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Ethyl Chloride – (Material) Safety Data Sheet

(according to Regulation (EC) No. 1907/2006 – REACH, and Regulation (EC) No 1272/2008 – CLP, both in valid wording, in wording of valid amendments)

Issue/last revision: 02.01.2023 processed by Jaroslav Brabec, BTC Pharma statutory

SECTION 1: Identification of the substance and of the company/undertaking

1.1. Product identifier

Product trade name:	**KELEN spray®**
Other product names/synonyms:	Chloroethane, Hydrochloric ether, Chlorethyl, Kelen
Active ingredient:	Chloraehyl
Presentation:	Aerosol can containing100ml chloraethyl
REACH registration number:	01-2119487479-17
CAS No.	75-00-3

1.2. Relevant identified use of the substance / product

Intended (recommended) use:	For external topical use as a vapo-coolant and cryo-analgesic.
Specific use:	Briefly spray area requiring analgesia from a distance of at least 10cm until 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 use minimise inhalation of vapours by the patient, especially when applying to head and/or neck. Do not spray into eyes.
Not recommended use:	According to user information issued by manufacturer (see warnings, H and P phrases).
Expiry date:	3 years. See base of can for lot number and expiry date. The expiry date valid for used spray too.

1.3. Details of the supplier of the safety data sheet

Manufacturer: **BTC Pharma, s.r.o./Ltd.** Address: Bořivojova 35/878, 130 00 Prague 3, Czech Republic, Telephone: +420 576 013 794, www.btcpharma.cz, jbrabec@btcpharma.cz

E-mail address for competent person responsible for the safety data sheet: Mr Jaroslav Brabec, manufacturer′s statutory person: jbrabec@btcpharma.cz,

1.4. Emergency telephone number

Czech Republic: +420 224 91 92 93; 224 91 54 02 (non-stop service): Occupational diseases Clinic – Toxicological information centre, Na Bojišti 1, 128 08 Praha 2, Czech Republic.

Local numbers to be checked by local distributor!

Austria +43 1 31304 5620, Belgium +32022649636, Bulgaria +359 2 9154 409, Croatia +38514686910, Cyprus +3572240561, Denmark +45 72 54 40 00, Estonia +3726943384, Finland +358 5052 000, France +33 3 85 21 92, Germany +49-30-18412-0, Greece +302106479250, Hungary +34 (1) 476 1136, Ireland +35318092566, Italy +390649906140, Latvia +371 67032600, Lithuania +370 70662008, Luxembourg +352 24785551, Netherland +31 88 75 585 61, Norway +47 21 07 70 00, Poland +48 42 2530 400, Portugal +351213303271, Romania +40213183606, Slovakia +421 2 5465 2307, Slovenia +38614006039, Spain +34 917689800, Sweden +46104566750 United Kingdom (England or Wales) 0845 46 47 or Scotland 08454 24 24 24 (UK only).

Portugal:

Centro de Informação Antivenenos – CIAV: Em caso de intoxicação, ligue 800 250 250 (24h) **Morada:** Instituto Nacional de Emergência Médica, Rua Almirante Barroso, 36, 1000-013 Lisboa **Telefone (Secretariado):** 213 303 271 | **Fax:** 213 303 275, **E-mail:** ciav.tox@inem.pt

SECTION 2: Hazards identification

Hazardous Components:

Ingredient	CAS No.	EINECS EC Name & No.	Concentration	Quantity Unit
Ethyl Chloride	75-00-3	Chlorethane, 200-830-5	>99	100%

2.1. Classification of the substance - according to CLP; 2.2. Label elements

Hazard category	**Signal words**	**Hazard (H) statements**	**Hazard Pictogram & Symbol** (Label element) (GHS)	**Precautionary (P) Statements** (below statements is full wording – wording applied for product may be a little bit modified by manufacturer, as to relevance)
Flammable gas / aerosol (category 1) /physical hazard	Danger	H 222: Extremely flammable aerosol.	 GHS02	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P270: Do no smoke when using this product. P410: Protect from sunlight. P412: Do no expose to temperatures exceeding 50°C.
Compressed gas/ physical hazard	Warning	H 229: Pressurised container, May burst if heated.	 GHS04	P243: Take precautionary measures against static discharge. P251: Do not pierce or burn, even after use. P270: Do no eat, drink or smoke when using this product. P403 Keep and use in a well-ventilated place. Store at 10-25°C.
Eye irritation (category 2B) /health hazard	Warning		 GHS07	P 262: Do not get in eyes.
Acute toxicity (category 4) /health hazard	Warning		 GHS07	P260: Do not breathe vapours.
General	Warning			P102 Keep out of reach of children. Do not store near HF (Hydrofluoric acid) and/or ultrasonic equipment. Do not dispose of the can until it is empty.
If a hazard would occur - see the Section 4: First Aid Measures.				

