

1. Substance Identification

Designation	: Combivent® Respimat®
Synonyms	: Active ingredient: Ipratropium bromide monohydrate and albuterol sulfate
Identified uses	: Pharmaceutical Product
Company	: Boehringer-Ingelheim Pharmaceuticals, Incorporated 900 Ridgebury Road Ridgefield, Connecticut 06877-0368
Emergency Contact Number	: 800-424-9300 CHEMTREC Emergency Phone Number
Routine Contact Number	: (203) 778-7759

2. Hazards Identification

This product is a solution of single components and does not need to be labeled according to Globally Harmonized System (GHS).

This is a pharmaceutical product, designed to be prescribed by a licensed health care professional.

3. Composition/Information on Ingredients

Hazardous ingredients

Chemical name	Classification	GHS classification	Concentration
3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate	Xn; R22	Category 4, H302	<= 1%
Molecular formula:	$C_{20}H_{30}BrNO_3 \times H_2O$	CAS-No.	66985-17-9
Molecular weight:	430.4		

Chemical name	Classification	GHS classification	Concentration
2-(tert-Butylamino)-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol hemisulphate			<= 3%
Molecular formula:	$(C_{13}H_{21}NO_3)_2 \times H_2SO_4$	CAS-No.	51022-70-9
Molecular weight:	576.7		

Chemical name	Classification	GHS classification	Concentration
Non-hazardous galenic excipients			>= 96%

4. First-aid Measures

- General advice : Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety.
- Eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- Skin contact : Wash off thoroughly with ample water. Seek medical attention.
- Inhalation : Keep patient calm, remove to fresh air, and seek medical attention.
- Ingestion : Rinse mouth immediately and then drink plenty of water, seek medical attention.

5. Fire-fighting Measures

- Suitable extinguishing media : Use extinguishing measures to suit surroundings., Water, Dry chemical, Foam, carbon dioxide
- 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, Sulfur oxides, Hydrogen bromide (HBr)
- Protective equipment for fire-fighting : Wear self-contained breathing apparatus and chemical-protective clothing.
- Further information : Collect separately contaminated extinguishing water; do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with Local, State, and Federal regulations.

6. Accidental Release Measures

- Personal precautions : Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.
- Environmental precautions : Do not discharge into drains/surface waters/groundwater.
- Methods for cleaning-up or taking-up : For large amounts: Pump off product. For residues: Contain with absorbent material (e.g. sand, silica gel, acid binder, general purpose binder, sawdust). Pack in tightly closed containers for disposal.
- Additional information : High risk of slipping due to leakage/spillage of product.

7. Handling and Storage

Handling

- Advice on safe handling : Ensure thorough ventilation of work areas. Do not open until use.
- Hygienic measures : General safety and hygiene measures. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

Storage

- Requirements for storage rooms and vessels : Protect from heat and direct sunlight. Keep container tightly closed.
- Advice on storage compatibility : Keep away from food, drink and animal feed.

8. Exposure controls/personal protections

Control parameters

Components	BIEL	Values	Remark
Ipratropium bromide	3A	15 µg/m ³	
Albuterol sulfate	3A	10 µg/m ³	
BIEL= Boehringer Ingelheim Exposure Limit			

Personal protective equipment

Respiratory protection	:	Generally, not required; except in case of aerosol formation.
Hand protection	:	Gloves
Eye protection	:	Safety glasses with side-shields
Body protection	:	Laboratory coat.
General protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not permit eating, drinking or smoking near this material.

9. Physical and Chemical Properties

Form	:	liquid
Color	:	No data available.
Odor	:	No data available.
Odor threshold	:	No data available.
pH value	:	No data available.
Melting point/ -range	:	No data available.
Boiling point/boiling range	:	No data available.
Flash point	:	not applicable
Ignition temperature	:	not applicable
Evaporation rate	:	No data available.
Flammability	:	does not ignite
Lower explosion limit	:	not applicable
Upper explosion limit	:	not applicable
Vapor pressure	:	No data available.
Relative vapor density	:	No data available.
Relative density	:	No data available.
Solubility in water	:	No data available.
Miscibility with water	:	miscible in all proportions
Partitioning coefficient n-octanol/water (log Pow)	:	No data available.
Thermal decomposition	:	No data available.

