SECTION 1. IDENTIFICATION

Product name	:	Combivent®, Combivent® Respimat, Combivent® Inhalation Aerosol
Synonyms	:	Active ingredient: Ipratropium bromide monohydrate (0,1 %) + Salbutamol sulphate (0,2 %) Aerosols, with not inflammable propellant, Ethanol and active pharmaceutical ingredient,
Product code	:	000000031085

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

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Salbutamol sulphate	51022-70-9	0.2
Ipratropium Bromide Monohydrate	66985-17-9	0.1

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 (NOx)

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.

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

Components	Basis	Factor	Catergory	Values	Remark
3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-8-azoniabicyclo(3.2.1)octane bromide monohydrate 66985-17-9	ECL BIPC		3A 1b	15 µg/m3	
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Catergory	Values	Remark
2-(tert-Butylamino)-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol hemisulphate 51022-70-9	ECL BIPC		3A 1b	10 µg/m3	
ECL (BIPI Exposure Control Limit)					

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	CA AB OEL

			4,950 mg/m3	
		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
Dichlorotetrafluoroethane	76-14-2		1,000 ppm 1,000 ml/m3 7,100 mg/m3	TRGS 900 (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

Engineering measures : Local exhaust

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
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 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	:	Hydrogen fluoride Fluorine phosgene

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

Components:

Salbutamol sulphate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Salbutamol sulphate:
Remarks: May cause skin irritation.
May cause irritation of the mucous membranes.

Ipratropium Bromide Monohydrate:
Remarks: No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Salbutamol sulphate:
Remarks: May cause eye irritation.

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:

Salbutamol sulphate:
Species: Guinea pig
Result: Does not cause skin sensitisation.

Ipratropium Bromide Monohydrate:
Species: Guinea pig
Result: No alert for skin sensitization

Germ cell mutagenicity

Not classified based on available information.

Components:

Salbutamol sulphate:

Genotoxicity in vitro	:	Test Type: Ames-test Species: Salmonella typhimurium Result: negative
	:	Test Type: Chromosomal aberration test Species: Human lymphocytes Result: negative Remarks: In vitro tests did not show mutagenic effects
Genotoxicity in vivo	:	Test Type: Micronucleus test Result: negative Remarks: No mutagenic effects reported.

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:

Salbutamol sulphate:
Remarks: No data available

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.

Reproductive toxicity

Not classified based on available information.

Components:

Salbutamol sulphate:

Effects on fertility : Remarks: No data available

Remarks: No data available

Effects on foetal development : Remarks: Indications of a developmental toxic / teratogenic effect were seen in animal studies.
The significance of these findings for humans is not certain.
Remarks: Indications of a developmental toxic / teratogenic effect were seen in animal studies.
The significance of these findings for humans is not certain.

STOT - single exposure

Not classified based on available information.

Components:

Salbutamol sulphate:
Remarks: No data available

STOT - repeated exposure

Not classified based on available information.

Components:

Salbutamol sulphate:
Remarks: No data available

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.

Components:

Salbutamol sulphate:
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Salbutamol sulphate:

Toxicity to fish	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia (water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae	:	Remarks: No data available
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	:	Remarks: No data available

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

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

Components:

Salbutamol sulphate:

Biodegradability	:	Remarks: No data available

Bioaccumulative potential

Components:

Salbutamol sulphate:

Bioaccumulation	:	Remarks: No data available
Partition coefficient: n-octanol/water	:	Remarks: No data available

Ipratropium Bromide Monohydrate:

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

Mobility in soil

Components:

Salbutamol sulphate:

Distribution among environmental compartments	:	Remarks: 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.

Components:

Salbutamol sulphate:

Results of PBT and vPvB assessment : Non-classified vPvB substance Non-classified PBT substance

Additional ecological information : No data available

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

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
	75-71-8	5000	

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 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Dichlorodifluoromethane	75-71-8	54 %
Trichlorofluoromethane	75-69-4	25 %
Dichlorotetrafluoroethane	76-14-2	24 %

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-12 75-71-8

Dichlorodifluoromethane	75-71-8
CFC-11	75-69-4
Trichlorofluoromethane	75-69-4
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).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

Dichlorodifluoromethane	75-71-8	54 %
Trichlorofluoromethane	75-69-4	25 %

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

Dichlorodifluoromethane	75-71-8	54 %
Trichlorofluoromethane	75-69-4	25 %

Massachusetts Right To Know

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

Pennsylvania Right To Know

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

New Jersey Right To Know

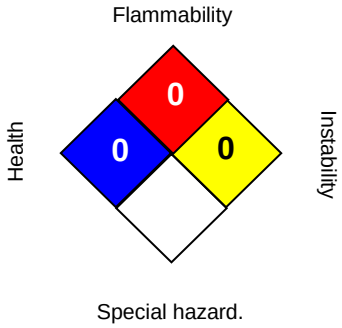
Dichlorodifluoromethane	75-71-8	50 - 70 %
Trichlorofluoromethane	75-69-4	20 - 30 %
Dichlorotetrafluoroethane	76-14-2	20 - 30 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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.