2.3. Other hazards

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.

Hazards summary according to COMMISSION REGULATION (EU) 2015/830, amending Regulation (EC) No 1907/2006

(a) acute toxicity – P260: Do not breathe vapours.

(b) skin corrosion/irritation – not applicable
(c) serious eye damage/irritation – P262: Do not get in eyes.
(d) respiratory or skin sensitisation – P260: Do not breathe vapours.
(e) germ cell mutagenicity – not applicable
(f) carcinogenicity – not applicable
(g) reproductive toxicity – not applicable
(h) STOT (Specific target organ toxicity) - single exposure – not applicable
(i) STOT (Specific target organ toxicity) - repeated exposure – not applicable
(j) aspiration hazard – not applicable.
Note: toxicity – see also Section 11. TOXICOLOGICAL INFORMATION and Ecotoxicity see Section 12. ECOLOGICAL INFORMATION.

SECTION 3: Composition/information on ingredients

Contains no
- substances with Annex XVII restrictions
- substance on the REACH candidate list
- REACH Annex XIV substances
- chlorofluorocarbons / CFC free

3.1. Substances

the product identifier (beside that in cl. 1.1 and 2 above)

Chemical name:	Ethyl Chloride / Chloroethane
(Chemical) Molecular formula:	C_2H_5Cl
Chemical family:	Halogenated Hydrocarbon
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.

3.2. Mixtures

Not applicable.

SECTION 4: First aid measures

4.1. Description of first aid measures; 4.2. Most important symptoms and effects, both acute and delayed; 4.3. Indication of any immediate medical attention and special treatment needed

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.

Cause		Effects	First aid measures
Potential health effects	Inhalation	Headache, dizziness, nausea, vomiting, loss of coordination and disorientation may produce narcotic and anaesthetic effects. Although absorbed through lungs and skin, it also is rapidly given off through the lungs.	Immediately remove to fresh air/Breathing fresh uncontaminated air relieves minor symptoms of toxicity. If not breathing, if breathing has stopped, or is impaired, give artificial respiration and supplemental oxygen. If breathing is difficult, qualified personnel may give oxygen. Keep patient warm and quiet. Call immediately a physician – Medical assistance service.
	Ingestion	Unlikely route of exposure due to gaseous nature.	Unlikely route of exposure due to gaseous nature.
	Skin contact	Rapid evaporation of liquid may cause frostbite. Symptoms of frostbite are blanching of the skin, cold feeling numbness. In rare cases cutaneous sensitisation may occur. Freezing can cause occasional alter pigmentation. A single prolonged skin exposure is not likely to result in absorption of harmful amounts	Rinse with water. If unintentional freezing occurs, flood or soak with tepid water/Do not use hot water. For exposure to liquid, immediately warm frostbite area with warm water not to exceed 105ºF (41ºC)/Do not use hot water. In case of massive exposure, remove contaminated clothing while showering with warm water. Call a physician – Medical assistance service.
		Long term exposure to high levels may produce the following: loss of muscle coordination, involuntary eye movements, tremors, speech disturbance, sluggish reflexes and hallucinations. These symptoms are alleviated when the overexposure is ended.	
	Aggravation of pre-existing conditions	The defatting properties of Ethyl Chloride may aggravate existing dermatitis.	
	Eye contact	Ethyl chloride is slightly irritant to the eye and mucosal tissue.	For exposure to liquid, check for and remove any contact lenses. Immediately flush eyes thoroughly with warm water for at least 15 minutes/Rinse thoroughly with water. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly. See a physician, preferably an ophthalmologist, immediately.

