

SECTION 1 IDENTIFICATION

GHS Product identifier:	Pharmachem Isoflurane Inhalation Anaesthetic
Other means of identification:	1-Chloro-2,2,2-Trifluoroethyl Difluoromethyl Ether
Recommended use of the product and restrictions on use:	Inhalation anaesthetic
Supplier's Details:	Pharmachem Australia Pty Ltd Unit 6, 70 Fison Ave West Eagle Farm QLD 4009 Telephone: (07) 3868 0333

Emergency phone number: 13 11 26 (Poisons Information Hotline)

SECTION 2 HAZARDS IDENTIFICATION

Classification of Product:

This product is classified as a health hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition.

Eye irritant:	Category 2B
Skin irritant:	Category 2
Reproductive toxicity:	Category 2

GHS label elements, including precautionary statements:

Pictogram:



Signal word:	Warning
Hazard statement:	Causes eye irritation
Precautionary statements:	
Prevention:	Wash hands after handling Wear eye protection
Response:	If in eyes, get medical advice / attention

Pictogram:



Signal word:	Warning
Hazard statement:	Causes skin irritation
Precautionary statements:	
Prevention:	Wash hands after handling Wear protective gloves
Response:	If on skin, get medical advice / attention See specific instructions in Section 4 – First Aid If skin irritation occurs, wash with plenty of soap and water. Remove immediately all contaminated clothing.



Pictogram:

Signal word: Warning
 Hazard statement: Suspected of damaging fertility or the unborn child
 Precautionary statements:
 Prevention: Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Use personal protective equipment as required.
 Response: If exposed or concerned, get medical attention / advice

Other Health Hazards: None known

Other Hazard Information:
 Classified as dangerous goods when transported by air.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion
1-Chloro-2,2,2-Trifluoroethyl Difluoromethyl Ether	26675-46-7	
100%		

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as part of the registration process:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 13 11 26.

However, the following additional information is provided for assistance in emergent circumstances while implementing the above First Aid instructions:

Inhalation: Remove to fresh air. If necessary, give artificial respiration and seek medical help
 Skin: Wash immediately with soap and water
 Eye: Flush eyes out for at least 15 minutes with water.
 Oral: Do not induce vomiting.

Advice to Doctors: Treat symptomatically

SECTION 5 FIRE FIGHTING MEASURES

Suitable extinguishing media: Non-flammable. Use extinguishing media appropriate for surrounding fire
 Hazards from combustion products: Emits toxic and corrosive fumes under fire conditions
 Special protective precautions and equipment for fire fighters: Wear self-contained breathing apparatus if there is leakage
 Additional information: None known
 Hazchem Code: None allocated

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures: large	Allow small spills to dissipate with good ventilation. For spills wear self-contained breathing apparatus
Methods and materials for containment and clean up: and	Absorb on vermiculite or other inert absorbent material place in closed container for disposal.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:
The following Safety Directions have been set by the APVMA as part of the assessment of this product for registration:
May irritate the eyes and skin. Avoid contact with eyes and skin.

Conditions for safe storage, including any incompatibilities:
The following Storage Directions have been set by the APVMA as part of the assessment of this product for registration:
Store below 25°C (air conditioning). Protect from direct sunlight and direct heat. Store in tightly closed original container.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards:	None allocated
Biological limit values:	None allocated
Engineering controls:	Ensure adequate ventilation during use.
Personal protective equipment:	
Respiratory:	Self-contained breathing apparatus for emergency use
Ventilation:	Adequate general and local ventilation
Eye and Face:	Safety glasses or goggles and/or face shield
Gloves:	Impervious gloves
Other Equipment:	Provide safety shower and eye wash facilities

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colourless liquid
Odour:	Slight pungent odour
Boiling Point:	48.5°C
Melting Point:	Not known
Specific Gravity (H ₂ O=1):	1.50
Vapour Pressure:	330mmHg @ 20°C
Vapour Density (Air=1):	>1
Solubility in Water:	Negligible

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	None known
Incompatible materials:	Reactive metals such as sodium, potassium, or finely divided zinc, aluminium or magnesium, especially at high temperature
Hazardous decomposition products:	Halogen acids and carbonyl halides formed by thermal or oxidative decomposition
Hazardous reactions:	Hazardous polymerization will not occur

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

Exposure to isoflurane can occur through inhalation, ingestion, and eye or skin contact. The major route of exposure is expected to be inhalation. Target organs are respiratory, cardiovascular and central nervous system.

Signs and symptoms of exposure

1. Acute symptoms: Anaesthesia, respiratory depression, coughing.
2. Chronic symptoms: No present evidence demonstrates that isoflurane is a mutagen, teratogen or carcinogen.

