1. *Identification of the Substance/Preparation and Company*

Commercial product name:	Cryogesic - The Original Ethyl Choride Spray
Active ingredient:	Ethyl chloride B.P.
Synonyms:	Ethyl chloride, Chloroethane, Hydrochloric ether, Chlorethyl
Presentation:	Aerosol dispenser containing 100ml or 50ml ethyl chloride.
Intended use:	Vapo-coolant for clinical use as a topical cryo-analgesic and cold spray

Distributor/Manufacturer:	Acorus Therapeutics Ltd	Dr Georg Friedrich Henning
Address:	Office Village Chester Business Park Chester CH4 9QZ UK	Chemische Fabrik Walldorf GmbH D-69190 Walldorf Germany
Telephone:	+44 (0) 1244 625 150	
Fax:	+44 (0) 1244 625 151	

2. *Composition/Information on Ingredients*

Hazardous Components:

CAS No.	EINECS Name	Index Number	Chemical Formula	Quantity Unit
75-00-3	Chlorethane	602-009-00-0	C_2H_5Cl	100%

Classification:

Risk phrases	Symbol Letters
F+: R12 Carc Cat 3: R40, R52, R53	F+, Xn

Description:
A gas at room temperature and a clear colourless, volatile liquid when compressed, or at lower temperatures. It has a pungent, ether-like odour.

3. *Hazard Identification*

Designation of hazard:
Aerosol package

Special information on hazard to man and environment:
In use, may form flammable/explosive vapour-air mixture. Ensure good ventilation. Avoid any kind of ignition source.

4. *First Aid Measures*

General information:
Ethyl chloride is the least toxic of the chlorinated hydrocarbons and there are no serious health hazards in connection with its occasional clinical use as vapo-coolant, provided it is used in a well-ventilated area. The skin and lungs can absorb ethyl chloride. A single prolonged skin exposure is not likely to result in absorption of harmful amounts. Over-exposure to ethyl chloride may cause headache, dizziness, vomiting, and loss of co-ordination and disorientation.

Inhalation:
Breathing fresh uncontaminated air relieves minor symptoms of toxicity.

If breathing has stopped, or is impaired, give artificial respiration and supplemental oxygen. Keep victim warm and quiet. Seek medical attention immediately.

Unintentional skin contact:
Rinse with water. In rare cases cutaneous sensitisation may occur.
Rapid evaporation of ethyl chloride may cause frostbite. If unintentional freezing occurs, flood or soak with tepid water. Do not use hot water. Seek medical attention.

Eye contact:
Ethyl chloride is slightly irritant to the eye and mucosal tissue. Rinse thoroughly with water. Seek medical attention.

Ingestion:
Seek medical attention immediately.

Information for the doctor:
Ethyl chloride is a liver and kidney toxin. No form of chronic poisoning has been reported. Repeated excessive exposure may cause incoordination and/or anaesthesia. May produce CNS depression, respiratory paralysis, or fatal coma with respiratory depression or cardiac arrest. May sensitise the myocardium to endogenous epinephrine, causing dangerous dysrhythmias. Ethyl chloride is rapidly eliminated through the lungs.

5. *Fire Fighting Measures*

Extinguishing media:
CO_2, foam, powder.

Do not use:
Water - because it will scatter and spread the fire.

Water spray may be used to cool aerosol containers.

Special risks posed by the substance, its combustion products or reaction products:
Formation of hydrochloric acid, phosgene or carbon monoxide.

Fire Fighting Protective Equipment:
Fire-fighters should wear a full set of protective clothing and self-contained breathing apparatus when fighting fires involving ethyl chloride.

6. *Accidental Release Measures*

Eliminate all sources of ignition. Allow spilled ethyl chloride to evaporate. Ventilate enclosed areas. In cases of large spill, evacuate all personnel from area.

Personal protective measures:
Full-vision safety glasses and safety gloves.

Environmental control measures:
Do not discharge into drains/surface water/groundwater.