SECTION 5: Firefighting measures

5.1. Extinguishing media
CO2, foam, powder.
Do not use:
Water - because it will scatter and spread the fire. Water spray may be used to cool aerosol containers.

5.2. Special hazards arising from the substance - special risks posed by the substance, its combustion products or reaction products:
Formation of hydrochloric acid, phosgene or carbon monoxide.

5.3. Advice for firefighters, 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.
Special fire-fighting procedures
Evacuate all personnel from danger area. Use water spray to cool fire-exposed containers, structures and equipment. Use water spray, carbon dioxide or dry chemicals as extinguishing media. Do not use stream of water because it will scatter and spread the fire. Remove sources of ignition if without risk. Remove all containers from fire area if without risk; continue cooling water spray while moving containers. Do not extinguish any flames emitted from containers, stop flow of material if without risk, or allow flames to burn out. Self contained breathing apparatus may be required by rescue workers.
Unusual Fire and Explosion Hazards
Very dangerous fire hazard when exposed to heat, flame or powerful oxidizers. Ethyl chloride is heavier than air and the vapors may hug the ground, making distant ignition and flashback possible. During a fire, toxic gases (hydrogen chloride, chlorine and phosgene) may be produced. Direct exposure to flames may cause container explosion. Static discharge may ignite ethyl chloride.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
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.
For entry into unknown concentrations – use full face self contained breathing apparatus.

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

6.3. Methods and material for containment and cleaning up - Cleaning/adsorption procedures:
Take up with non-combustible absorbent material such as sand.

6.4. Reference to other sections
Exposure controls/personal protection – see section 8.
Disposal considerations – see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Use in a cool, dry, well ventilated area. Solvent vapours can form explosive mixtures with air. Do not expose to temperatures exceeding 50°C (122F). Do not spray on or near a naked flame or incandescent material. Protect against physical damage. Do not use near open flame.

7.2. Conditions for safe storage, including any incompatibilities
Store at room temperature in a dry well-ventilated area only. Do not store on or near high frequency ultrasound equipment. Do not store near non-explosion proof electrical equipment. Protect from sunlight. Do not store above 25°C. Store at 10-25ºC.

7.3. Specific end use(s)
The information is given on the product label, by specific symbols for end use, in compliance with local regulations – see section 13, 13.1.

SECTION 8: Exposure controls/personal protection – personal protective equipment

8.1. Control parameters; 8.2. Exposure controls
Exposure limit values:
The Maximum Exposure Limit (MEL) is 50 parts per million (50 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/product user, 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 patient's eyes in order to minimise risk of inadvertent exposure. Users do not need to wear eye protection/safety glasses, except when dealing with large spills.

Body protection:

Not essential.

Exposure controls:

Use in a well-ventilated area. Avoid breathing fumes.

The air odour threshold concentration for ethyl chloride has been reported as 4.2 ppm parts of air (10-12 mg/m3).

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Information:

Presentation form:	aerosol can
Contents colour, appearance:	clear, colourless liquid
Contents odour:	similar to ether/ethereal

Important Health, Safety and Environmental Information:

pH:	essentially neutral
Boiling point/boiling range:	12.3 °C
Flash point:	-43°C (propellant)
Ignition temperature:	510°C (propellant)
Freezing Point:	-136.4°C
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°C)
Partition coefficient:	
Viscosity (at 20°C):	
Evaporation rate (butyl acetate = 1):	Greater than 1.0

9.2. Other information

Other Information:

Auto-ignition:	519°C
Melting point/melting range:	-138.7 °C
Molecular weight:	64.51

SECTION 10: Stability and reactivity

10.1. Reactivity; 10.2. Chemical stability; 10.3. Possibility of hazardous reactions; 10.4. Conditions to avoid; 10.5. Incompatible materials; 10.6. Hazardous decomposition products

Chemical stability

Normally stable in air. Where moisture, slowly hydrolyses forming hydrochloric acid.

Conditions to avoid:

Do not heat above 50°C. Exposure to heat/high heat, sparks and other sources of ignitron.

Materials to avoid / incompatible materials:
Contact between ethyl chloride and chemically active metals (alkali ones) such as sodium, potassium, calcium, powdered aluminium, zinc, and magnesium may cause fires and explosions. Ethyl chloride reacts vigorously with oxidising materials (strong oxidizers). 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. Carbon monoxide, hydrogen chloride gas, phosgene gas, and carbon dioxide.

