

This safety data sheet complies with the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date: 12/16/2010

Revision Date: 06/23/2016

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

SDS Number: 1087151
Product Name: Isoflurane, USP
Product Code(s): 4DG9621, 4DG9623, ADG9623, AADG9621, AADG9623, ALDG9621, ALDG9623, AVISO, CANONEISOFLU, DDG9621, DDG9623, FGV15KSBUEK, FDG9623, FDG9623J, FDG9623SE, FDG9621, FDG9621ME, FDG9621PU, FDG9621SE, HDG9621A, HDG9621APU, HDG9623, HDG9623A, HDG9623APU, KDG9621, KDG9623, KDG9623PU, LDG9621, LDG9621PU, LDG9623, MDG9623, MDG9621, PDG9623, PDG9623PU, TEC5, TEC51SO, VAPORISO, V15KCBUEK, V15KDBUEK, V15KNBUEK, V15KSBUEK, WDG9623, ZDG9623, ZDG9623V, ZDG9623VS, 091055540, 091055541, 280043, 280044, 201182, 201194, 5DG9621, 5DG9623, 422593, 422705, 8DG9621, 8DG9623, 6DG9621, 6DG9623, 7DG9621, 7DG9623, 641500, FDG9621IRI, FDG9623IRI, FDG9621P, FDG9623P, 99U102282, FDG9621NA, FDG9623NA, 880901133, 880901377, 880901378, 881901630, 881901771, 9DG9621, 11059104000, ADG9621, WDG9621, FDG9621J, V15KNBIHK, V15KSBIHK, V15PCBIHZ, V15PDBIHZ, V15PNBIHZ, V15PSBIHZ, V15KCBIIHK, V15KDBIIHK, V15KNBIHK, V15KDBIIHK, M36110, 3159900025, BE3001392, BZDG9621, 2L040401FR01001, CADG9623, BE3001441, 2L040101FR0001, BE3001497, 2L040101FI000, 11003025000, 11009029000, M35054, FDG9621IRQ, FDG9621ILBY, FDG9621IRN

Synonyms: Forane
Isoflurane
Aerrane
1-chloro-2,2,2-trifluoroethyl difluoromethyl ether
Isorrane
Isovet

1.2. Relevant identified uses of the substance or mixture and uses advised against

Product Use: Anesthetic.
Product Type: Regulated Prescription Drug
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
0044 1635 206345

E-mail address

medinfo_emea@baxter.com

1.4. Emergency telephone number

Carechem24 International
+44 (0) 1235 239 670

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive Toxicity	Category 2 - (H361)

Specific target organ toxicity (repeated exposure)	Category 2 - (H373)
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2.2. Label elements

Product Identifier
Contains Isoflurane



Signal Word
Warning

Hazard Statements

H319 - Causes serious eye irritation
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Component	EU EINECS List	CAS-No	Weight-%	EU - GHS Substance Classification	REACH Reg. No
Isoflurane 26675-46-7	247-897-7	26675-46-7	100	Repr. 2 (H361) Eye Irrit. 2 (H319) STOT RE 2 (H373)	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice	Treat symptomatically and supportively.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops.
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 of this material are swallowed, call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

A dose less than that needed to produce anesthesia (approximately 1%) may result in symptoms such as dizziness. See patient package insert in shipping carton for complete information.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

Section 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Use foam or all purpose dry chemicals to extinguish.

Extinguishing media which must not be used for safety reasons

No information available

5.2. Special hazards arising from the substance or mixture

No information available

5.3. Advice for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Depending on local ventilation, clean-up crews may need to wear a chemical cartridge respirator, with a cartridge for organic vapors. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

6.2. Environmental precautions

No information available.

6.3. Methods and material for containment and cleaning up

Methods for Containment:

Small volumes of liquid anesthetic agents may evaporate readily at normal room temperatures, and may dissipate before any clean up attempts are initiated. For large spills, one or more bottles break, ensure adequate ventilation or evacuate area. Large volumes of anesthetic agents may cause sedative effects.

Methods for cleaning up

Restrict persons not wearing protective equipment from areas of spills or leaks until clean up is complete. Large spills should be absorbed using a sorbent that is designed for clean up of organic chemicals. Spill pillows, vermiculite, and carbon-based sorbents are some suitable materials. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

See Section 12 for more information

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Technical measures/precautions: Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions Keep containers tightly closed in a cool, well-ventilated place. Store between 15-30°C (59 to 86°F).

Incompatible materials

No special restrictions on storage with other products.

