

**SECTION 1 IDENTIFICATION**

GHS Product identifier:	Pharmachem Halothane BP
Other means of identification:	Ethane, 2-bromo-2-chloro-1,1,1-trifluoro-
Recommended use of the product and restrictions on use:	Veterinary anaesthetic
Supplier's Details:	Pharmachem Australia Pty Ltd Unit 6, 70 Fison Ave West Eagle Farm QLD 4009 Telephone: (07) 3868 0333
<b>Emergency phone number:</b>	<b>13 11 26 (Poisons Information Hotline)</b>

**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), Eighth Revised Edition.

Eye irritant:	Category 2A
Reproductive toxicity:	Category 1
Specific target organism toxicity following repeated exposure:	Category 2

GHS label elements, including precautionary statements:  
 Pictogram:



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

Pictogram:



Signal word:	Danger
Hazard statement:	May damage 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

Pictogram:



Signal word: Danger  
 Hazard statement: May cause damage to liver through prolonged or repeated exposure  
 Precautionary statements: Prevention: Do not breathe vapours.  
 Wash exposed parts thoroughly after handling.  
 Do not eat, drink or smoke when using this product  
 Response: Get medical advice / attention if you feel unwell.

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

### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

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

### SECTION 4 FIRST AID MEASURES

The following First Aid directions have been derived from the FAISD Handbook published by the Australian Pesticides and Veterinary Medicines Authority (APVMA). These directions have been developed on the basis of advice provided by the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and are applicable to all veterinary chemical products unless different directions have been specified:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

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 material 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 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 <sup>3</sup> ) – 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 <sub>2</sub> 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 is light sensitive unless stabilised
Conditions to avoid:	Light, sources of heat and flame
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

Routes of Exposure:

Exposure to halothane can occur through inhalation, ingestion, and eye or skin contact.

Signs and symptoms of exposure

1. Acute symptoms: The signs and symptoms of acute exposure to halothane in humans may include redness and tearing of the eyes and central nervous system effects (dizziness, a sense of fatigue, headache, sleepiness, slurred speech, reduced respiratory rate).
2. Chronic symptoms: The signs and symptoms of chronic exposure to halothane may include jaundice, enlarged and tender liver, and reproductive effects (spontaneous abortion, infertility, premature delivery, and congenital abnormalities).

Summary of Toxicology

1. Effects on animals: Halothane causes eye irritation and liver and kidney damage. This substance may also be a reproductive toxin in animals [ACGIH 1991; NIOSH 1993]. Instilled into the eyes of rabbits, halothane caused severe eye irritation [NIOSH 1993]. The LC(50) in rats is 29,000 mg/kg for an unspecified duration, and the oral LD50 in rats is 5,680 mg/kg [NIOSH 1993]. Guinea pigs repeatedly given anaesthetic doses of halothane developed hepatic lesions and necrosis of the liver [ACGIH 1991]. Other studies in rabbits and rats exposed subchronically showed dose-dependent increases in liver-to-body weight ratios in these animals [ACGIH 1991]. The offspring of rats exposed daily during gestation to 10 mg/kg of halothane showed reduced learning ability and, at autopsy, liver damage [ACGIH 1991]. Daily exposure of pregnant mice to 500 mg/kg halothane caused only a small decrease in maternal and foetal weight gain [ACGIH 1991]. The offspring of mice anaesthetised with halothane on 3 consecutive days during pregnancy showed an increased incidence of cleft palate and reduced ossification [ACGIH 1991]. Other studies have failed to show reproductive effects [ACGIH 1991]. The International Agency for Research on Cancer (IARC) has determined that the evidence for the carcinogenicity of halothane in animals is inadequate [ACGIH 1991; IARC 1987].

2. Effects on Humans: Halothane causes central nervous system depression, affects the cardiovascular system, may cause hepatitis, and has reproductive effects in humans. When used as a clinical anaesthetic, halothane induces amnesia, analgesia, anaesthesia, and respiratory depression [Hathaway et al. 1991]. Anaesthetic doses range from 5000 to 30,000 mg/kg [ACGIH 1991]. During anaesthesia, cardiac output may be reduced and arrhythmias may occur [Hathaway et al. 1991]. A syndrome called "halothane hepatitis" occurs in 1 in 10,000 halothane-induced anaesthesia patients; this syndrome involves fever, anorexia, nausea, and vomiting and may progress to hepatic failure and death [Hathaway et al. 1991]. This syndrome usually occurs in patients who have been anaesthetised with halothane more than once in a short period of time [ACGIH 1991; Hathaway et al. 1991]. Volunteers exposed to 4,000 mg/kg halothane exhibited amnesia for word pairs and impaired manual dexterity, while those exposed to 1,000 mg/kg showed no effects [ACGIH 1991]. A number of epidemiological studies of occupationally exposed populations, primarily operating room personnel, have shown increased risks of spontaneous abortion, premature delivery, involuntary infertility, cancer, diseases of the liver and kidney, and congenital abnormalities in their children [Hathaway et al. 1991]. Some authors point out that the populations in these studies were exposed to other potential reproductive toxins, such as cigarette smoke and other anaesthetic gases [ACGIH 1991].

References:

- ACGIH [1991]. Documentation of the threshold limit values and biological exposure indices. 6th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.
- ACGIH [1994-1995]. Threshold limit values for chemical substances and physical agents and biological exposure indices. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.

