Date: 31st August, 2010

Former date: 3rd January, 2009

IDENTIFICATION OF THE CHEMICAL AND OF THE MANUFACTURER, IMPORTER OR OTHER UNDERTAKING

Identification of the substance or preparation

Trade name

Ice Power Cold Spray

Purpose of use

Expressed in writing

Cooling aerosol

Identification of the manufacturer, importer or other undertaking

Manufacturer, importer, other undertaking

Fysioline Oy, Pharma Arvionkatu 2 FI-33840 Tampere FINLAND info@fysioline.fi

Telephone number

+ 358 3 233 0300

Telefax

+ 358 3 233 0333

LY code

FI 0927611-8

Emergency telephone number

Name and address of the informant in emergency cases

Hospital District of Helsinki and Uusimaa, Intoxication Information Central (24 h)

PL 340, Haartmaninkatu 4 00029 HUS, FINLAND

Emergency telephone number

+ 358 9 471 977

2. COMPOSITION AND INFORMATION ON INGREDIENTS

Description

Cold spray

Hazardous ingredients

CAS number or other code	Name of the ingredient	Concentration	Warning symbol, R phrases and other data on the ingredient
64-17-5	Ethanol	2-8%	F, R11
68476-49-3	Propane	30 – 50 %	F+, R12
68476-40-4	Butane	30 - 50 %	F+, R12

3. HAZARDS IDENTIFICATION

Danger of fire and explosion: Extremely flammable. Easily volatile. Risks to health: Inhale of great amounts of vapor may cause headache, dizziness and nausea. Excessive use may cause local frostbite.

4. FIRST AID MEASURES

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Inhalation

If a person has been exposed to vapors and feels unusually tired or nauseous,

he must removed to fresh air. If the symptons are continuous, seek for medical treatment.

Skin

Take notice of that contaminated clothing can be flammable.

Contaminated clothing must be wet before removing. Clothing must be washed

before next use. Wash skin with soap and water. If irritation continues,

seek for medical treatment.

Splashes in eyes

Immediately wash eyes under running water. If irritation continues,

seek for medical treatment.

Information to doctor or other trained persons giving first aid

Symptomatic treatment. Frostbites can be covered up with a sterile bandage.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Foam, dry extinguishing media, carbon dioxide, sand and soil - in small fires.

Special exposure hazards in a fire

Danger of explosion: pressure increases in the spray cans, if they heat up in a fire.

Special protective equipment for a fire

Proper protective equipments and pneumatic respirator.

Other instructions

Spray cans near open fire must be chilled with water syringe from a sufficient distance.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Unnecessary persons must be evacuated from the area.

Methods for cleaning up

Vaporizing under surveillance. Take notice of the fire-, explosive- and health risks.

7. HANDLING AND STORAGE

Handling

Avoid inhaling the vapours and repetitive or long contact with skin.

Keep away from sources of ignition. No smoking. Avoid sparks.

Storage

In a warehouse suitable for extremely flammable aerosols.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Limit values for air at workplace

HTP values

Propane:

800 ppm (8h), 1 100 ppm (15 min)

1 500 mg/m³ (8h), 2 000 mg/m³ (15 min)

Butane:

800 ppm (8h), 1 000 ppm (15 min)

1 900 mg/m³ (8h), 2 400 mg/m³ (15 min)

Ethanol:

1 000 ppm (8h), 1 300 ppm (15 min)

1 900 mg/m³ (8h), 2 500 mg/m³ (15 min)

Preventing exposure

Eye protection

Wear protective goggles or mask if splashing is possible.

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Skin Protection

Avoid continuous skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state (form of existence, colour and odour)

Colourless, non-perfumed, menthol-like odour gas.

Information on changes in the physical state

Boiling point/boiling range

- 22 ℃

Flash point

Below 0 ℃

Autoflammability

+ 405 °C (Butane)

Lower explosion limit

1.9 percentage by volume (Butane)

Upper explosion limit

8.5 percentage by volume (Butane)

Relative density

0.55 g/cm³

Water solubility

Insoluble

Partition coefficient (for ingredients): n-octanol/water

No information accessible.

10. STABILITY AND REACTIVITY

11. TOXICOLOGICAL INFORMATION

Acute toxicity

In practice slightly toxic.

Irritancy and corrosiveness

Slightly irritative to skin. Not assumed to irritate eyes.

Sensitization

No to be assumed allergenic to skin.

Subacute, subchronic and prolonged toxicity

No mutagenic risk is assumed.

12. ECOLOGICAL INFORMATION

Toxic effects on organisms

Mobility

Vaporizes easily to air.

Persistence in the environment

13. DISPOSAL CONSIDERATIONS

Empty cans must be disposed of in accordance with local regulations.

14. TRANSPORT INFORMATION

UN number

Teade name: Ice Power Cold Spray

Date: 31st August, 2010

1950

Packaging category

2

Land transport Transport class

2 (ADŘ) Risk code

23

Name according to bill of freight

Aerosol

Sea transport IMDG class

21

Correct technical name

Aerosol

Air transport ICAO/ IATA class

2.1

Correct technical name

Aerosol

15. REGULATORY INFORMATION

Letter code of the warning symbol and indications of danger for the preparation

Former date: 3rd January, 2009

F+ Extremely flammable.

Names of the ingredients given on the warning label

Propane/Butane, Ethanol, Menthol

R phrases

R12 Extremely flammable.

S phrases

S16 Keep away from sources of ignition. No smoking.

Special regulations on certain preparations

Pressurized container. Protect from sunlight and do not expose to temperatures exceeding +50 °C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition – No smoking. Do not spray towards eyes. Keep out of the reach of children.

16. OTHER INFORMATION

Catalog of R phases

R12 Extremely flammable.

Sources of information used in the compilation of the safety data sheet

Material safety data sheets delivered by raw material manufacturers. International Chemical Safety Cards.

DECLARATION OF CONFORMITY

We



l ysiulle							
(manufacturer's name)							
Arvionkatu 2, FIN-33840 Tampere, FINLAND							
(address)							
hereby declare under our sole responsibility that the product Ice Power Cold Spray							
(product name, type or model, and lot, batch or serial identification)							
to which this declaration relates is in conformity with the provisions of Council Directive 93/42/EEC concerning medical devices, class IIa.							
30 th March 2011 in Tampere							
(place and date of issue)							
Fysioline Oy							
Pertti Välikoski Director							
(name, position and signature of authorized person of the manufacturer)							