

## 1. Identification

<b>Product identifier</b>	<b>RESPONTIN NEBULES</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	RESPONTIN NEBULES 250MCG/ML * IPRATROPIUM BROMIDE, FORMULATED PRODUCT
<b>Recommended use</b>	Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
 5 Moore Drive  
 Research Triangle Park, NC 27709 USA  
 US General Information (normal business hours): +1-888-825-5249  
 Email Address: msds@gsk.com  
 Website: www.gsk.com  
 EMERGENCY PHONE NUMBERS -  
 TRANSPORT EMERGENCIES::  
 US / International toll call +1 703 527 3887  
 available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
IPRATROPIUM BROMIDE	AH 14211AA 8-AZONIABICYCLO(3.2.1)OCTANE, 3-(3-HYDROXY-1-OXO-2-PHENYLPROPOX Y)-8-METHYL-8-(1-METHYLETHYL)-, (ENDO, SYN)-(+)- N-ISOPROPYLATROPINIUM BROMIDE 1720 (GW ACN)	22254-24-6	0.03
Other components below reportable levels			99.97

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth thoroughly. Get medical advice/attention if you feel unwell. Do not induce vomiting.
<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: dyspeptic symptoms; nausea; dry mouth; palpitations.

**Indication of immediate medical attention and special treatment needed**

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

**General information**

The need for pre-placement and periodic health surveillance must be determined by risk assessment.

**5. Fire-fighting measures****Suitable extinguishing media**

Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). Water.

**Unsuitable extinguishing media**

None known.

**Specific hazards arising from the chemical**

During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters**

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire-fighting equipment/instructions**

Move containers from fire area if you can do so without risk.

**Specific methods**

Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**

This product is expected to be non-combustible.

**6. Accidental release measures****Personal precautions, protective equipment and emergency procedures**

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage****Precautions for safe handling**

Avoid prolonged exposure. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection****Occupational exposure limits****GSK****Components****Type****Value**

IPRATROPIUM BROMIDE  
(CAS 22254-24-6)

8 HR TWA

2 mcg/m<sup>3</sup>

OHC

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**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

No particular ventilation requirements. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

**Hand protection**

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

**Other**

Wear suitable protective clothing.

**Respiratory protection**

No personal respiratory protective equipment normally required.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**9. Physical and chemical properties****Appearance**

Material name: RESPONTIN NEBULES

127363 Version #: 05 Revision date: 04-01-2014 Issue date: 04-01-2014

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<b>Physical state</b>	Liquid.
<b>Form</b>	Plastic container.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Non-Flammable
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	The following adverse effects have been noted with therapeutic use of this material: dry mouth; increased heart rate; palpitations; dyspeptic symptoms; nausea.

### Information on toxicological effects

<b>Acute toxicity</b>	May be harmful if swallowed.
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<b>Components</b>	<b>Species</b>	<b>Test Results</b>
IPRATROPIUM BROMIDE (CAS 22254-24-6)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	1001 mg/kg

Components	Species	Test Results
	Rat	1663 mg/kg
* Estimates for product may be based on additional component data not shown.		
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.	
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use.	
<b>Eye</b>		
IPRATROPIUM BROMIDE		Acute ocular irritation; OECD 405 Result: Moderate Irritant Notes: Pfizer SDS
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not available.	
<b>Skin sensitization</b>	None known.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>		
IPRATROPIUM BROMIDE		Ames Result: Negative Notes: Boehringer Ingelheim prescribing information. Chromosomal Aberration Assay In Vitro Result: Negative Notes: Boehringer Ingelheim prescribing information. Dominant lethal assay Result: Negative Species: Mouse Notes: Boehringer Ingelheim prescribing information. In vivo Micronucleus Result: Negative Species: Mouse Notes: Boehringer Ingelheim prescribing information.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.	
IPRATROPIUM BROMIDE		<= 6 mg/kg/day ICH S1B - Inhalation Result: Negative Species: Mouse Test Duration: 2 years Notes: Boehringer Ingelheim prescribing information. <= 6 mg/kg/day ICH S1B - Inhalation Result: Negative Species: Rat Test Duration: 2 years Notes: Boehringer Ingelheim prescribing information.
<b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction	
<b>Reproductivity</b>		
IPRATROPIUM BROMIDE		1.5 mg/kg/day Foetal development - inhalation Result: Foetal NOAEL Species: Rat Notes: Boehringer Ingelheim prescribing information. 1.8 mg/kg/day Foetal development - inhalation Result: Foetal NOAEL Species: Rabbit Notes: Boehringer Ingelheim prescribing information. 10 mg/kg/day Embryo-foetal development, Oral NOAEL. Result: No malformations. Species: Mouse Notes: Boehringer Ingelheim prescribing information. 1000 mg/kg/day Embryo-foetal development, Oral NOAEL. Result: No malformations. Species: Rat Notes: Boehringer Ingelheim prescribing information. 125 mg/kg/day Embryo-foetal development, Oral NOAEL. Result: No malformations. Species: Rabbit Notes: Boehringer Ingelheim prescribing information.

<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.
<b>Further information</b>	None known.

## 12. Ecological information

<b>Ecotoxicity</b>	No information is available about the potential of this product to produce adverse environmental effects.
<b>Persistence and degradability</b>	Not available.
<b>Bioaccumulative potential</b>	Not available.
<b>Mobility in soil</b>	Not available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## 15. Regulatory information

<b>US federal regulations</b>	One or more components are not listed on TSCA.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

#### Other federal regulations

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 04-01-2014

**Revision date** 04-01-2014

**Version #** 05

**Further information** HMIS® is a registered trade and service mark of the NPCA.

**HMIS® ratings**  
Health: 1  
Flammability: 0  
Physical hazard: 0

**NFPA ratings**  
Health: 1  
Flammability: 0  
Instability: 0

**References** GSK Hazard Determination

**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision Information**

Product and Company Identification: Business Units  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Toxicological Information:  
Regulatory Information: United States  
GHS: Classification