Cleaning/adsorption procedures:
Take up with non-combustible absorbent material such as sand.

7. Handling and Storage

Safe handling:
Use in a well ventilated area.
Solvent vapours can form explosive mixtures with air.
Do not expose to temperatures exceeding 50¡C.
Do not spray on or near a naked flame or incandescent material.

Storage:
Keep at a temperature not exceeding 20ûC in a dry well-ventilated area. Do not refrigerate.
Do not store on or near high frequency ultrasound equipment.
Protect from sunlight.
The UK Health & Safety Executive advises that flammable liquids should be stored in a separate storage area, or in a purpose-made bin or cupboard.

Specific uses:
For external topical use as a vapo-coolant and cryo-analgesic. Briefly spray area requiring analgesia until a thin snow film forms. Do not spray on open wounds. Do not over-cool skin as this may cause frostbite. Repeated exposure may cause skin dryness or cracking. In clinical use minimise inhalation of vapours by the patient, especially when applying to head and/or neck. Do not spray into eyes.

8. Exposure Controls/Personal Protection

Exposure limit values:
The Maximum Exposure Limit (MEL) is 50 parts per million (ppm) (8-hour Time Weighted Average (EH40/2002 Occupational Exposure Limits Supplement 2003).

Exposure must never exceed the MEL. COSHH Regulations 2002 require employers to prevent, or if this is not reasonably practicable, adequately control, employees' exposure as far below the MEL as is reasonably practicable.

Personal protection:

General protective and hygienic measures:
When using do not eat, drink or smoke.

Respiratory protection:
In clinical use minimise inhalation of vapours by patient, especially when applying to head and/or neck. For large spills use full-face positive pressure, self-contained breathing apparatus. Not essential for small spills.

Hand protection:
Not necessary during normal clinical use unless user has known sensitivity to ethyl chloride, otherwise recommended. Do not use PVC, silicone or natural rubber gloves.

Eye protection:
In clinical use around face or neck, cover patientÕs eyes in order to minimise risk of inadvertent exposure Users do not need to wear eye protection except when dealing with large spills.

Body protection:
Not essential.

Exposure controls:
Use in a well ventilated area. Avoid breathing fumes.

Additional Information:
The air odour threshold concentration for ethyl chloride has been reported as 4.2 ppm parts of air (10-12 mg/m^3).

Occupational exposure controls:
In clinical situations where the gas is regularly and frequently being released into the working environment a risk assessment should be conducted to ensure adequate ventilation is provided to reduce users exposure as far below the MEL as is reasonably practicable.

9. *Physical and Chemical Properties*

General Information:

Presentation form:	Aerosol can
Contents colour:	Clear, colourless liquid
Contents odour:	Similar to ether

Important Health, Safety and Environmental Information:

pH:		
Boiling point/boiling range:	12.3 ¡C	
Flash point:	-43¡C (propellant)	
Ignition temperature:	510¡C (propellant)	
Lower explosion limit UEG:	3.6%	
Upper explosion limit OEG:	14.8%	
Oxidising properties:		
Vapour pressure (at 20¡C):	3500hPa	(1064 mm Hg)
Density (at 20¡C):	0,89g/ml	(complete filling)
Specific gravity (at 0¡C):	0.921 to 0.926	
Solubility in water (at 20¡C):	Not soluble *Reacts with water at concentrations of 0.57g/108g water at 20℃*	
Partition coefficient:		
Viscosity (at 20¡C):		
Evaporation rate (butyl acetate = 1):	Greater than 1.0	

Other Information:

Auto-ignition:	519¡C
Melting point/melting range:	-138.7 ¡C

10. *Stability and Reactivity*

Conditions to avoid:
Do not heat above 50¡C.

Materials to avoid:
Contact between ethyl chloride and chemically active metals such as sodium, potassium, calcium, powdered aluminium, zinc, and magnesium may cause fires and explosions. Ethyl chloride reacts vigorously with oxidising materials. Contact with water, steam, or alkalis may produce toxic and corrosive fumes.

