.
H361d Suspected of damaging the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

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

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Chemical name	CAS-No.	Concentration (% w/w)
Bosentan monohydrate	157212-55-0	$\geq 70 - < 90$
Starch	9005-84-9	$\geq 5 - < 10$
pregelatinized potato starch	65996-62-5	$\geq 1 - < 5$
titandioxide	13463-67-7	$\geq 1 - < 5$
Octadecanoic acid, magnesium salt	557-04-0	$\geq 0.1 - < 1$

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 immediately with plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before reuse.
- 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 : sensitising effects
respiratory tract irritation
headache
fainting
flushing
Lowered blood pressure
sinusitis
joint pain
irregular heart beat
- 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 : In the event of fire, wear self-contained breathing apparatus.

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

for firefighters

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : 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.
Do not flush into surface water or sanitary sewer system.
- 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.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
- Recommended storage temperature : 59 - 77 °F / 15 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible	Basis
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SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

			concentration	
Bosentan monohydrate	157212-55-0	TWA	0.022 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	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 2., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development				
Starch	9005-84-9	TWA	10 mg/m3	ACGIH
pregelatinized potato starch	65996-62-5	TWA (inhalable dust)	0.5 mg/m3	ACGIH
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.
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

Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

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, orange

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 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 : No data available

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

Auto-ignition temperature : No data available

Viscosity

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

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 recommended storage 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 sunlight.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Components:

Bosentan monohydrate:

Acute oral toxicity : LDLo (Rat): > 3,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

pregelatinized potato starch:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

Bosentan monohydrate:

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Species : Rabbit
Result : No skin irritation

Starch:

Remarks : slight irritation

pregelatinized potato starch:

Remarks : No data available

Serious eye damage/eye irritation

Components:

Bosentan monohydrate:

Species : Rabbit
Result : No eye irritation

pregelatinized potato starch:

Remarks : No data available

Respiratory or skin sensitisation

Components:

Bosentan monohydrate:

Species : Guinea pig
Result : May cause sensitisation by skin contact.

pregelatinized potato starch:

Remarks : No data available

Germ cell mutagenicity

Components:

Bosentan monohydrate:

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

pregelatinized potato starch:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Carcinogenicity

Components:

Bosentan monohydrate:

Carcinogenicity - Assessment : No evidence of carcinogenicity.

pregelatinized potato starch:

Remarks : No data 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.

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:

Bosentan monohydrate:

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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

pregelatinized potato starch:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Components:

pregelatinized potato starch:

Remarks : No data available

STOT - repeated exposure

Components:

pregelatinized potato starch:

Remarks : No data available

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Repeated dose toxicity

No data available

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

Components:

Starch:

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

pregelatinized potato starch:

Remarks : No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Bosentan monohydrate:

Toxicity to fish : (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test Type: LC50
Method: OECD Test Guideline 203

NOEC: < 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 66 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

EC0 (Daphnia magna (Water flea)): 33 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Toxicity to microorganisms : EC50 (activated sludge): > 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

pregelatinized potato starch:

Toxicity to fish : Remarks: No data available

Persistence and degradability

Components:

Bosentan monohydrate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Result: Not inherently biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 302C

pregelatinized potato starch:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

pregelatinized potato starch:

Bioaccumulation : Remarks: No data available

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

titandioxide:

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

Octadecanoic acid, magnesium salt:

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

Mobility in soil

Components:

pregelatinized potato starch:

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

pregelatinized potato starch:

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

SARA 311/312 Hazards : Respiratory or skin sensitisation
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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Bosentan monohydrate	157212-55-0
Starch	9005-84-9
sodium starch glycolate	9063-38-1
pregelatinized potato starch	65996-62-5

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

pregelatinized potato starch	65996-62-5
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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.

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
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	

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---

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

Revision Date : 2025/09/10

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.

US / EN

SAFETY DATA SHEET



Version 10.2	Revision Date: 2025/09/10	SDS Number: 100000014756	Date of last issue: 2025/09/09 Date of first issue: 2018/10/01
-----------------	------------------------------	-----------------------------	---