

# Ambroxol hydrochloride

sc-200816



The Power is Question

## Material Safety Data Sheet

Hazard Alert Code  
Key:

EXTREME

HIGH

MODERATE

LOW

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

Ambroxol hydrochloride

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
2145 Delaware Avenue  
Santa Cruz, California 95060  
800.457.3801 or 831.457.3800

### EMERGENCY

ChemWatch

Within the US & Canada: 877-715-9305

Outside the US & Canada: +800 2436 2255

(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C13-H18-Br2-N2-O.HCl, "trans-4-((2-amino-3, 5-dibromobenzyl)amino)cyclohexanol", "N-(2-amino-3, 4-dibromocyclohexyl)-trans-4-aminocyclohexanol", "N-(trans-p-hydroxycyclohexyl)-(2-amino-3, 5-dibromobenzyl)amine", "N-(trans-4-hydroxycyclohexyl)-(2-amino-3, 5-dibromobenzyl)amine", NA-872, Bronchopront, Duramuca, Fluibron, Fluixol, Frenopect, Lindoxyl, Muco-Burg, Mucosolvan, Mucoclear, Mucovent, Pect, Stas-Hustenloser, Surbronc, Surfactal, expectorant

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

	Min	Max	
Flammability:	1		
Toxicity:	2		
Body Contact:	0		Min/Nil=0 Low=1
Reactivity:	1		Moderate=2 High=3
Chronic:	3		Extreme=4

### CANADIAN WHMIS SYMBOLS



## EMERGENCY OVERVIEW

### RISK

Harmful if swallowed.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Cumulative effects may result following exposure\*.

May be harmful to the foetus/embryo\*.

\* (limited evidence).

## POTENTIAL HEALTH EFFECTS

### ACUTE HEALTH EFFECTS

#### SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

#### EYE

■ Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

#### SKIN

■ Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

#### INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

### CHRONIC HEALTH EFFECTS

■ Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Chronic intoxication with ionic bromides, historically, has resulted from medical use of bromides but not from environmental or occupational exposure; depression, hallucinosis, and schizophreniform psychosis can be seen in the absence of other signs of intoxication. Bromides may also induce sedation, irritability, agitation, delirium, memory loss, confusion, disorientation, forgetfulness (aphasias), dysarthria, weakness, fatigue, vertigo, stupor, coma, decreased appetite, nausea and vomiting, diarrhoea, hallucinations, an acne like rash on the face, legs and trunk, known as bronchoderma (seen in 25-30% of case involving bromide ion), and a profuse discharge from the nostrils (coryza). Ataxia and generalised hyperreflexia have also been observed. Correlation of neurologic symptoms with blood levels of bromide is inexact. The use of substances such as brompheniramine, as antihistamines, largely reflect current day usage of bromides; ionic bromides have been largely withdrawn from therapeutic use due to their toxicity. Several cases of foetal abnormalities have been described in mothers who took large doses of bromides during pregnancy.

## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
ambroxol hydrochloride	23828-92-4	>98

## Section 4 - FIRST AID MEASURES

### SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
- If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
- If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

- INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

### EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

### SKIN

If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

### INHALED

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

### NOTES TO PHYSICIAN

- for poisons (where specific treatment regime is absent):

#### BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema .
- Monitor and treat, where necessary, for shock.
- Anticipate seizures .
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

#### ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994.

Treat symptomatically.

## Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.

Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

#### EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

#### FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 100 metres in all directions.

#### GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- When processed with flammable liquids/vapors/mists,ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-meter/sec
- A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source
- One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
- Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), hydrogen chloride, phosgene, nitrogen oxides (NO<sub>x</sub>), other pyrolysis products typical of burning organic material.

#### FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

## Section 6 - ACCIDENTAL RELEASE MEASURES

### MINOR SPILLS

Environmental hazard - contain spillage.

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

#### **MAJOR SPILLS**

Environmental hazard - contain spillage.

Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise Emergency Services.

## **Section 7 - HANDLING AND STORAGE**

### **PROCEDURE FOR HANDLING**

- Avoid all personal contact, including inhalation.
  - Wear protective clothing when risk of exposure occurs.
  - Use in a well-ventilated area.
  - Prevent concentration in hollows and sumps.
  - DO NOT enter confined spaces until atmosphere has been checked.
  - DO NOT allow material to contact humans, exposed food or food utensils.
  - Avoid contact with incompatible materials.
  - When handling, DO NOT eat, drink or smoke.
  - Keep containers securely sealed when not in use.
  - Avoid physical damage to containers.
  - Always wash hands with soap and water after handling.
  - Work clothes should be laundered separately. Launder contaminated clothing before re-use.
  - Use good occupational work practice.
  - Observe manufacturer's storing and handling recommendations.
  - Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
  - Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
  - Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
  - Establish good housekeeping practices.
  - Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
  - Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.
  - Do not use air hoses for cleaning.
  - Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used.
  - Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition.
  - Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance.
  - Do not empty directly into flammable solvents or in the presence of flammable vapors.
  - The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
  - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

## RECOMMENDED STORAGE METHODS

- Glass container is suitable for laboratory quantities
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

## STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations

For major quantities:

- Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).
- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

Protect from light.