Hazardous decomposition products:
Forms phosgene on combustion.
Forms hydrogen chloride with water or steam.

Further information:
Liquid ethyl chloride will attack some forms of plastic, rubber and coatings.

11. Toxicological Information

Acute toxicity:
LC 50: >160mg/l (~ 60,000 ppm) inhalation/rat (2 hours).

Specific symptoms shown in experiments with animals:
Ethyl chloride produces narcosis and pathological alterations in the liver, kidneys, lungs, and heart of exposed animals. Rats subjected to a 2-hour anaesthesia with ethyl chloride experienced a complete disappearance of glycogen in the liver, a decrease in acid phosphatase levels, and increases in alkaline phosphates and succinic dehydrogenase levels. Exposure to 23 % ethyl chloride in air caused guinea pigs to lose consciousness in 5 to 10 minutes; some of the animals died from this exposure. In guinea pigs exposed to 40,000 ppm ethyl chloride, incoordination was seen after 3 minutes and eye irritation and inability to stand were noted within 40 minutes. However, all animals survived 4.5 hours of exposure at this level, although some died within 9 hours. Pathological changes in the liver, lungs, and kidneys were observed. At 9,000 ppm ethyl chloride, all guinea pigs survived, but histopathological changes were noted in the liver, kidneys, and lungs.

Experience in man:
On inhalation of high concentrations mucous membranes could become irritated and toxic effects may occur. Ethyl chloride is a mild irritant of the eyes, mucous membranes, and respiratory tract and is also a narcotic. It is absorbed through the mucous membranes and quickly eliminated through the lungs. The inhalation of a 0.1% concentration of ethyl chloride does not produce narcosis in humans. Intoxication began at 1.3 % and increased at increasing dosages. At a dose of 3.36 %, noisy talkativeness and incoordination was followed by cyanosis, nausea, and vomiting during recovery. Memory loss was induced at 1.9% and increased at increasing dosages. In another study, inhalation of 40,000 ppm by human subjects produced dizziness, eye irritation and stomach cramp, whereas inhalation of 25,000 ppm caused incoordination.

Corrosivity/irritation:
Skin: Frequent and prolonged skin contact can cause skin irritation and inflammation. Liquefied ethyl chloride spilled on the skin or eye may cause frostbite.
Eye: Irritant. Liquid ethyl chloride sprayed into the eyes of rabbits damaged the cornea.
Respiratory tract: Irritant.

Sensitisation:
Skin sensitisation may occur on repeated exposure. During an allergy testing procedure, two individuals developed acute allergic eczematous dermatitis after ethyl chloride. A case of delayed allergic reaction has been reported.

Repeated-dose toxicity:
Not tested/no data.

Mutagenicity:
Not tested/no data.

Carcinogenicity:
Ethyl chloride has been shown to have carcinogenic activity in rodents when exposed to 15,000 ppm via inhalation for 4 - 6 hours per day, five days a week, for two years. It is unknown whether ethyl chloride could also be carcinogenic in humans. Because of this finding the HSC has set a Maximum Exposure Limit (MEL) Ð See section 8.

Reproductive toxicity:
Not tested/no data.

12. Ecological Information

Most of the chloroethane released to the environment vaporises as a gas into the atmosphere where it breaks down by reaction with substances in the air. It takes about 40 days for half of any given amount of chloroethane that is released to the atmosphere to disappear.

With large spills, small amounts may enter groundwater as a result of passage through soil. In groundwater, chloroethane changes slowly to ethanol and a chloride salt as a result of reaction with water. In addition, some types of bacteria present in the water may break down chloroethane to smaller compounds. However, not enough is known about chloroethane to be sure if this occurs or how long it may remain in groundwater.

Do not discharge into drains/surface waters/groundwater.

