

Version 1.2 Revision Date: 06/03/2015 MSDS Number: 000000029260 Date of last issue: 05/28/2015
Date of first issue: 05/22/2015

SECTION 1. IDENTIFICATION

Product name : Stiolto®, Stiolto® Respimat®

Synonyms : Active ingredient: Olodaterol hydrochloride <= 0,05 % and
Tiotropiumbromide monohydrate <= 0,05 %
Stiolto® Respimat® Inhalation Spray

Product code : 000000029260

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 : Mixture 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 hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

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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.
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 : Cough
Back pain
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- 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
Hydrogen bromide (HBr)
- 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.
Ensure adequate ventilation.
Never return spills in original containers for re-use.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Cleaning operations should be carried out only while wearing breathing apparatus.
Clean-up methods - large spillage
Pump off product.
Clean-up methods - small spillage
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.
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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Breathing must be protected when large quantities are decanted without local exhaust ventilation.
Keep container closed when not in use.
- Conditions for safe storage : Store in original container.
Protect from heat and direct sunlight.
Jointless smooth floor
Keep container tightly closed.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation
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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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Components	Basis	Factor	Cateryory	Values	Remark
1-alpha,2-beta,4-beta,5-alpha,7-beta-7-((Hydroxydi-(2-thienyl)acetyl)oxy)-9,9-dimethyl-3-oxa-9-azatricyclo[3.3.1.0(2,4)]nonane Bromide 411207-31-3	ECL		4	0.1 µg/m ³	(respirable fraction)
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Cateryory	Values	Remark
1-alpha,2-beta,4-beta,5-alpha,7-beta-7-((Hydroxydi-(2-thienyl)acetyl)oxy)-9,9-dimethyl-3-oxa-9-azatricyclo[3.3.1.0(2,4)]nonane Bromide 411207-31-3	ECL		4	0.4 µg/m ³	(inhalable fraction)
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Cateryory	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 : Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields

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- 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.
Do not breathe vapour/spray.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
- Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.
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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- pH : 2.9
- Melting point/range : Not applicable
- Boiling point/boiling range : No data available
- Flash point : Not applicable
- 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
- Density : No data available
- Bulk density : No data available

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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

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 reactions	:	No hazardous reactions if stored and handled as prescribed/indicated.
Conditions to avoid	:	Extremes of temperature and direct sunlight.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Carcinogenicity

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.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

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Persistence and degradability

No data available

Bioaccumulative potential

No data available

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).

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.

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 : No SARA Hazards

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

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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 SOCM 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.

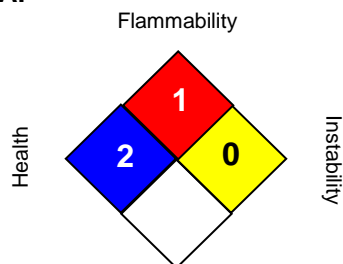
Pennsylvania Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %

New Jersey Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %

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:**

Special hazard.

HMIS III:

HEALTH	1
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.