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- ambroxol hydrochloride: CAS:18683-91-5

### PERSONAL PROTECTION



### RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

### EYE

When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

### HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.

- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.
- Wash hands immediately after removing gloves.
- Protective shoe covers. [AS/NZS 2210]
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

#### OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit

#### ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

10; high efficiency particulate (HEPA) filters or cartridges

10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.

25-50; a full face-piece negative pressure respirator with HEPA filters

50-100; tight-fitting, full face-piece HEPA PAPR

100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	414.6
Melting Range (°F)	451- 453	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not available.	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

### APPEARANCE

Odourless, crystalline powder; does not mix well with water.

## Section 10 - CHEMICAL STABILITY

### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

### STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents

For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

ambroxol hydrochloride

### TOXICITY AND IRRITATION

AMBROXOL HYDROCHLORIDE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: 13400 mg/kg	Nil Reported
Intraperitoneal (rat) LD50: 380 mg/kg	
Oral (mouse) LD50: 2720 mg/kg	
Intraperitoneal (mouse) LD50: 268 mg/kg	
Intravenous (mouse) LD50: 138 mg/kg	

Oral (g.pig) LD50: 1180 mg/kg

### CARCINOGEN

BROMINE COMPOUNDS (ORGANIC OR INORGANIC)

US Environmental Defense Scorecard Suspected Carcinogens

Reference(s) P65-MC

## Section 12 - ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/ safety data sheets.

### Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
ambroxol hydrochloride	No Data Available	No Data Available		

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

## Section 14 - TRANSPORTATION INFORMATION



DOT:

Symbols:

G

Hazard class or Division:

9

Identification Numbers:	UN3077	PG:	III
Label Codes:	9	Special provisions:	8, 146, 335, B54, IB8, IP3, N20, T1, TP33
Packaging: Exceptions:	155	Packaging: Non-bulk:	213
Packaging: Exceptions:	155	Quantity limitations: Passenger aircraft/rail:	No limit
Quantity Limitations: Cargo aircraft only:	No limit	Vessel stowage: Location:	A
Vessel stowage: Other:	None		

Hazardous materials descriptions and proper shipping names:  
Environmentally hazardous substance, solid, n.o.s

**Air Transport IATA:**

ICAO/IATA Class:	9	ICAO/IATA Subrisk:	None
UN/ID Number:	3077	Packing Group:	III
Special provisions:	A97		

**Cargo Only**

Packing Instructions:	956	Maximum Qty/Pack:	400 kg
Passenger and Cargo		Passenger and Cargo	
Packing Instructions:	956	Maximum Qty/Pack:	400 kg
Passenger and Cargo Limited Quantity		Passenger and Cargo Limited Quantity	
Packing Instructions:	Y956	Maximum Qty/Pack:	30 kg G

Shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(contains ambroxol hydrochloride)

**Maritime Transport IMDG:**

IMDG Class:	9	IMDG Subrisk:	None
UN Number:	3077	Packing Group:	III
EMS Number:	F-A,S-F	Special provisions:	274 335
Limited Quantities:	5 kg	Marine Pollutant:	Yes

Shipping name:ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(contains ambroxol hydrochloride)

**Section 15 - REGULATORY INFORMATION**



**ambroxol hydrochloride (CAS: 18683-91-5) is found on the following regulatory lists;**

"Canada - Alberta Ambient Air Quality Guidelines","Canada - Alberta Ambient Air Quality Objectives","Canada - British Columbia Occupational Exposure Limits","Canada - Ontario Occupational Exposure Limits","Canada - Quebec Permissible Exposure Values for Airborne Contaminants (English)","Canada List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient ""Hotlist""),"Canada National Pollutant Release Inventory (NPRI)","Canada Substances in Products Regulated Under the Food and Drugs Act (F&DA) That Were In Commerce between January 1, 1987 and September 13, 2001 (English)","US - California Permissible Exposure Limits for Chemical Contaminants","US - Massachusetts Drinking Water - Secondary Contaminants Maximum Contaminant Levels (MCLs)","US - Michigan Exposure Limits for Air Contaminants","US - Oregon Permissible Exposure Limits (Z-1)","US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants","US - Utah Secondary Drinking Water Standards - Inorganic Contaminants","US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants","US Clean Air Act (CAA) National Ambient Air Quality Standards (NAAQS)","US FDA Maximum Recommended Therapeutic Dose (MRTD) Database","WHO Guidelines for Drinking-water Quality - Chemicals for which guideline values have not been established"

## Section 16 - OTHER INFORMATION

### LIMITED EVIDENCE

- Cumulative effects may result following exposure\*.
- May be harmful to the foetus/embryo\*.

\* (limited evidence).

### Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
ambroxol hydrochloride	18683- 91- 5	Xi; R38 N; R51/53

- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

[www.chemwatch.net/references](http://www.chemwatch.net/references).

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

- For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:

OSHA Standards - 29 CFR:

1910.132 - Personal Protective Equipment - General requirements

1910.133 - Eye and face protection

1910.134 - Respiratory Protection

1910.136 - Occupational foot protection

1910.138 - Hand Protection

Eye and face protection - ANSI Z87.1

Foot protection - ANSI Z41

Respirators must be NIOSH approved.

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[www.Chemwatch.net](http://www.Chemwatch.net)

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