

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Atrovent® Metered Aerosol with CFC
Synonyms : Active ingredient: Ipratropium bromide monohydrate
Atrovent® Metered Aerosol, Ipratropio, Alovent®
Product code : 000000031473

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 : Pharmaceutical substance
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

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

Hazard statements : H420 Harms public health and the environment by destroying ozone in the upper atmosphere.
Precautionary statements : **Disposal:**
P501 Dispose of contents/ container to an approved incineration plant.

Other hazards

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 99 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Pure substance

Chemical Name	CAS-No.	Concentration (%)
Ipratropium Bromide Monohydrate	66985-17-9	<= 0.1

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

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.
If symptoms persist, call a physician.
- In case of skin contact : No hazards anticipated.
- 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 : Swallowing is not regarded as possible way of exposition.
- Most important symptoms and effects, both acute and delayed : None known.
- 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
Dry chemical
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)
- Further information : Cool endangered containers with water spray jet.
Fire or intense heat may cause violent rupture of packages.
Product itself is non-combustible.
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 : In case of fire and/or explosion do not breathe fumes.
Wear self-contained breathing apparatus and chemical-protective clothing.
-

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

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.
- Environmental precautions : No special environmental precautions required.
- Methods and materials for containment and cleaning up : Allow to evaporate.
Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Keep away from heat and sources of ignition.
- Advice on safe handling : Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.
Do not spray on a naked flame or any incandescent material.
Keep away from sources of ignition - No smoking. Keep away from children.
- Conditions for safe storage : Store in original container.
Protect from heat and direct sunlight.
- Materials to avoid : Keep away from food, drink and animal feeding stuffs.
Advice on Segregation

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate 66985-17-9			15 µg/m ³)	ECL
				BIPC
ECL (BIPI Exposure Control Limit)				
Dichlorotetrafluoroethane	76-14-2		1,000 ppm	TRGS 900

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

			1,000 ml/m3 7,100 mg/m3	(Germany)
--	--	--	----------------------------	-----------

		TWA	1,000 ppm 7,000 mg/m3	CA AB OEL
		TWA	1,000 ppm	CA BC OEL
		TWAEV	1,000 ppm 6,990 mg/m3	CA QC OEL
		TWA	1,000 ppm	ACGIH
		TWA	1,000 ppm 7,000 mg/m3	NIOSH REL
		TWA	1,000 ppm 7,000 mg/m3	OSHA Z-1
		TWA	1,000 ppm 7,000 mg/m3	OSHA P0
Trichlorofluoromethane	75-69-4		1,000 ppm 1,000 ml/m3 5,700 mg/m3 (Y = A risk of foetal disease must not be expected with the compliance of AGW and BGW threshold values.)	TRGS 900 (Germany)

Dichlorodifluoromethane	75-71-8		1,000 ppm 1,000 ml/m3 5,000 mg/m3 (Y = A risk of foetal disease must not be expected with the compliance of AGW and BGW threshold values.)	TRGS 900 (Germany)
-------------------------	---------	--	---	--------------------

		TWA	1,000 ppm 4,950 mg/m3	CA AB OEL
		TWA	1,000 ppm	CA BC OEL
		TWAEV	1,000 ppm 4,950 mg/m3	CA QC OEL
		TWA	1,000 ppm	ACGIH
		TWA	1,000 ppm 4,950 mg/m3	NIOSH REL
		TWA	1,000 ppm 4,950 mg/m3	OSHA Z-1
		TWA	1,000 ppm 4,950 mg/m3	OSHA P0

Contains no substances with occupational exposure limit values.

Engineering measures : Local exhaust

Atrovent® HFA Inhalation Aerosol

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000031473	Date of first issue: 06/03/2015

Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.
- 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 : Protective work clothing
- Protective measures : Avoid contact with skin, eyes and clothing.
Handle in accordance with good industrial hygiene and safety practice.
- 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 : aerosol
- Colour : colourless
- 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 : Not applicable
- Evaporation rate : No data available
- Flammability (solid, gas) : does not ignite
- Upper explosion limit : No data available
- Lower explosion limit : No data available
- Vapour pressure : 13,171 hPa (50 °C)
- Relative vapour density : No data available

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

Relative density : No data available

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 : Keep away from sources of ignition - No smoking. Heating can release hazardous gases.