13. Disposal Considerations

Completely empty container:

Recommendation:	Recycling
Waste disposal code:	15 01 07, D01,
Designation of waste:	Glass packaging

Containers containing residues:

Recommendation:	Special disposal of waste
Waste disposal code:	18 01 06 / 15 01 10, D10, R01
Designation of waste:	H3A Hazardous Ð Flammable aerosol

Recommended cleaning:
White spirit.

14. Transport Information

Road/Rail/Inland Waterways carriage ADR/RID:

UN No.:	1950
Class:	2
Hazard Label:	No. 2.1 (Flammable Gas)
Classification Code:	5F
PSN:	AEROSOLS
Transport Category:	2

Shipment by sea IMGD(Sea):

UN No.:	1950
EMS:	F-D, S-U
CLASS:	2
Marine pollutant:	No
PSN:	AEROSOLS
Label:	No 2.1 (Flammable Gas)
Remarks:	Maximum 1l

Air transport IATA-Dangerous Goods Regulations:

Class:	2.1
UNNo.:	1950
Proper Shipping Name:	AEROSOLS, FLAMMABLE
Label:	No. 2.1 (Flammable Gas)
Packing Instructions:	Y203 or 203

15. Regulatory Information

Cryogesic® - The Original Ethyl Choride Spray presentations of ethyl chloride BP are intended for clinical use and are registered under the Medical Devices Directive 93/42/EEC Class I Medical Devices. Whilst the Chemicals (Hazard Information and Packaging of Supply) Regulations 2002 do not apply to a substance that is a medical device (within the meaning of the Medical Devices Regulations 2002), this Safety Data Sheet has been prepared according to these regulations.

During normal clinical use of Cryogesic®, ethyl chloride is released into the work environment due to the gas evaporating from the patientõ skin. Ethyl chloride (chloroethane) is listed in Part 1 of the Approved Supply List and is designated a substance hazardous to health under the Control of Substances Hazardous to Health Regulations 1999. These regulations place a responsibility on employers to make a suitable and sufficient assessment of the risks related to work with a hazardous substance, and to prevent or, where this is not reasonably practicable, adequately control exposure. Further guidance is given in the publication, COSHH Essentials.

Labelling according to the Control of Substances Hazardous to Health Regulations 1999:
Symbol:
F+: Extremely flammable
Xn: Harmful*

Risk phrases:
12: Extremely flammable
40: Limited evidence of a carcinogenic effect*
52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment*
66: Repeated exposure may cause skin dryness or cracking

Safety phrases:
2: Keep out of the reach of children
9: Keep container in a well-ventilated place
16: Keep away from sources of ignition Ð No smoking
23: Do not breathe vapours
25: Avoid contact with eyes
33: Take precautionary measures against static discharges
36/37: Wear suitable protective clothing and gloves*
47: Keep at a temperature not exceeding 20ûC
51: Use only in well-ventilated areas
61: Avoid release to the environment. Refer to special instructions/safety data sheet*

*As Cryogesic® contains less than 125ml of ethyl chloride and is not intended for supply to the general public CHIPS3 Regulations (section 8;(11)) permit not listing R & S phrases. These phrases have been omitted to avoid causing undue patient concern and because there is no foreseeable risk under the conditions of use with the quantities supplied.

EC Number: 200-830-5. EC label.

Additional labelling for aerosol presentations according to EC Directives 75/324/EEC and 94/1/EC and subsequent amendments:
Pressurised 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.
Without adequate ventilation formation of explosive mixtures may be possible.

16. Other Information:

The above information has been compiled from that provided by our suppliers and other sources. None of the original information relating to hazards or potential hazards has been omitted and so the absence of a particular reference merely implies either that such information has not been determined or that it is not applicable. The above information is furnished without warranty of any kind. Users should consider this data only as a supplement to other information gathered by them and make independent determinations of suitability and completeness of information from all sources to ensure proper use and disposal of the product and the safety of employees and customers.