

Piramal Critical Care

Revision Date

01/03/11

Isoflurane, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product name: Isoflurane, USP

Synonyms: Terrell

Attane Isoflurane Escain Isofane Isofluran Isoflurano

1-CHLORO-2,2,2-TRIFLUOROETHYL DIFLUOROMETHYL ETHER

CAS Number: 26675-46-7

CHF₂OCCIHCF₃ Formula:

Chemical Family: Anesthetic, Halogenated Ether

Manufacturer: Piramal Critical Care

> 3950 Schelden Circle Bethlehem, PA 18017

24 Hour Emergency Number: CHEMTREC 1-703-527-3887

2) COMPOSITION/INFORMATION ON INGREDIENTS

Weight % Component Classification Isoflurane 100 None

3) HAZARDS IDENTIFICATION

Emergency Overview: CAUTION! Anesthetic Agent. Overexposure by inhalation to the vapors may

cause temporary nervous system depression with anesthetic effects such as dizziness, headache, confusion, incoordination, or loss of conciousness, they should be moved to an area of fresh air. Concentrations of anesthetic in the air would have to reach approximately 2-3 % before personnel would be expected to experience significant dizziness. Gross overexposure (> 20%) may possibly alter the heart's electrical activity with irregular pulse, palpitations, or inadequate

circulation.

Exposure Routes: Inhalation. Skin contact. Eye contact. Ingestion.

Inhalation: Practically non-toxic by inhalation. 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, headaches, dizziness, blurred vision.

Skin Contact: May cause skin irritation. **Eye Contact:** May cause eye irritation.

Ingestion: Practically non-toxic if swallowed. No specific hazards other than therapeutic

effects. See inhalation.

4) FIRST AID MEASURES

Inhalation: If high concentrations are inhaled, immediately remove to fresh air. If not

breathing, perform artificial respiration. Keep the affected person warm and

at rest. Get medical attention as soon as possible

Skin Contact: In case of contact, remove contaminated clothing, and wash contaminated

skin with soap and water. Seek medical attention if irritation is present.

Eye Contact: In case of contact, immediately wash (irrigate) the eyes with large amounts of

tepid potable water, occasionally lifting the lower and upper lids. Get medical

attention immediately.

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

are swallowed, get medical attention immediately.

Note to Physician: Due to the possible disturbances of cardiac rhythm, catecholamine drugs,

such as epinephrine, should be considered only as a last resort in life-

threatening emergencies.

5) FIRE FIGHTING MEASURES

Flash Point: Not determined

Specific Methods: No information available

Flammable Limits in air-lower (%):

Flammable Limits in air-upper (%):

Autoignition:

Not available
Not available

Extinguishing Media: Use extinguishing media appropriate to surrounding fire conditions

Fire Fighting Instructions: Fire fighters and others should wear NIOSH approved positive pressure self-

contained breathing apparatus (SCBA) and turnout gear.

Fire and Explosion Hazard: Use water spray to cool containers. Containers may rupture under fire

conditions.

6) ACCIDENTAL RELEASE MEASURES

In Case of Spill or Leak: Small volumes of liquid anesthetic agents may readily evaporate at room

temperatures and may dissipate before any clean up attempts are initiated. For large spills, provide adequate ventilation or evacuate area. Large quantities of anesthetic agents may cause sedative effects. Restrict personnel not donning protective equipment from areas of spills or leaks until clean up is complete. A sorbent designed for organic chemicals should be use for large spills. Spill pillows, vermiculite, and carbon-based sorbents are examples of suitable materials. Dike spill and prevent liquid from entering sewers, waterways or low areas. Sweep or scoop up and remove to a suitable container. Close container and dispose of container in accordance with

federal, state, and local regulations.

7) HANDLING AND STORAGE

Handling: Wash thoroughly after handling.

Storage: Keep container tightly sealed. Store in a dry, cool, and well ventilated place.

Store between 15 - 30°C (59 - 86°F)

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Investigate engineering techniques, process enclosures or local exhaust

ventilation to keep airborne levels below recommended exposure limits.

