Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet Isocare inhalation vapour



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Isocare inhalation vapour Product code(s): XVD 703 (250 ml bottle)

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

Relevant identified uses: Veterinary medicinal product

Uses advised against: Not for human use. Refer to the product information leaflet

Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
Address: 10 Great Northway
York Business Park
Nether Poppleton

York YO26 6RB United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008

This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to

point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation

(EC) 1272/2008

This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according

to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms:Not applicableSignal word:Not applicableHazard statements:Not applicable

Precautionary statements: Caution! This product has reasonable odor warning properties. If personnel smell

vapors, or experience dizziness or headaches, they should be moved to an area with fresh air. Concentrations of anesthetic in the air would have to reach approximately

2-3% before people would be expected to experience significant dizziness

Supplemental information: Principle routs of exposure: Absorbed through skin. Eye contact. Inhalation.

Ingestion.

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)

None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substance name in the mixture	CAS No	Quantity
Isoflurane	[26675-46-7]	100%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: In case of contact, immediately flush eyes with plenty of water for at least 15

minutes. Get medical attention if irritation develops

Skin: In case of contact, immediately flush skin with plenty of water. Remove

contaminated clothing and shoes. Get medical attention if irritation develops

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give

anything by mouth to an unconscious person. If large quantities of this material are

swallowed, call a physician immediately

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If

breathing is difficult, give oxygen. Get medical attention

4.2 Most important symptoms and effects, both acute and delayed

Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision). May cause skin and eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during

firefighting:

Not flammable or combustible

Hazardous combustion products: Decomposition products may include the following materials: Carbon oxides (CO_x)

5.3 Advice for fire-fighters

Special protective equipment for

firefighters:

Fire fighters should wear positive pressure self-contained breathing apparatus

(SCBA) and full turnout gear

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in

accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency

personnel:

Depending on local ventilation, clean-up crews may need to wear a chemical cartridge respirator, with a cartridge for organic vapors. Use suitable protective equipment. Follow all fire fighting procedures. Refer to protective measures listed

in sections 7 and 8

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any

information is section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Large spills: For large spills, were one or more bottles break, ensure adequate ventilation or

evacuate area. Large volumes of anesthetic agents may cause sedative effects. Restrict persons not wearing protective equipment from areas of spills or leaks until clean up is complete. Large spills should be absorbed using a sorbent that is designed for clean up of organic chemicals. Spill pillows, vermiculite, and carbonbased sorbents are some suitable materials. Keep in suitable, closed and sealed

containers for disposal

Small spills: Small volumes of liquid anesthetic agents may evaporate readily at normal room

temperatures, and may dissipate before any clean up attempts are initiated

6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Wash thoroughly after handling

Hygiene measures: None identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas

and containers:

Keep out of reach of children. Keep in the original packaging. Keep container tightly

closed

Store between 15-30 °C

Storage temperature:

Further information on storage

conditions:

Keep in a dry, cool and well-ventilated place

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, the other constituents have no known exposure limits

Substance name in the mixture	Туре	Value
Isoflurane	NIOSH (60 min)	2 ppm

8.2 Exposure controls

Engineering measures: Use process enclosures, local exhaust ventilation, or other engineering controls to

keep airborne levels below recommended exposure limits. Well designed and maintained scavenging system on the anesthesia equipment (combined with a good general room ventilation) is important in limiting the exposures of all

personnel

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Eye protection not required for normal final product use. Safety glasses with

sideshields are recommended for laboratory and manufacturing use

Skin/body protection: Work uniform or laboratory coat. Additional body garments should be used based

upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits)

Hand protection: Use chemical resistant, impervious gloves

Respiratory protection: Personal respiratory protection equipment not typically required if engineering

controls are in place. If exposure levels may exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other

regions

Environmental exposure controls: Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Liquid

Colour: Clear colourless

Odour: Pungent. Ethereal. Musty

Odour threshold:No data availablepH:No data availableDensity:No data availableMelting point:No data available

Boiling point: 48.5 °C

No data available Flash point: **Evaporation rate:** No data available Flammability: No data available Water solubility: 0.275% in water **Partition coefficient:** No data available **Auto-ignition temperature:** No data available Thermal decomposition: No data available Viscosity: No data available Vapour pressure: 238 mmHg at 20 °C Vapour density: No data available **Explosive properties:** No data available

Oxidizing properties: The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

These products are halogenated compounds (hydrochloric and hydrofluoric acids). Phosgene

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Isoflurane LD₅₀ 5080 μl/kg (Mouse, oral)

$$\begin{split} & Isoflurane \ LD_{50} \ 4770 \ \mu l/kg \ (Rat, oral) \\ & Isoflurane \ LD_{50} \ 15300 \ ppm \ (Rat, inhalation) \\ & Isoflurane \ LD_{50} \ 16800 \ ppm \ (Mouse, inhalation) \end{split}$$

Chronic toxicity: Target Organs: Nervous system. Heart. Liver

Skin irritation/sensitization: No data available

Reproductive toxicity: No impairment to fertility based on animal data. May be fetotoxic at high doses

based on animal data. Epidemiological studies suggest higher than normal incidences of problem pregnancies (particularly spontaneous abortions) among

exposed personnel

Carcinogenicity: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related

carcinogenic/tumorigenic effects based on animal data

Mutagenicity: No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

DOT:

DOT shipping name: Aviation regulated liquid n.o.s. (Isoflurane)

UN Number: UN3334
DOT Packing Group: None
DOT Hazard class: 9

TDG (Canada):

TDG Proper shipping name:

TDG UN/NA Number:

Not Available.

TDG Packing Group:

Not Available.

TDG Hazard class:

Not Available.

ADR/RID:

ADR Official Transport Name:

ADR Proper shipping name:

ADR UN/NA number:

ADR Hazard Class:

Not Available.

Not Available.

Not Available.

ICAO / IATA:

IATA Proper shipping name: Aviation regulated liquid n.o.s. (Isoflurane)

IATA UN NUMBER UN3334
IATA Primary Hazard 9
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: Not Available.

IMDG Hazard Class and Division: Not Available.

IMDG Packing Group: Not Available. IMDG Subsidiary Risks: Not Available.

EU EINECS List This product complies with EINECS

Risk Phrases: Not determined Safety Phrases: Not Determined

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

End of document