

SAFETY DATA SHEET

305788 VETFLURANE 250ML AT-BE-DE-NL VBI



According to EC-Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

SAFETY DATA SHEET

Ref: SDS-38765

Version: 2

Date of Issue: 10/08/2017

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

1.1 Product Identifier

Product Name: Isoflurane

Synonym(s): Forane; Forene; Isoflurane liquid; Isoflurane USP; 1-Chloro-2,2,2-trifluoroethylidifluoromethyl ether

Product Code: 38765V / 38765D

CAS No: 26675-46-7

EINECS No: 247-897-7

REACH Registration No: A registration number is not available for this substance as the substance or its uses are exempted from registration

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Identified Use(s): General inhalation anaesthetic

Uses Advised Against: Not determined

1.3 Details of the Supplier of the Safety Data Sheet1.3.1 Manufacturer:

Company Identification: Aesica Queenborough Limited
North Road
Queenborough
Kent
ME11 5EL
UK

Telephone: +44 (0) 1795 543000

E-Mail (competent person): SDS.EnquiriesQB@aesica-pharma.com

1.4 Emergency Telephone Number

Telephone: +44 (0) 1795 543000
(24 hours, English spoken)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

2.1.1 Regulation (EC) No 1272/2008

General Note

Specific Target Organ Systemic Toxicity (single exposure) STOT SE 3, H336

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SECTION 2: HAZARDS IDENTIFICATION

2.2 Label Elements

2.2.1 Product Name: Isoflurane

Hazard Pictogram(s):



Signal Word(s): Warning

Hazard Statement(s): H336: May cause drowsiness or dizziness.

Precautionary Statement(s):
 P261: Avoid breathing dust/fume/gas/vapours/spray.
 P271: Use only outdoors or in a well-ventilated area.
 P304+P350: If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing.
 P312: Call a POISON CENTRE or doctor/physician if you feel unwell.
 P403+P233: Store in a well-ventilated place. Keep container tightly closed.

Supplemental Information:

2.3 Other Hazards Not determined

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

EC Classification No. 1272/2008

Substance	CAS No.	EC No.	EU/GHS Substance Classification	REACH Registration No.	% W/W
Isoflurane	26675-46-7	247-897-7	STOT SE 3, H336	N/A	98-100

3.2 Mixtures (substances in preparations/mixtures)

Not applicable

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SECTION 4: FIRST AID MEASURES



4.1	<u>Description of First Aid Measures</u>	
	Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
	Skin Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
	Eye Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
	Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
	Self-Protection of the First Aider:	Not determined
4.2	<u>Most Important Symptoms and Effects, Both Acute and Delayed</u>	For information on potential signs and symptoms of exposure:- see Section 2 – Hazards Identification and/or Section 11 – Toxicological Information
4.3	<u>Indication of Any Immediate Medical Attention and Special Treatment Needed</u>	Maintain ventilation, electrolyte balance and monitor cardiovascular function, as necessary.
	Notes to Physician:	Not determined

SECTION 5: FIRE-FIGHTING MEASURES

5.1	<u>Extinguishing Media</u>	
	Suitable Extinguishing Media:	Use extinguishing agent suitable for type of surrounding fire.
	Unsuitable Extinguishing Media:	Not determined
5.2	<u>Special Hazards Arising from the Substance or Mixture</u>	Not determined
5.3	<u>Advice for Fire Fighters</u>	Wear self-contained breathing apparatus pressure-demand, MSHA/ NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	<u>Personal Precautions, Protective Equipment and Emergency Procedures</u>	For personal protection – see Section 8
6.2	<u>Environmental Precautions</u>	Contain material and prevent release to waterways or soil.
6.3	<u>Methods and Material for Containment and Cleaning Up</u>	Material evaporates very rapidly. Evacuate the area of the spill immediately and provide ventilation until the applicable exposure levels are below those described in Section 8.
6.4	<u>Reference to Other Sections</u>	Refer to Sections 8, 12 and 13 for further information.

