

Striverdi® Respimat®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000034932 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Striverdi® Respimat®
Synonyms : Active ingredient: Olodaterol hydrochloride<= 1%
Product code : 000000034932

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated
Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368
Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours
Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Solution for production of finished medicinal products.
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a dangerous substance according to GHS.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a dangerous substance according to GHS.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Olodaterol hydrochloride	869477-96-3	<= 1

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SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Move to fresh air.
Call a physician immediately.
- In case of skin contact : Wash off immediately with plenty of water.
Cover wound with sterile dressing.
Call a physician immediately.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
Call a physician immediately.
- If swallowed : Rinse mouth.
Drink plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure if inhaled.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
-

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Foam
Carbon dioxide (CO₂)
Dry chemical
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)
Hydrogen chloride gas
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
- Special protective equipment for firefighters : Self-contained breathing apparatus (EN 133)
complete suit protecting against chemicals
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
Keep people away from and upwind of spill/leak.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Keep away from heat and sources of ignition. Take precautionary measures against static discharges.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Keep container closed when not in use.
- Conditions for safe storage : Protect from heat and direct sunlight.
Keep container tightly closed.
Jointless smooth floor
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

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

Components	Basis	Factor	Category	Values	Remark
6-Hydroxy-8-((1R)-1-hydroxy-2-((2-(4-methoxyphenyl)-1,1-dimethyl-ethyl)amino)ethyl)-2H-1,4-benzoxazin-3(4H)-one Hydrochloride 869477-96-3	ECL		4	0.1 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

- Engineering measures** : Local exhaust

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Personal protective equipment

- Respiratory protection : Not required; except in case of aerosol formation.
- Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms
- Eye protection : Safety glasses with side-shields
- Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.
- Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.
- Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.
-

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Aqueous solution
- Colour : No data available
- 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 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

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Density : No data available

Bulk density : Not applicable

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

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reac-
tions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition
products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Olodaterol hydrochloride:**

Acute oral toxicity : Acute toxicity estimate (Rat, male): > 1,000 mg/kg
Method: OECD Test Guideline 423

Acute toxicity estimate (Rat, female): >= 316 - 1,000 mg/kg

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Method: OECD Test Guideline 423

Acute inhalation toxicity : LC 50 (estimated) (Rat): > 25 mg/l
Exposure time: 4 h

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:

Olodaterol hydrochloride:

Species: Rabbit

Assessment: No skin irritation

Method: OECD Test Guideline 404

Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Olodaterol hydrochloride:

Species: Rabbit

Result: Severe eye irritation

Assessment: Irritating to eyes.

Method: OECD Test Guideline 405

GLP: yes

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

Olodaterol hydrochloride:

Remarks: No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Olodaterol hydrochloride:

Genotoxicity in vitro : Test Type: Ames-test
Species: Salmonella typhimurium
Result: negative

: Test Type: Mouse lymphoma assay
Species: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: by inhalation
Result: negative

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Carcinogenicity

Not classified based on available information.

Components:**Olodaterol hydrochloride:**

Species: Rat

Application Route: Inhalation

Exposure time: 104 weeks weeks

Dose: 25, 75, 250 µg/kg/day

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 identified as a carcinogen or potential carcinogen by OSHA.

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

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure if inhaled.

Components:**Olodaterol hydrochloride:**

Exposure routes: inhalation (dust/mist/fume)

Assessment: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

Repeated dose toxicity**Components:****Olodaterol hydrochloride:**

Species: Rat

NOAEL: 0.049 mg/kg

Application Route: Inhalation

Exposure time: 26 weeks

Species: Rat

NOAEL: 0.015 mg/kg

Application Route: Inhalation

Exposure time: 52 weeks

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Aspiration toxicity

Not classified based on available information.

Components:**Olodaterol hydrochloride:**

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Olodaterol hydrochloride:**

Toxicity to fish : Remarks: No data available

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

Toxicity to algae : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to bacteria : Remarks: No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Olodaterol hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: 3

Mobility in soil

No data available

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).

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SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : Dispose of in accordance with local regulations.
- Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.
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SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations

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

- SARA 311/312 Hazards** : Acute Health Hazard
- SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- 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 12 (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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489).

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

Massachusetts Right To Know

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

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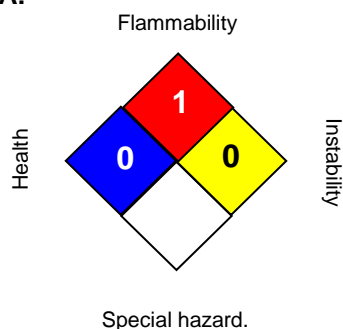
Pennsylvania Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %

New Jersey Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %
Olodaterol hydrochloride 869477-96-3 1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version.
Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.
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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.