

Section – 1: Product and Company Identification
Product Name: Isoflurane

Synonyms: 1-chloro-2,2,2-trifluoroethyl difluoromethyl ether;
 2-Chloro-2-(difluoromethoxy)-1, 1, 1-trifluoroethane, "ISOFOR"

CAS NO: 26675-46-7

Empirical Formulae: C₃H₂ClF₅O/ CF₃CHClOCHF₂
Molecular Weight: 184.50

Product Use: Volatile anaesthetic administered by inhalation

Company Address:
Head Office (Hyderabad)
Piramal Enterprises Limited
 5-9-30, Road No.4,
 Basheerbagh Palace Colony,
 Basheerbagh, Hyderabad-500 063.
 Andhra Pradesh, India.

Site Address:
Piramal Enterprises Limited
 Digwal Village, Kohir Mandal, Medak District,
 Andhra Pradesh – 502321, India.

 Emergency telephone: +91-8008788557
 E mail: srinivasa.chari@piramal.com
Section – 2: Hazard Identifications
GHS Classification
Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008

Skin Corrosion/Irritation - Category 3

STOT - SE - Category 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Xn Harmful, R67

Label elements
Labelling according Regulation (EC) No 1272/2008
Pictogram

Signal word:
Warning
Hazard statement(s)
H316 Causes mild skin irritation

H336 May cause drowsiness or dizziness.

Precautionary statement(s)
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P271 Use only outdoors or in a well-ventilated area.

P304+P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P332+P313 If skin irritation occurs: Get medical advice/ attention.

Classification/Specific hazards :

According to EC criteria, this product is not classified as a "hazardous substance".



Document No.: SF-FM-Isoflurane/09

Section – 3: Composition / Information on Ingredients

Name	CAS No.	Molecular Wt
Isoflurane (ISOFOR)	26675-46-7	184.5

Section – 4: First Aid Measures

Inhalation: Fresh air, rest. Artificial respiration may be needed. Refer for medical attention
Skin: Remove contaminated clothes. Rinse and then wash skin with water and soap
Eyes: First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.

Section – 5: Fire Fighting Measures

FIRE AND EXPLOSION HAZARDS: Very negligible fire hazard.
EXTINGUISHING MEDIA: carbon dioxide, regular dry chemical
 Large fires: Use regular foam or flood with fine water spray.
FIRE FIGHTING: Do not get water inside container. Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out. Stay away from the ends of tanks. Keep unnecessary people away, isolate hazard area and deny entry. Use extinguishing agents appropriate for surrounding fire. Flood with fine water spray. Cool containers with water spray until well after the fire is out. Apply water from a protected location or from a safe distance. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas. Consider downwind evacuation if material is leaking.
FLASH POINT: Will not burn

Section – 6: Accidental Release Measures

Collect leaking and spilled liquid in sealable containers as far as possible. Ventilation. Absorb remaining liquid in sand or inert absorbent and remove to safe place. (Extra personal protection: self-contained breathing apparatus.)
OCCUPATIONAL RELEASE:
 Stop leak if possible without personal risk. Reduce vapors with water spray. Do not get water directly on material. Do not get water inside container. Keep unnecessary people away, isolate hazard area and deny entry.
 Small spills: Flood with water. Large spills: Dike for later disposal. Stay upwind and keep out of low areas. Ventilate closed spaces before entering. Evacuation radius: 150 feet

Section – 7: Handling and Storage

Handling (ventilation and fire prevention) ;
 Avoid contact with eyes, skin, and clothing. Avoid generating or breathing product aerosol. Wash after handling.
Storage (conditions and limitations) ;
 Store tightly closed in original container. Keep containers in a well ventilated, secure location.

Section – 8: Exposure Controls / Personal Protection

Personal Protection:
Inhalation: Ventilation, local exhaust, or breathing protection
Skin: Protective gloves- rubber.
Eyes: Safety spectacles, or eye protection in combination with breathing protection
Ingestion: Do not eat, drink, or smoke during work.

ISOFLURANE

Document No.: SF-FM-Isoflurane/09

For Unknown Concentrations or Immediately Dangerous to Life or Health -Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full face piece

Exposure Control:**EXPOSURE LIMITS:**

TLV not established. See Regulatory information.

INHALATION RISK:

A harmful contamination of the air can be reached very quickly on evaporation of this substance at 20°C.

