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**SECTION 1. IDENTIFICATION**

Product name : Spiriva® Respimat®  
Synonyms : Active ingredient: Tiotropium bromide monohydrate  
Product code : 000000028912

**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](mailto:EHS-service@boehringer-ingelheim.com)

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

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Tiotropiumbromide monohydrate	411207-31-3	< 1

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#### SECTION 4. FIRST AID MEASURES

- |   |   |   |
|---|---|---|
| General advice  | : | Remove from exposure, lie down.<br>Take off immediately all contaminated clothing.<br>Victim to lie down in the recovery position, cover and keep him warm.<br>First Aid responders should pay attention to self-protection and use the recommended protective clothing |
| If inhaled  | : | Move to fresh air.<br>Call a physician immediately.   |
| In case of skin contact                                     | : | Wash off immediately with plenty of water.<br>Cover wound with sterile dressing.<br>Call a physician immediately.   |
| In case of eye contact                                      | : | Rinse immediately with plenty of water for at least 15 minutes.<br>Keep eye wide open while rinsing.<br>Call a physician immediately.   |
| If swallowed  | : | Rinse mouth.<br>Drink plenty of water.<br>Call a physician immediately.   |
| Most important symptoms and effects, both acute and delayed | : | May cause damage to organs through prolonged or repeated exposure if inhaled.   |
| 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.<br>Water<br>Foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical   |
| Specific hazards during fire-fighting         | : | In case of fire and/or explosion do not breathe fumes.<br>Can be released in case of fire:<br>Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Hydrogen bromide (HBr)   |
| Further information                           | : | Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.<br>Collect contaminated fire extinguishing water separately. This must not be discharged into drains. |
| Special protective equipment for firefighters | : | Self-contained breathing apparatus (EN 133)   |

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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.
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## 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
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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

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Components	Basis	Factor	Category	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 <sup>3</sup>	(respirable fraction)
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Category	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 <sup>3</sup>	(inhalable fraction)
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

**Engineering measures** : Local exhaust

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aqueous solution

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : 2.9

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

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

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**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 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

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**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

Acute inhalation toxicity : Acute toxicity estimate: > 40 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method

**Components:****Tiotropiumbromide monohydrate:**

Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg  
  
LD50 (Rat, female): = 3,550 mg/kg  
  
LD50 (Mouse): = 1,217 mg/kg

Acute inhalation toxicity : LC50 (Rat): = 2.7 mg/l  
Exposure time: 4 h  
  
LC50 (Mouse): = 0.67 mg/l  
Exposure time: 4 h

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

Result: No skin irritation

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**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

Result: No eye irritation

Remarks: Dilatation of the pupil

**Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

Test Type: Guinea pig maximization test

Species: Guinea pig

Result: Did not cause sensitisation on laboratory animals.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

- Genotoxicity in vitro
- : Test Type: Ames-test  
Species: S. typhimurium and E. coli  
Result: negative
  - : Test Type: In vitro mammalian cell gene mutation test  
Species: V79 cells (Chinese hamster)  
Result: negative
  - : Test Type: Chromosomal aberration test  
Species: Human lymphocytes  
Result: negative
  - : Test Type: Unscheduled DNA synthesis  
Species: mammalian liver cells  
Result: negative
- Genotoxicity in vivo
- : Test Type: Micronucleus test  
Species: Rat  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

Remarks: Did not show carcinogenic effects in animal experiments.

**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.

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**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**

May cause damage to organs through prolonged or repeated exposure if inhaled.

**Components:****Tiotropiumbromide monohydrate:**

Exposure routes: inhalation (dust/mist/fume)

Assessment: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

**Repeated dose toxicity****Components:****Tiotropiumbromide monohydrate:**

Species: Rat

NOAEL: 0,1 mg/kg/day

Application Route: Oral

Exposure time: 13 weeks

Species: Rat

NOAEL: 0,01 mg/kg/day

Application Route: intravenous

Exposure time: 28-day

Species: dog

NOAEL: 0,004 mg/kg/day

Application Route: intravenous

Exposure time: 28-day

**Aspiration toxicity**

Not classified based on available information.

**Components:****Tiotropiumbromide monohydrate:**

No data available



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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Tiotropiumbromide monohydrate:**

- Toxicity to fish : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): = 69 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: ISO 6341
- Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): = 138 mg/l  
End point: Biomass  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- EC50 (Pseudokirchneriella subcapitata (green algae)): = 314 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- 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 : NOEC (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD 209

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****Tiotropiumbromide monohydrate:**

- Partition coefficient: n-octanol/water : log Pow: -2.28  
Method: OECD Test Guideline 117

**Mobility in soil****Product:**

- Distribution among environmental compartments : Remarks: No data available

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**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** : 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**

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 I Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

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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 %

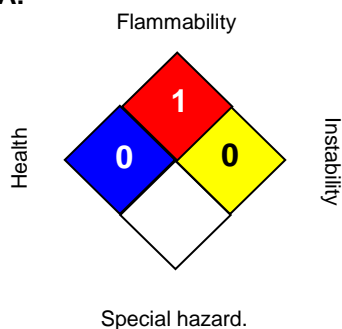
**New Jersey Right To Know**

Non-hazardous galenic excipients      Not Assigned      90 - 100 %

Tiotropiumbromide monohydrate      411207-31-3      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:**

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

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

# SAFETY DATA SHEET

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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.