Hazardous Polymerization
Not expected.

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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 phosphatise 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:
A 2-year study in mice did not yield increases in bone marrow micronuclei.

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) - See section 8.

Reproductive toxicity:
No effects on reproductive organs were observed after 13 weeks of mice exposure during organogenesis to vapors.

SECTION 12: Ecological information

12.1. Toxicity; 12.2. Persistence and degradability; 12.3. Bioaccumulative potential; 12.4. Mobility in soil; 12.5. Results of PBT and vPvB assessment; 12.6. Other adverse effects

Most of the chloraethyl 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 chloraethyl that is released to the atmosphere to disappear.
Gas is dissipated rapidly in a ventilated area.
With large spills, small amounts may enter groundwater as a result of passage through soil. In groundwater, chloraethyl 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 chloraethyl to smaller compounds. However, not enough is known about chloraethyl to be sure if this occurs or how long it may remain in groundwater.
No information on adverse effects to plant life except for frost produced upon evaporation.

Do not discharge into drains/surface waters/groundwater.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not dispose of the can until it is empty
Completely empty cans:

Recommendation:	Recycling
Waste disposal code:	15 01 04 (Non-dangerous/hazardous waste: metal containers) / D1
Designation of waste:	Metallic packaging/container – metallic waste
Accountability:	Yes

Packaging containing residues:

Recommendation:	Special disposal of waste
Waste disposal code:	18 01 06 (Dangerous/hazardous waste: chemicals being or containing dangerous /hazardous substances)/15 01 10 / D10, R01

Dangerous waste characteristic: H3-A Highly flammable / Hazardous – Flammable aerosol
Recommended cleaning:
White spirit.
Waste and packaging/container treatment symbols:

Consult local regulations for waste disposal in each country where product is being/was used.

SECTION 14: Transport information

14.1. UN number; 14.2. UN proper shipping name; 14.3. Transport hazard class(es); 14.4. Packing group; 14.5. Environmental hazards; 14.6. Special precautions for user; 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

UN No. : 1037 / Ethyl chloride
Road/Rail/Inland Waterways carriage ADR/RID:

UN No.:	1950 / Aerosols, flammable
Class:	2
Hazard Label:	No. 2.1 (Flammable Gas)
ADR Classification Code:	5F / Flammable (Code 5-Aerosols and receptacles, small, containing gas)
PSN:	AEROSOLS
Transport Category:	2

DANGEROUS GOODS IN **LIMITED QUANTITY** OF CLASS 2 UN 1950 aerosols
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
UN No.:	1950
Proper Shipping Name:	AEROSOLS, FLAMMABLE
Label:	No. 2.1 (Flammable Gas)

SECTION 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance; 15.2. Chemical safety assessment

All below regulations are EU and Czech Republic ones in valid wording (in wording of later amendments) – status to date of safety data current revision issue. Local regulations to be added according to country in question – responsibility is on local distributor.

1/ Czech act No. 350/2011 Coll., chemical act
2/ Regulation (EC) No. 1907/2006 of the European Parliament and of the Council - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), in valid wording (last consolidate version 08/01/2022)
3/ Regulation (EC) No. 1272/2008 of the European Parliament and of the Council - on classification, labelling and packaging of substances and mixtures (CLP), in valid wording (last consolidate version 01/10/2021)
4/ REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, in valid wording (last consolidate version 24/04/2020)
5/ Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers, in valid wording (last consolidate version 12/02/2018), Czech equivalent – regulation No. 194/2001
6/ Commission Directive 94/1/EC adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers, in valid wording (last consolidate version 24/04/2020)
7/ Czech act 541/2020 Coll., on wastes/wastes handling.
8/ Czech regulation No. 273/2021 Coll., details on wastes handling.
9/ GHS - Globally Harmonized System of Classification and Labelling of Chemicals (in wording of last Rev. 5, 2013).

Chemical safety assessment: was not performed by the product supplier.

Product labelling - pictograms/label elements, Hazard (H) statements, Precautionary (P) Statements
See section 2, 2.1.

SECTION 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.