CFR. Code of Federal regulations. Washington, DC: U.S. Government Printing Office, Office of the Federal Register.

Forsberg K, Mansdorf SZ [1993]. Quick selection guide to chemical protective clothing. New York, NY: Van Nostrand Reinhold.

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Hathaway GJ, Proctor NH, Hughes JP, and Fischman ML [1991]. Proctor and Hughes' chemical hazards of the workplace. 3rd ed. New York, NY: Van Nostrand Reinhold.

IARC [1987]. IARC monographs on the evaluation of carcinogenic risks to humans. Volumes 1 to 42, Supplement 7. Lyon, France: World Health Organization, International Agency for Research on Cancer.

Lewis RJ, ed. [1993] Hawley's condensed chemical dictionary. 12 ed. New York, NY: Van Nostrand Reinhold Company.

Mickelsen RL, Hall RC [1987]. A breakthrough time comparison of nitrile and neoprene glove materials produced by different glove manufacturers. Am Ind Hyg Assoc J 48 (11): 941-947.

Mickelsen RL, Hall RC, Chern RT, Myers JR [1991]. Evaluation of a simple weight-loss method for determining the permeation of organic liquids through rubber films. Am Ind Hyg Assoc J 52(10): 445-447.

NFPA [1986]. Fire protection guide on hazardous materials. 9th ed. Quincy, MA: National Fire Protection Association.

NIOSH [1993]. Registry of toxic effects of chemical substances: Halothane. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Standards Development and Technology Transfer, Technical Information Branch.

NIOSH [1992]. Recommendations for occupational safety and health: Compendium of policy documents and statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 92-100.

NIOSH [1987a]. NIOSH guide to industrial respiratory protection. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-116.

NIOSH [1987b]. Respirator decision logic. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-108.

OSHA [1992]. Computerized information system. Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration.

Patnaik, P [1992]. A comprehensive guide to the hazardous properties of chemical substances. New York, NY: Van Nostrand Reinhold.

Sax NI, Lewis RJ [1989]. Dangerous properties of industrial materials. 7th ed. New York, NY: Van Nostrand Reinhold Company.

Sittig M [1991]. Handbook of toxic and hazardous chemicals. 3rd ed. Park Ridge, NJ: Noyes Publications.

USC. United States code. Washington. DC: U.S. Government Printing Office.

Windholz M. ed. [1983]. Merck Index. 10th ed. Rahway, NJ: Merck & Company.

## SECTION 12 ECOLOGICAL INFORMATION

Halothane is volatile and expected to be released into the atmosphere comparatively quickly from soil and water. In the atmosphere, its major degradation pathway is through reaction with hydroxyl free radicals and it has an estimated half life of 12 months. Given its long atmospheric lifetime, some percentage is expected to diffuse slowly into the stratosphere where it will undergo direct photolysis by UV-C radiation, releasing radicals that contribute to damage of the ozone layer.

However, given that Halothane is an inhalation anaesthetic, it is considered unlikely that amounts affecting the environment will be released from registered use or disposal of containers and unused product.

## 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. Contact local authority for advice.

#### SECTION 14 TRANSPORT INFORMATION

This product is classified as dangerous goods only when transported by air and so is not subject to the Australian Code for the Transport of Dangerous Goods by Road And Rail (Australian Dangerous Goods (ADG) Code).

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.

This material is listed in the Australian Inventory of Chemical Substances (AICS) and is an excluded (non-industrial) use chemical under the AICIS (Australian industrial Chemicals Introduction Scheme) targeted tier I approach. Agricultural and therapeutic uses were not assessed. It is considered to pose no unreasonable risk to human health based on Tier I assessment under the AICIS IMAF assessment framework.

Halothane as presented in this context appears in Schedule 4 of Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and is therefore available only by prescription.

#### 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, (as updated), APVMA (Australian Pesticides and Veterinary Medicines Authority), <https://apvma.gov.au/node/26586>

2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals>
3. Australian Inventory of Industrial Chemicals (as updated), AICIS (Australian industrial Chemicals Introduction Scheme), Australian Government Department of Health, <https://www.industrialchemicals.gov.au/search-inventory>
4. APVMA Registrations and Permits, <https://apvma.gov.au/node/1060>
5. ADI [Acceptable Daily Intake] List (as updated), Commonwealth Department of Health, TGA (Therapeutic Goods Administration), <https://apvma.gov.au/sites/default/files/publication/74511-acceptable-daily-intakes-adi-for-agricultural-and-veterinary-chemicals-used-in-food-producing-crops-or-animals-edition-4-2020.pdf>
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), Edition 7.7, 2020, [https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7\\_0.pdf](https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7_0.pdf)
7. SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) (as updated), Chemicals and Medicines Scheduling Secretariat (MD122), Scheduling and Committee Governance, TGA, Commonwealth Department of Health, <https://www.tga.gov.au/publication/poisons-standard-susmp>
8. Hazardous Chemical Information System (HCIS), Safework Australia (as updated), <http://hcis.safeworkaustralia.gov.au/>
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition, United Nations, New York and Geneva, 2019, <https://unece.org/ghs-rev8-2019>
10. NIOSH Pocket Guide to Chemical Hazards
11. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority, <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>

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