Eye Protection: Safety glasses, chemical splash goggles, face shield, or other full faced

protection should be available for use if potential exists for exposure to

splashes.

Skin Protection: Chemical resistant, impervious gloves should be used to avoid prolonged or

repeated exposure. Wear a work uniform or laboratory coat. Additional body

garments should be used based upon the tasks being performed.

Respiratory Protection: When working with small quantities in a well ventilated area, respiratory

protection may not be required. If exposure levels exceed regulatory limits, implement a respiratory protection program that is in compliance with OSHA 29 CFR1910.134 or equivalent in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive

pressure mode.

OSHA-Time Weighted Average:
OSHA-Short Term Exposure Limit:
None
OSHA-Ceiling Limits:
None
ACGIH-Time Weighted Average:
None
ACGIH-Short Term Exposure Limit:
None
ACGIH-Ceiling Limit Value:
None

NIOSH REL: Ceiling 2 ppm (60 minutes) recommended exposure limit for halogenated

waste anesthetic gas.

9) PHYSICAL AND CHEMICAL PROPERTIES

Physical State:LiquidAppearance:ClearColor:ColorlessOdor:Slight etherealpH:NeutralMolecular Weight:184.5 g/mole

Boiling Point: 48.5°C (119.3°F) at 760 mm Hg. **Vapor Pressure:** 330 mm Hg at 25°C (77°F)

Evaporation Rate: Not available
Water Solubility: Slightly soluble
% Volatile by Volume: 100 WT%

10) STABILITY AND REACTIVITY

Stability: Material is stable under recommended storage conditions.

Incompatibility: Peroxides **Polymerization:** Not applicable

Hazardous Decomposition Products: These products are halogenated compounds (e.g., hydrochloric and

hydroflouric acids, phosgene).

11) TOXICOLOGICAL INFORMATION

 LD_{50} 4770 mg/Kg oral-rat

 LC_{50} 16300 ppm/3H inhalation-rat LD_{50} 4280 g/Kg intraperitoneal-rat LD_{50} 5080 g/Kg oral mouse

LC₅₀ 16800 ppm/3H inhalation-mouse LD₅₀ 3030 mg/Kg intraperitoneal-mouse

Acute Toxicity: Cardiovascular effects - may include fluctuation in heart rate, change 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 - ataxia, tremor, disturbance of speech, lethargy,

headache, dizziness, blurred vision.

Chronic Toxicity: Target Organs- nervous system, heart, liver

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

related carcinogenic/tumorigenic effects based on animal data.

Mutagenic Effects: Not 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.

FDA Pregnancy Category: C

12) ECOLOGICAL INFORMATION

Ecotoxicity Effects: No data available **Bioaccumulation:** No data available

13) DISPOSAL CONSIDERATIONS

Waste Disposal: Comply with federal, state, and local regulations in the disposal of waste.

14) TRANSPORT INFORMATION

DOT: Not regulated for inner packagings not exceeding 5.0 L (1.3 gallons) net

capacity each. Regulated for inner packagings exceeding 5.0 L (1.3 gallons)

net capacity each.

DOT shipping name: Aviation regulated liquid, N.O.S., (Isoflurane)

UN number: UN3334 **Packing Group:** None **DOT hazard class:** 9

ICAO/IATA: IATA proper shipping name: Aviation regulated liquid, N.O.S., (Isoflurane)

IATA UN number: UN3334 IATA primary hazard class: 9 IATA packing group: None IATA packing instruction: 906

TDG (Canada): Not regulated IMO/IMDG: Not regulated ADR/RID: Not regulated

15) REGULATORY INFORMATION

FDA: Regulated

TSCA Inventory List: This product is excempt from TSCA.

16) OTHER INFORMATION

New MSDS format.

The information above is believed to be accurate and is intended only as a guide. Piramal Critical Care assumes no responsibility for any damages resulting from handling or contact with the above material.