

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product (material) name: Halothane BP
Other names: Not Applicable
Recommended use: Veterinary anaesthetic
Supplier Details: Pharmachem
Unit 6, 70 Fison Ave West
Eagle Farm QLD 4009
Telephone: (07) 3868 0333
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SECTION 2 HAZARDS IDENTIFICATION

This product is classified as dangerous goods only when transported by air and so is not subject to the Australian Dangerous Goods (ADG) Code. However, it is classified as hazardous according to the classification criteria of NOHSC:1008(2004), Approved Criteria For Classifying Hazardous Substances and the National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011(2003)].

Health Hazard Information

Severe eye irritant. May act as a carcinogen or mutagen. May cause reproductive damage. Experimental teratogen. Harmful if inhaled. May be harmful in contact with the skin or if swallowed. Narcotic. ceiling limit 2 ppm.

Risk Phrases:

R37 Irritating to respiratory system
R38 Irritating to skin
R41 Risk of serious eye damage
R61 May cause harm to the unborn child

Safety Phrases:

S23 Do not breathe fumes
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S36 Wear suitable protective clothing
S37 Wear suitable gloves
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S53 Avoid exposure – Obtain special instructions before use

Acute Effects:

Swallowed: Not available
Eyes: Irritating to eyes
Skin: Irritating to skin
Inhaled: Anesthesia, dizziness, depressed breathing

Chronic Effects:

Chronic effects of overexposure - mostly unknown. Liver damage has been reported after repeated anesthetic exposure.

Other Health Hazard Information:

Halothane is an APVMA approved general inhalation anaesthetic. Health professionals using this anaesthetic as prescribed by the drug insert will control handling procedures for medical use. The anaesthetic range begins at about 0.7% but initial induction may be as high as 3% or higher.

Acute accidental exposure to large doses may cause dizziness and depress breathing. Continued exposure to higher levels will cause cessation of breathing. If this occurs, give artificial respiration and administer oxygen and obtain immediate medical help from an anaesthetist if available.

Halothane is essentially non toxic by single dose ingestion (rat oral LD₅₀: 6.7g/kg). It is slightly irritating to rabbit eyes but not the skin. Because of concerns of the health of those operating room personnel exposed to waste anesthetic gases there have been many animal studies on the effects of low levels of anesthetic gases and many epidemiological studies on operating room personnel. These were fully reviewed in 1978 (1) and in 1982 (2) and in part in 1985 (3) and 1990 (4).

The epidemiological studies were seriously challenged (1,2) and after careful review of those studies an eminent group of statisticians and epidemiologists (3) found the studies inconclusive and stated that, 'prospective cohort studies are needed to determine whether there is a relationship between current levels of occupational exposure to anaesthetic gases and adverse gases and adverse outcomes, particularly spontaneous abortion, and liver disease.

In 1987 an epidemiological study on veterinary personnel (5) showed that the reproductive outcome for those personnel exposed to anesthetic gases is no different from the general public.

In a comprehensive mortality study among US physicians (6) anaesthetists had a death rate of only 98% of that of all physicians and less than 66% of US white males as a whole. Thus, anesthesiologists were shown to have above average health.

The 1990 review lists many animal studies showing microscopic changes after prolonged exposures during gestation to small concentrations of halothane. The most significant of the animal studies (7), was on a very large number of animals. It showed that exposures at 500 ppm of halothane for two hours daily to both males and females for nine weeks prior to mating and then to females throughout pregnancy showed no differences from the controls for fertility, reproduction and postnatal survival.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion
Halothane BP	151-67-7	100%

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set by the Office of Chemical Safety and Environmental Health (OCSEH) of the Commonwealth Department of Health and Aging:

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone 131126. (*FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals*)

However, the following additional information is provided to assist in emergent circumstances:

Swallowed:	Do not induce vomiting
Eye:	Wash with copious amounts of water.
Skin:	Wash with soap and water.
Inhaled:	Remove to fresh air, give artificial respiration if needed.
First Aid Facilities:	Eye wash facilities.
Advice To Doctor:	Not available.