7.3. Specific end use(s)

Other Guidelines

None.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits:

Component	European Union	Uk oes/mel:	France	Spain	Germany
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Isoflurane 26675-46-7	None	None	None	50 ppm TWA 383 mg/m ³ TWA	None
Component	Italy	Portugal	Netherlands	Finland	Denmark
Isoflurane 26675-46-7	None	None	None	10 ppm TWA 77 mg/m ³ TWA 20 ppm STEL 150 mg/m ³ STEL	5 ppm TWA 38 mg/m ³ TWA
Component	Austria	Switzerland	Poland	Norway	Ireland
Isoflurane 26675-46-7	10 ppm TWA 80 mg/m ³ TWA 20 ppm STEL 160 mg/m ³ STEL	None	32 mg/m ³ TWA	2 ppm TWA 15 mg/m ³ TWA 2 ppm STEL 15 mg/m ³ STEL	150 ppm STEL 1140 mg/m ³ STEL 50 ppm TWA 380 mg/m ³ TWA
Component	Sweden				
Isoflurane 26675-46-7	10 ppm TLV 80 mg/m ³ TLV 20 ppm STV; 150 mg/m ³ STV				

8.2. Exposure controls

Engineering Measures

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. Well designed and maintained scavenging system on the anesthesia equipment (combined with a good general room ventilation) is important in limiting the exposures of all personnel.

Personal protective equipment

Eye protection

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Respiratory protection

Personal respiratory protection equipment not typically required if engineering controls are in place. If exposure levels may exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions.

Hand protection

Use chemical resistant, impervious gloves.

Skin and body protection

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Environmental exposure controls

Do not allow material to contaminate ground water system.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Clear, Colorless.
Odor:	Pungent. Ethereal. Musty.
Odor Threshold:	No information available
pH:	Not applicable.
Melting point / melting range:	Not available
Boiling point / boiling range:	48.5°C (119.3°F)
Flash point:	No information available
Flammability (solid, gas):	No information available
Evaporation rate:	Not available
Flammable limits in air-upper (%):	No information available
Flammable limits in air-lower (%):	No information available
Vapor pressure:	238 mmHg at 20°C (68°F)
Vapor Density:	No information available
Density:	1.496 g/cm ³ at 25°C (72°F)
Solubility:	Slightly soluble in water.
Partition coefficient (n-octanol/water):	Not available

Autoignition temperature: No information available
Decomposition Temperature: No information available
Viscosity: Not available
Explosive Properties: No information available
Oxidizing Properties: No information available

9.2. Other information

Molecular weight: 184.5 g/mole

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

Polymerization Not applicable
Hazardous Reactions None under normal processing

10.4. Conditions to avoid

Do not freeze.

10.5. Incompatible materials

Peroxides.

10.6. Hazardous decomposition products

These products are halogenated compounds (hydrochloric and hydrofluoric acids). Phosgene.

Section 11: TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Isoflurane 26675-46-7	15300 ppm 3 h (Rat) 58.5 g/m ³ 4 h (Rat)	-	= 4770 µL/kg (Rat)

11.1. Information on toxicological effects

Acute Toxicity

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, headache, dizziness, blurred vision).

Eye contact: May cause eye irritation.

Skin contact: May cause skin irritation.

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

Unknown Acute Toxicity

Unknown Acute Toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.

Acute Oral Toxicity 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
Acute dermal toxicity 100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
Acute inhalation toxicity - gas 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
Acute inhalation toxicity - Vapor 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
Acute inhalation toxicity - dust/mist 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 4,755.69 mg/kg

Irritation: Irritating to eyes. Mild skin irritation.
Corrosivity: Not classified
Sensitization: Not classified.
Mutagenic effects: Not classified
Carcinogenic effects: No drug related carcinogenic/tumorigenic effects based on animal data.

Component	ACGIH	IARC	NTP	OSHA	EU Annex I Carcinogen Information	UK
Isoflurane 26675-46-7	-	Group 3	-	-	-	-

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.
STOT - single exposure: Not classified.
STOT - repeated exposure: Liver.
Aspiration Hazard: Not classified

Section 12: ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Isoflurane 26675-46-7	None.	None.	None.	None.

12.1. Toxicity

No information available

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available

12.4. Mobility in soil

No information available

12.5. Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

Section 14: TRANSPORT INFORMATION

IMDG/IMO

14.1 UN-No:	Not regulated.
14.2 Proper Shipping Name	Not regulated.
14.3 Hazard Class	Not regulated.
14.4 Packing Group	Not regulated.
14.5 Marine Pollutant	Not applicable
14.6 Special Provisions	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1 UN-No	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

ADR Road Transport

14.1 UN-No	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing Group:	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

IATA UN Numbers:

14.1 UN-No	UN3334
14.2 Proper Shipping Name	Aviation regulated liquid n.o.s. (Isoflurane)
14.3 Hazard Class	9
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

Section 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****International Inventories**

EU EINECS List This product complies with EINECS

Legend

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

15.2. Chemical safety assessment

No

Section 16: OTHER INFORMATION**Full text of H-Statements referred to under section 3**

H361 - Suspected of damaging fertility or the unborn child if inhaled

H319 - Causes serious eye irritation

H373 - May cause damage to organs through prolonged or repeated exposure if inhaled

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Additional information:

Not Available.

Key literature references and sources for data

www.ChemADVISOR.com/

Prepared by Baxter Research & Development

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This data sheet contains changes from the previous version in section(s):

New GHS format. Changes to Section 1. Changes to Section 9.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet