Date of issue 17/06/2015

SAFETY DATA SHEET

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

1.1. Product identifier

Product names: **Ethyl Chloride Vidant Pharma Fine Spray Aerosol and Glass Vial**
Ethyl Chloride Vidant Pharma Direct Stream Aerosol and Glass Vial

1.2. Relevant identified uses of the substance or mixture and uses advised against

Vapo-coolant for clinical use as a topical cryo-analgesic and cold spray

1.3. Details of the supplier of the safety data sheet

Company: Vidant Pharma Ltd
International House
24 Holborn Viaduct
London
EC1A 2BN
United Kingdom

Tel: +44(0)7432 071201 Fax: +44 (0)207 681 2236
E-mail:info@vidantpharma.com

1.4. Emergency telephone number

Emergency telephone No.: +44 (0)7432071201 (UK office hours only)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2009
Flammable aerosol category 1, Carcinogen category 2, Aquatic chronic toxicity category 3
H222-H280-H351-H412
Extremely flammable aerosol. Contains gas under pressure; may explode if heated. Suspected of causing cancer. Harmful to aquatic life with long lasting effects.

Classification according to Directive 67/548/EEC
F+ Xn
R12-40-52/53
Extremely flammable. Limited evidence of a carcinogenic effect. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2. Label elements

Danger
Extremely flammable aerosol.
Do not breathe vapours. Use only in a well-ventilated area. Do not get in eyes. Use personal protective equipment as required.

Additional labelling for aerosol presentations according to EC Directives 75/324/EEC and 94/1/EC and subsequent amendments:
Pressurised container: Do not pierce or burn, even after use.
Protect from sunlight. Do not expose to temperatures exceeding 50°C
Keep away from heat/sparks/open flames/hot surfaces. – No smoking Do not spray on an open flame or other ignition source

2.3. Other hazards

Without adequate ventilation formation of explosive mixtures may be possible.

SECTION 3: Composition/information on ingredients

Aerosol presentations: Fine Spray Can 100ml and Direct Fine Stream Can 100ml
Glass presentations: Direct stream glass vials 50ml and 100ml
Fine spray glass vial 100ml

Contains: Ethyl chloride >99%

CAS number: 75-00-3 EC-No.: 200-830-5
EC Index No.: 602-009-00-0
Molecular formula: C_2H_5Cl = 64.51 g/mol

SECTION 4: First aid measures

4.1. Description of first aid measures

- Eye contact: Irrigate thoroughly with water for at least 10 minutes. OBTAIN MEDICAL ATTENTION. - Inhalation: Remove from exposure, rest and keep warm. In severe cases obtain medical attention. - Unintentional skin contact: Wash off skin with warm water. Remove contaminated clothing. Unless contact has been slight, OBTAIN MEDICAL ATTENTION.
- Ingestion: Wash out mouth thoroughly with water. OBTAIN MEDICAL ATTENTION.

4.2. Most important symptoms and effects, both acute and delayed

- After inhalation: Irritation of the mucous membranes, coughing, and shortness of breath.
- After eye contact: Slight irritation.
- After the uptake of large quantities: Possible effects: headaches, giddiness, tiredness, nausea, vomiting, heart beat disturbance, intoxication, danger of reduced reaction capability (sedation). Risk of deterioration due to consumption of alcohol.

Further hazardous properties cannot be excluded.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor: If swallowed, flush stomach adding activated charcoal. Treat frozen parts of the body in appropriate manner.
May sensitise the myocardium to endogenous epinephrine. Do not administer any preparations of the adrenaline-ephedrine group.
If breathing has stopped, or is impaired, give artificial respiration and supplemental oxygen.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Foam, dry powder, or carbon dioxide.
Do not use water because it could spread the fire.
Cool containers with water spray.

5.2. Special hazards arising from the substance or mixture

Extremely flammable. Vapour/air mixture explosive.
May evolve toxic fumes in fire. (hydrochloric acid, phosgene, carbon monoxide).

5.3. Advice for fire-fighters

Exercise caution when fighting any chemical fire. Only trained personnel should attempt to tackle a fire. Do not stay in dangerous zone without respiratory protective equipment. Prevent fire fighting water entering watercourses or ground-water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Shut off all sources of ignition. Wear appropriate protective clothing. Inform others to keep at a safe distance.

6.2. Environmental precautions

Do not allow to enter sewerage system; risk of explosion!

6.3. Methods and material for containment and cleaning up

Take up as much as possible with a non-combustible absorbent material. Disperse vapour by thorough ventilation of the area using flameproof equipment.

6.4. Reference to other sections

See Section 8 for advice on protective equipment and Section 13 for recommendations on disposal
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Use in a well-ventilated area. Do not use near naked flames. All nearby electrical equipment must be flame proofed. Do not expose the aerosol to temperatures in excess of 50°C Do not inhale the vapour. Avoid contact with eyes. Spray only the area to be treated.

7.2. Conditions for safe storage, including any incompatibilities

Store at room temperature in a dry well-ventilated area. Do not store on or near high frequency ultrasound equipment. Protect from sunlight. Do not store in a fridge. Store in a suitable flammable liquid storage cabinet.