Summary of Toxicology

1. Effects on animals: Animal studies of the effects of long-term exposure to low concentrations of isoflurane have been carried out with several species. The lowest concentration said to have significant effects on the body weight development of juvenile mice was 150 ml/m³; these data, however, come from a single publication and were obtained with unconvincing methods. In other chronic toxicity studies, the NOAEL for mice exposed for 78 weeks was 1000 ml/m³.

2. Effects on Humans: Inhalation of isoflurane at a concentration of 0.5-3.0% can induce general anaesthesia in 7 to 10 minutes, with analgesia, muscle relaxation, and loss of consciousness. Isoflurane is mildly pungent and may cause coughing, laryngospasm and breath holding in an unconscious individual; secretions may be slightly stimulated and pharyngeal and laryngeal reflexes may be obtunded. Isoflurane is a severe respiratory depressant, causing a decreased tidal volume that may produce hypercapnia. Blood pressure is depressed with an initial decrease in systemic vascular resistance, heart rate and cardiac output, although rate and output may increase due to compensatory mechanisms. Arrhythmias can occur, and the myocardium may be slightly sensitized to epinephrine. Renal blood flow, glomerular filtration and urine flow are decreased without residual renal depression or renal injury following isoflurane anesthesia. Isoflurane does not appear to produce liver injury when given for prolonged periods. Inhalation of higher concentrations may lead to death by medullary paralysis. Those recovering from exposure may exhibit shivering, nausea, vomiting, ileus, or excitation, and there may be a transient white blood count increase. A slight decrease in intellectual function may persist for 2-3 days, with small mood changes or symptoms possible for 6 days. Induction of general anesthesia may cause malignant hyperthermia from hypermetabolism of skeletal muscles in susceptible individuals.

3. Reproductive toxicity (fertility, developmental): 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.

SECTION 12 ECOLOGICAL INFORMATION

No ecological information available. However, this material is a veterinary inhalation anaesthetic supplied in packs containing 250 mL of isoflurane and is therefore unlikely to have significant ecological effects.

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:

The following disposal directions for containers have been set by the APVMA as part of the assessment of this product for registration:

Dispose of empty containers by wrapping in paper and placing in garbage. Alternatively, glass bottles should be completely emptied before disposal and placed in a glass recycle bin.

Dispose of unused chemical in a local authority landfill in accordance with local authority instructions.

Special precautions for landfill or incineration: None known

SECTION 14 TRANSPORT INFORMATION

Isoflurane is not defined as dangerous goods by the Australian Code for the Transport of Dangerous Goods by Road and Rail. However, it is an aviation regulated liquid (UN 3334).

SECTION 15 REGULATORY INFORMATION

This product has been registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). In granting registration to any product, the APVMA has exercised its legislative responsibility to ensure that the product is suitably formulated and properly labelled and, when used according to instructions is:

- safe to the host, the user, consumers and the environment;
- efficacious (that is, the product does the job it claims it shall do); and
- not unduly prejudicial to trade.

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations of applications for registration of agricultural and veterinary chemical products. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Ageing which:
 - evaluates and reports on toxicology and metabolism studies; proposes first aid and safety directions; determines poison schedule classifications; and establishes acceptable daily intakes (ADIs) and acute reference doses (ARfD); and
 - evaluates the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Material Safety Data Sheet (MSDS);
- the Commonwealth Department of the Environment and Heritage (DEH) which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment; and
- State and Territory departments responsible for agricultural and primary industries which evaluate and reports on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products. In some cases the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts.

This substance has not been assessed by NICNAS (National Industrial Chemicals Notification and Assessment Scheme).

Isoflurane as presented in this context appears in Schedule 4 of Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

SECTION 16 OTHER INFORMATION

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, <https://apvma.gov.au/node/26586>, (as updated)
2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018
3. AICS (Australian Inventory of Chemical Substances), NICNAS (National Industrial Chemicals Notification and Assessment Scheme), Commonwealth Department of Health
4. Australian Pesticides and Veterinary Medicines Authority (APVMA) Guidelines, <https://apvma.gov.au/node/1060>, (as updated)
5. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health, TGA, (as updated)
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7th Edition
7. The Poisons Standard (as updated), Therapeutic Goods Administration (TGA), Commonwealth Department of Health
8. Hazardous Chemical Information System (HCIS), Safe Work Australia (as updated)

9. Chemical Classification and Information Database (CCID), Environmental Protection Authority, New Zealand (as updated)
10. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition, United Nations, New York and Geneva, 2017

All information contained in this Safety Data Sheet is as accurate and up to date as possible. Since Pharmachem cannot anticipate or control the conditions under which this information may be used, each user should review the information in the specific context of the intended application. Pharmachem will not be responsible for damages of any nature resulting from use of or reliance upon the information. No expressed or implied warranties are given other than those implied as mandatory by Commonwealth State or Territory legislation.