Viscosity, dynamic	:	No data available.
Explosiveness	:	No data available.
Peroxides	:	No data available.

10. Stability and Reactivity

Conditions to avoid	:	No data available.
Substances to avoid	:	No data available.

11. Toxicological Information

Acute oral toxicity	:	LD50 = 1722 mg/kg rat (male/female) The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) LD50 = 1038 mg/kg mouse (male/female) The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) LD50 > 2000 mg/kg rat The values mentioned are those of the active ingredient. (Albuterol Sulfate) LD50 = 3800 mg/kg mouse The values mentioned are those of the active ingredient. (Albuterol Sulfate)
Acute inhalation toxicity	:	No data available.
Acute dermal toxicity	:	No data available.
Skin irritation	:	No data available.
Eye irritation	:	No data available.
Sensitization	:	Non-sensitizing. (guinea pig) The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) Did not cause sensitization on laboratory animals. (guinea pig) The values mentioned are those of the active ingredient. (Albuterol Sulfate)
Genetic toxicity in vitro	:	Ames-test Salmonella typhimurium Result: negative The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate)
Genetic toxicity in vivo	:	Micronucleus assay Result: negative The values mentioned are those of the active ingredient.
Carcinogenicity	:	No data available.

Reproductive toxicity	:	No data available.
Teratogenicity	:	No data available.
Assessment of reproduction toxicity	:	Experiments have shown no reproductive toxicity effects on laboratory animals. The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate)
Assessment of carcinogenicity	:	Did not show carcinogenic effects in animal experiments. The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate)
Assessment of mutagenicity	:	Micronucleus test: negative, The values mentioned are those of the active ingredient. (Albuterol Sulfate)
Assessment of mutagenicity	:	Test in human lymphocytes: negative, The values mentioned are those of the active ingredient. (Albuterol Sulfate)

12. Ecological information

Ecotoxicity

Toxicity to fish	:	No data available.
Toxicity to daphnia	:	NOEC = 3.16 mg/l (Daphnia magna) Exposition time: 21 d The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) Lowest observed effect concentration = 10 mg/l (Daphnia magna) Exposition time: 21 d The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) EC50 > 100 mg/l (Daphnia) Exposition time: 48 h The values mentioned are those of the active ingredient. (Albuterol)
Toxicity to algae	:	No data available.
Toxicity to bacteria	:	NOEC = 200 mg/l (activated sludge) The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate) NOEC = 1.000 mg/l (activated sludge, industrial) The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate)
Chronic toxicity to fish	:	No data available.
Chronic toxicity to aquatic invertebrates	:	No data available.

Persistence and degradability

- Biological degradation : Not readily biodegradable.
The values mentioned are those of the active ingredient. (Albuterol)
- Transport between environmental compartments : No data available.
- Bioaccumulation : Accumulation in organisms is not to be expected. The values mentioned are those of the active ingredient. (Ipratropium Bromide Monohydrate)
- Bioaccumulation : No appreciable bioaccumulation potential is to be expected (log P(o/w) 1-3),. The values mentioned are those of the active ingredient. (Albuterol)

13. Disposal Considerations

- Product : 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.

14. Transport Information

D.O.T. Proper Shipping Name:	Not Regulated
Hazard Class:	N/A
Identification Number:	N/A
Packing Group:	N/A
Label:	N/A
Emergency Response Guidebook:	N/A

15. Regulatory information

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

16. Other particulars

Prepared by: Environmental Health & Safety
Date Prepared: March 13, 2012
Replaces: N/A

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