SECTION 5 FIRE FIGHTING MEASURES

Fire/Explosion Hazard:	Non-flammable.
Suitable Extinguishing Media:	Use extinguishing media suitable for surrounding fire
Special Fire Fighting Procedures:	Wear self-contained breathing apparatus if there is danger of leakage.
Hazards from combustion products:	Thermal decomposition products are toxic and corrosive

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Contain spills using inert absorbent materials. Wear self-contained breathing apparatus for cleaning up spills
Methods and materials for containment and clean up:	Absorb spilled materials with inert absorbent materials such as powdered clay, vermiculite, sand etc. Collect waste material and dispose of in accordance with local authority instructions.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:	Do not eat, drink, smoke, apply cosmetics, or take medications in areas where halothane or a solution containing halothane is handled, processed, or stored.
Conditions for safe storage, including any incompatibilities:	Approved storage directions for Halothane BP from the Australian Pesticides & Veterinary Medicines Authority (APVMA) indicate that Halothane should be stored in air conditioning and protected from light. Opaque, chemically resistant containers should be used for storage. Containers of halothane should be protected from physical damage and should be stored separately from acids, direct sunlight, heat, sparks, and open flame. Because containers that formerly contained halothane may still hold product residues, they should be handled appropriately.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards:	TWA (ppm) – 0.5 TWA (mg/m ³) – 4.1
Biological limit values:	None Set
Engineering controls:	Provide adequate ventilation to meet the TWA
Personal protective equipment:	
Respiratory:	None normally needed.
Eye and Face:	Safety glasses or goggles.
Gloves:	Impervious gloves.
Other Equipment:	None normally needed.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colorless liquid with ethereal odour
Boiling Point:	50°C
Melting Point:	N/A
Vapour Pressure:	243 mm Hg (20°C)
Specific Gravity:	1.87 (H ₂ O=1)
Flash Point:	None
Flammability Limits:	N/A
Autoignition Temp:	Not determined
Rel. Vapour density:	6.9 (Air=1)
Other Properties:	Solubility in water – Negligible

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable, but may be light sensitive
Conditions to avoid:	No information available
Incompatible materials:	Incompatible with rubber, plastics, strong oxidizing agents. Reactive with metals such as sodium, potassium and finely divided zinc, aluminium and magnesium, especially at high temperatures
Hazardous decomposition products:	Thermal, oxidative decomposition gives halogen acids and carbonyl halides
Hazardous reactions:	Hazardous polymerisation will not occur

SECTION 11 TOXICOLOGICAL INFORMATION

Health effects from the likely routes of exposure:
Halothane is essentially non toxic by single dose ingestion. It is slightly irritating to rabbit eyes but not to skin.

LDLO ^a Oral (Human)	140 mg kg ⁻¹
LCLO ^b Inhalation (Human)	7000 ppm/3h
LDLO Intravenous (Man)	129 mg kg ⁻¹
LD ₅₀ Oral (Rat)	5680 mg kg ⁻¹
LC ₅₀ Inhalational (Rat)	29000 ppm
LC ₅₀ Inhalational (Mouse)	98 g/m ³ /2h
LD ₅₀ Oral (Guinea Pig)	6000 mg kg ⁻¹

- (a) Lowest published lethal dose
(b) Lowest published lethal concentration

SECTION 12 ECOLOGICAL INFORMATION

No ecological information available

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:	APVMA approved container disposal directions indicate that containers may be wrapped in paper and placed in household garbage. Unused product should be disposed of in accordance with local authority instructions
Special precautions for landfill or incineration:	None known

SECTION 14 TRANSPORT INFORMATION

This material is dangerous goods only when transported by air.	
UN Number:	3334
UN Proper Shipping Name:	AVIATION REGULATED LIQUID N.O.S. (HALOTHANE)
Class and subsidiary risk:	9.0
Packing Group:	None allocated
Special precautions for user:	None known
Hazchem Code:	None allocated

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.

Although all ingredients appear in the Australian Inventory of Chemical Substances (AICS), they have not been assessed by NICNAS (National Industrial Chemicals Notification and Assessment Scheme)

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

SECTION 16 OTHER INFORMATION

MSDS version:	2
Date of Revision:	March 2011
Update of sections:	2, 4, 10, 15, 16

CONTACT POINT

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References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated)
2. Approved Criteria For Classifying Hazardous Substances, NOHSC:1008 (2004)
3. National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011 (2003)]
4. AICS (Australian Inventory of Chemical Substances), Safework Australia
5. APVMA Manual of Requirements and Guidelines for Agricultural Chemicals, Version 4.1, (as updated)
6. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, (as updated)
7. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7th Edition
8. The Poisons Standard (as updated), National Drugs and Poisons Schedule Committee
9. Hazardous Substances Information System, Safework Australia (as updated)

All information contained in this Material 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.