7.3. Specific end use(s)

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. In clinical use minimise inhalation of vapours by the patient, especially when applying to head and/or neck. Do not spray into eyes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Chloroethane:
WEL
Long-term: 268 mg/m³ (100 ppm) (IOELV)

DN (M) EL - workers
Inhalation: Long term systemic: 268 mg/m³
Dermal: Long term systemic: 38.3mg/kg/day

PNEC
Water: 0.058mg/l (freshwater); 0.0058mg/l (marine); 0.58mg/l (intermittent)
Sewage treatment plant: 140mg/l
Sediment: 0.3098mg/kg (freshwater); 0.031mg/kg (marine)
Soil: 28.2849mg/kg

A risk assessment must be conducted to ensure that exposure is controlled so that it is as far below the workplace exposure limit (WEL) as is reasonably practicable.
Release should be controlled so that levels in the environment remain, if practicable, below the Predicted no effect concentration (PNEC)

8.2. Exposure controls

As appropriate to the situation and the quantity handled.

- Respirator: Filter type AX when large volumes of vapours are generated.
- Ventilation: Use only in a well-ventilated area.
- Gloves: Butyl rubber if user is sensitive to ethyl chloride, or for prolonged use.
- Eye Protection: Not required unless spray may contact the face.

Environmental exposure controls:

Do not allow to enter sewerage system.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:

Form:		Aerosol
Colour of contents:		colourless
Odour:		ether-like
Melting temperature:		-138.7°C
Boiling temperature:		12.3°C
Density: (g/ml)		~0.92
Vapour pressure:		134.2 kPa (20°C)
Relative vapour density:		2.23
Solubility in water:		Slightly soluble (~5.8g/l, 20°C)
Flash point:		-50°C
Explosion limits:	lower:	3.16%
	upper:	15%
Auto-ignition temperature:		519°C
Decomposition temperature:		No data available
Log P(o/w):		1.43
Explosive properties:		Vapour/air mixture explosive
Oxidising properties:		None

9.2. Other information

Additional data: None

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

Slowly hydrolyses in contact with water.

10.3. Possibility of hazardous reactions

Vigorous reactions possible with: aluminium, strong oxidizing agents.
The possibility of reaction with other substances cannot be excluded.

10.4. Conditions to avoid

Heating. (>50°C)

10.5. Incompatible materials

Aluminium, zinc, various plastics, rubber.

10.6. Hazardous decomposition products

Hydrochloric acid

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

LC50: >19000ppm/4hr inhalation, rat.

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 did not produce narcosis in humans. Intoxication began at 1.3 % and increased at increasing dosages. At a dose of 3.36 %, noisy talkativeness and in coordination 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 in coordination.

Skin corrosion/irritation:

Frequent and prolonged skin contact can cause skin irritation and inflammation. Liquefied ethyl chloride spilled on the skin or eye may cause frostbite.

Serious eye damage/irritation:

Liquid ethyl chloride sprayed into the eyes of rabbits damaged the cornea.

Respiratory or skin 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.

Germ cell mutagenicity:

Micronucleus-Test: negative

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.

Reproductive toxicity:

Data conclusive but not sufficient for classification.

STOT-single exposure:

No data available

STOT-repeated exposure:

No data available

Aspiration hazard:

No data available

Further toxicological information

None

SECTION 12: Ecological information

12.1. Toxicity

Daphnia toxicity: EC50: 58mg/l/48hr
Algal toxicity: EC50: 9.4mg/l/72hr (Scenedesmus subspicatus)

12.2. Persistence and degradability

Biological degradability: poor.

12.3. Bioaccumulative potential

Bioaccumulation potential: low (Log Pow <2).

12.4. Mobility in soil

Henry's law constant: 0.0111 atm m^3/mol (24.8°C)

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

Remarks:

Most of the ethyl chloride 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 ethyl chloride 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, ethyl chloride 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 ethyl chloride to smaller compounds. However, not enough is known about ethyl chloride to be sure if this occurs or how long it may remain in groundwater. Do not allow to enter drinking water supplies, waste water, or soil!

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Aerosols containing residues are generally classified as hazardous or special waste, and as such are covered by regulations which vary according to location. Waste codes 18 01 06 / 15 01 10, D10, R01 may apply. Contact your local waste disposal authority if you require advice, or pass to a licensed chemical disposal company. Completely empty containers may be sent for recycling.

SECTION 14: Transport information

14.1. UN number

1950 (all modes)

14.2. UN proper shipping name

Aerosols (Road and Sea)
Aerosols, flammable (Air)

14.3. Transport hazard class(es)

2 (Road and Sea)
2.1 (Air)

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

None known

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regional Regulations

Data sheet compiled according to Regulation (EU) 453/2010
The Ethyl Chloride Vidant Pharma presentation of ethyl chloride BP is intended for clinical use only and is registered under the Medical Devices Directive 93/42/EEC as a Class IIa Medical Device and marked CE 0473

Local Regulations

Within the UK, the use of this material must be assessed under the Dangerous Substances and Explosive Atmospheres (DSEAR) Regulations.
Within the UK, the use of this material must be assessed under the Control of Substances Hazardous to Health (COSHH) regulations.
The product is a medical device used in direct contact with the human body within the meaning of the Medical Devices Regulations 2002 and thus labelling according to Regulation (EC) 1272/2008 is not legally required.

15.2. Chemical safety assessment

Not available

SECTION 16: Other information

Revision.
Supersedes issue of 10/06/15
Reason for alteration: Updated telephone contact details

Source information

IUCLID
Supplier SDS

Classification method

Classified according to the requirements of Regulation (EC) 1272/2008

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