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SECTION 7: HANDLING AND STORAGE

- 7.1 **Precautions for Safe Handling** Avoid contact with skin, eyes and clothing. Avoid breathing vapours or mists. Handle in accordance with good industrial hygiene and safety practice.
- 7.2 **Conditions for Safe Storage, Including any Incompatibilities**
- Storage Temperature:** Store according to label instructions
- Storage Life:** Store according to label instructions
- Incompatible Materials:** Store according to label instructions
- 7.3 **Specific End Use(s)** General inhalation anaesthetic

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control Parameters
8.1.1 Occupational Exposure Limits:

Substance	Cas No.	LTEL (8hr TWA ppm)	LTEL (8hr TWA mg/m ³)	STEL (ppm)	OHC (mcg/m ³)	STEL (mcg/m ³)	Note:
Isflurane	26675-46-7	50	383	150	N/A	1149	

Source: Occupational Health Categorisation / UK EH40/2005 Workplace Exposure Limits

8.1.2 Biological Limit Value: Not determined

8.1.3 PNECs and DNELs: Not determined

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls: Anaesthetic gas scavenging systems should be used during typical product application. Handle inside a process enclosure or chemical fume hood during manufacturing or laboratory use.

8.2.2 Individual protection measures, such as personal protective equipment (PPE):

Eye/Face Protection



Eye protection not required during typical product use conditions. Wear eye protection appropriate to exposures during manufacturing/laboratory use.

Skin Protection


 Impervious gloves.
Wear appropriate body coverings if contact may occur.

Respiratory Protection



If engineering controls are in place, respirators are generally not required during normal conditions of use.

Thermal Hazards

Not determined

8.2.3 Environmental Exposure Controls:

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Warning – substance not yet tested completely

9.1	<u>Information on Basic Physical and Chemical Properties</u>	
	Appearance	Clear, colourless liquid
	Odour	Mild, pungent, musty, ethereal odour
	Odour Threshold	Not determined
	pH	Not determined
	Melting Point/Freezing Point	Not determined
	Initial Boiling Point	48.5 (@ 760mm Hg)
	Flash Point (°C)	Not determined
	Evaporation Rate	Not determined
	Flammability (solid, gas)	Not expected to be flammable in air
	Lower Explosive Limits	14.5 (in 100% oxygen)
	Vapour Pressure	295-330 mmHg @ 25°C
	Vapour Density	6.3 (Air=1)
	Bulk Density	1.45 @ 20°C
	Specific Gravity	1.496 @ 25°C
	Solubility (ies)	Slightly soluble in water / Soluble in organic solvents
	Partition Coefficient (n-Octanol/water)	Not determined
	Auto Ignition Temperature	Not determined
	Decomposition Temperature	Not determined
	Viscosity	Not determined
	Explosive Properties	Not determined
	Oxidising Properties	Not determined
9.2	<u>Other Information</u>	
	Molecular Weight	Not determined
	Min Ignition Energy-Cloud (mJ)	>5000 (no ignition)

SECTION 10: STABILITY AND REACTIVITY

10.1	<u>Reactivity</u>	Not determined
10.2	<u>Chemical Stability</u>	Stable under normal conditions
10.3	<u>Possibility of Hazardous Reactions</u>	Not determined
10.4	<u>Conditions to Avoid</u>	Not determined
10.5	<u>Incompatible Materials</u>	Strong bases, Alkaline metals
10.6	<u>Hazardous Decomposition Product(s)</u>	When heated to decomposition it emits; Hydrogen Fluoride, Hydrogen Chloride, Carbon Oxides

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects (substances in preparations/mixtures)**Acute Toxicity:**

Ingestion	Not determined
Inhalation	Clinical route
Skin Contact	Not determined
Eye Contact	Not determined