Section – 9: Physical and Chemical Properties**PHYSICAL STATE:** Liquid**APPEARANCE:** clear**COLOR:** colorless**ODOR:** sweet odor**MOLECULAR WEIGHT:** 184.50**BOILING POINT:** 120 F (49 C)**FREEZING POINT:** Not available**VAPOR PRESSURE:** 330 mmHg @ 25 C

Relative density of the vapour/air-mixture at 20°C (air = 1):1.2

SPECIFIC GRAVITY (water=1): 1.496 @ 25 C**WATER SOLUBILITY:** insoluble**PH:** Not available**VOLATILITY:** Not available**ODOR THRESHOLD:** Not available**EVAPORATION RATE:** Not available

Octanol/water partition coefficient as log Pow: 2.1

SOLVENT SOLUBILITY:

Soluble: oils, fats, organic solvents

Section – 10: Stability and Reactivity**PHYSICAL DANGERS:**

The vapour is heavier than air and may accumulate in lowered spaces causing a deficiency of oxygen.

CHEMICAL DANGERS:

On contact with hot surfaces or flames this substance decomposes forming corrosive fumes such as phosgene hydrogen chloride and hydrogen fluoride.

REACTIVITY: Stable at normal temperatures and pressure.**CONDITIONS TO AVOID:** Minimize contact with material. Avoid inhalation of material or combustion by-products. Containers may rupture or explode if exposed to heat.**INCOMPATIBILITIES:** No data available.**HAZARDOUS DECOMPOSITION:**

Thermal decomposition products: halogenated compounds, oxides of carbon

POLYMERIZATION: Will not polymerize**Section – 11: Toxicological Information****ROUTES OF EXPOSURE:**

The substance can be absorbed into the body by inhalation of its vapour and by ingestion.

TOXICITY DATA:

ISOFLURANE

Document No.: SF-FM-Isoflurane/09

Test	Result	Route	Species
LD50	4470 mg/kg	Oral	Rat
LD50	5080 mg/kg	Oral	Mouse
LC50	16300ppm/3Hrs	Inhalation	Rat
LC50	16800ppm/3Hrs	Inhalation	Mouse
LD50	No established data is available	Dermal	--

HALOGENATED ANESTHETIC AGENTS:

2 ppm (15.1 mg/m³) NIOSH recommended ceiling 60 minute(s)

CARCINOGEN STATUS: IARC: Human Inadequate Evidence, Animal Inadequate Evidence, Group 3

ACUTE TOXICITY LEVEL:

Moderately Toxic: ingestion

TARGET ORGANS: central nervous system

MUTAGENIC DATA: Available.

REPRODUCTIVE EFFECTS DATA: Available.

ADDITIONAL DATA: Interactions with drugs may occur

Section – 12: Ecological Information

Not available

Section – 13: Disposal Considerations

Collect leaking and spilled liquid in sealable containers as far as possible. Ventilation. Absorb remaining liquid in sand or inert absorbent and remove to safe place. (Extra personal protection: self-contained breathing apparatus.)

Section – 14: Transport Information



Labels Required: MISCELLANEOUS

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)
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	964
TDG (Canada)	Not regulated



Document No.: SF-FM-Isoflurane/09

IMO/IMDG	Not regulated
ADR/RID	Not regulated


Section – 15: Regulatory Information

OCCUPATIONAL EXPOSURE LIMITS:

TLV not established

Check oxygen content before entering area. High concentrations in the air cause a deficiency of oxygen with the risk of unconsciousness or death. Forane is a trade name. MAK value not established but full documentation is available (MAK IIb).

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated

(R) Risk Phrases	R-36- Irritation to eyes	 [X] Irritant.
(S) Safety Phrases	S36-Wear suitable protective clothing.	

U.S. REGULATIONS:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product complies with EINECS

Section – 16: Other Information

The (M) SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

(M)SDS prepared date: 04/03/2014

(M)SDS review date: 03/03/2016

Revision of Change:

1. Company and LOGO name change
2. Packing Instruction changed from 906 to 964 as per abstract of IATA DG Regulations for UN3334
3. Updating of legal classification from Annex 1 of Regulation (EC) 1272/2008

Disclaimer: The information above is believed to be accurate and represents the best information currently available to us. Users should make their own investigations to determine the suitability of the information for their particular purposes. This document is intended as a guide to the appropriate precautionary handling of the material by a properly trained person using this product.

Prepared By: 
04/03/14
Manager - EHS