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 decomposition if stored and applied as directed.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : Hydrogen fluoride
Fluorine phosgene

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Ipratropium Bromide Monohydrate:**

Acute oral toxicity : LD50 (Rat, male and female): = 1,722 mg/kg
LD50 (Mouse, male and female): = 1,038 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

Skin corrosion/irritation

Not classified based on available information.

Components:**Ipratropium Bromide Monohydrate:**

Remarks: No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ipratropium Bromide Monohydrate:**

Remarks: No data available

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Ipratropium Bromide Monohydrate:**

Species: Guinea pig

Result: No alert for skin sensitization

Germ cell mutagenicity

Not classified based on available information.

Components:**Ipratropium Bromide Monohydrate:**

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

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:**Ipratropium Bromide 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.

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.

Atrovent® HFA Inhalation Aerosol

Version Revision Date: MSDS Number: Date of last issue: -
1.0 06/03/2015 000000031473 Date of first issue: 06/03/2015

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Ipratropium Bromide Monohydrate:**

Species: Rat
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 78 weeks

Species: Rat
NOAEL: 0.128 mg/kg
Application Route: Inhalation
Exposure time: 26 weeks

Species: dog
NOAEL: 1.5 mg/kg
Application Route: Oral
Exposure time: 13 weeks

Species: dog
NOAEL: 0.01 mg/kg
Application Route: Inhalation
Exposure time: 13 weeks

Species: Monkey
NOAEL: 0.8 mg/kg
Application Route: Inhalation
Exposure time: 6 weeks

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Ipratropium Bromide Monohydrate:**

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

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

- Toxicity to fish (Chronic toxicity) : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): = 3.16 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
- Lowest Observed Effect Concentration (Daphnia magna (Water flea)): = 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
- Toxicity to bacteria : NOEC (activated sludge): = 200 mg/l
NOEC (activated sludge, industrial): = 1,000 mg/l

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Ipratropium Bromide Monohydrate:**

Partition coefficient: n-octanol/water : Pow: 0.006

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: Warning: Manufactured with /\$, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

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**

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

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****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
	75-69-4	5000	

SARA 311/312 Hazards : No SARA 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 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Trichlorofluoromethane	75-69-4	53 %
Dichlorodifluoromethane	75-71-8	24 %
Dichlorotetrafluoroethane	76-14-2	22 %

Clean Air Act

Warning: Manufactured with /\$, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

Ozone-Depletion Potential	: CFC-11	75-69-4
	Trichlorofluoromethane	75-69-4
	CFC-12	75-71-8
	Dichlorodifluoromethane	75-71-8
	CFC-114	76-14-2
	CFC-114	76-14-2
	Dichlorotetrafluoroethane	76-14-2
	Dichlorotetrafluoroethane	76-14-2

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).

Atrovent® HFA Inhalation Aerosol

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000031473	Date of first issue: 06/03/2015

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermedi-ate or Final VOC's (40 CFR 60.489):

Trichlorofluoromethane	75-69-4	53 %
Dichlorodifluoromethane	75-71-8	24 %

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 contains the following toxic pollutants listed under the U.S. Clean Water Act Section 307

Trichlorofluoromethane	75-69-4	53 %
Dichlorodifluoromethane	75-71-8	24 %

Massachusetts Right To Know

Trichlorofluoromethane	75-69-4	50 - 70 %
Dichlorodifluoromethane	75-71-8	20 - 30 %
Dichlorotetrafluoroethane	76-14-2	20 - 30 %

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Trichlorofluoromethane	75-69-4	50 - 70 %
Dichlorodifluoromethane	75-71-8	20 - 30 %
Dichlorotetrafluoroethane	76-14-2	20 - 30 %

New Jersey Right To Know

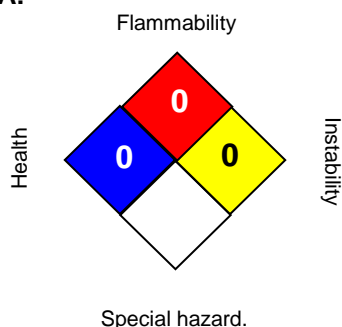
Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Trichlorofluoromethane	75-69-4	50 - 70 %
Dichlorodifluoromethane	75-71-8	20 - 30 %
Dichlorotetrafluoroethane	76-14-2	20 - 30 %

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other re-productive harm.

Atrovent® HFA Inhalation Aerosol

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000031473 Date of last issue: -
Date of first issue: 06/03/2015

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

HEALTH	0
FLAMMABILITY	0
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.
Revision Date : 06/03/2015

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.