Acute Toxicity – Oral: Data for component (s) given below

Chemical Name	Acute Test	Value	Units	Species
Isoflurane 26675-46-7	LD50 =	4770	mg/Kg	Mice
		5080		Rats

Acute Toxicity – Inhalation: Data for component(s) given below

Chemical Name	Test	Value	Units	Species
Isoflurane 26675-46-7	LC50 =	15,300	ppm	Rats
		16,800		Mice

Skin Corrosion/Irritation: Not determined

Serious Eye Damage/Irritation: A similar eye material is an eye irritant

Respiratory or Skin Sensitisation: Not determined

Inhalation Not determined

Skin Contact Not determined

Germ Cell Mutagenicity: Not determined

Carcinogenicity: Not determined

Target Organ Effects: In clinical use target organ effects include: central nervous system

Reproductive Toxicity:

Effects on Fertility Not determined

Developmental Toxicity Not determined

Mutagenicity Data for Component(s) Given Below:

Chemical Name	Micronucleus Assay	Ames Test	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Isoflurane 26675-46-7	No data	Negative	No data	Negative

Aspiration Hazard: Not determined

11.2 Other Information Not determined

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SECTION 12: ECOLOGICAL INFORMATION		
12.1	<u>Toxicity</u>	Not determined
12.2	<u>Persistence and Degradability</u> Photolysis Hydrolysis Biodegradability	Not determined
12.3	<u>Bioaccumulative Potential</u>	Not determined
12.4	<u>Mobility in Soil</u>	Not determined
12.5	<u>Results of PBT and vPvB Assessment</u>	Chemical safety report is not required for this substance/ product
12.6	<u>Other Adverse Effects</u>	Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.
SECTION 13: DISPOSAL CONSIDERATIONS		
13.1	<u>Waste Treatment Methods</u>	Disposal should be made in accordance with country, federal, state and local regulations.
13.2	<u>Additional Information</u>	Not determined
SECTION 14: TRANSPORT INFORMATION		
<u>ICAO/IATA</u>		
Status:		Regulated
14.1	<u>UN Number</u>	UN3334
14.2	<u>UN Proper Shipping Name</u>	Aviation regulated liquid, n.o.s. (1-Chloro-1-difluoromethoxy)-2,2,2-trifluoroethane)
14.3	<u>Transport Hazard Class(es)</u>	9
14.4	<u>Packing Group</u>	III
14.5	<u>Environmental Hazards</u>	Not applicable
14.6	<u>Special Precautions for User</u>	A27
14.7	<u>Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code</u>	Not applicable
<u>ADR, DOT, IMDG/IMO</u>		
Status:		Not regulated
14.1	<u>UN Number</u>	Not applicable
14.2	<u>Proper Shipping Name</u>	Not applicable
14.3	<u>Hazard Class(es)</u>	Not applicable
14.4	<u>Packing Group</u>	Not applicable
14.5	<u>Environmental Hazards</u>	Not applicable
14.6	<u>Special Provisions</u>	Not applicable

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SECTION 15: REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

International Inventories:

Chemical Name	EINECS/ELINCS	TSCA	DSL	NDSL	PICCS
Isoflurane 26675-46-7	247-897-7	-	-	Not listed	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Isoflurane 26675-46-7	-	-	-	-	-	HSR003785

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Isoflurane	98-100	Not listed	Not listed	Not listed

SARA 313 Information:

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Isoflurane	98-100	Not listed	Not listed	Not listed

15.2 Chemical Safety Assessment

Chemical safety assessment has not been conducted on the substance/product

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

New format has been issued, all sections updated to include new format. Review SDS with care.

References: Existing Safety Data Sheet(s) for component parts (SDS). This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) and 2015/830

LEGEND:

LTEL Long Term Exposure Limit

STEL Short Term Exposure Limit

Training Advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

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Annex to the Extended Safety Data Sheet (eSDS)

No information available