Material Safety Data Sheet

ISOFLURANE

Section 1. Chemical Identification

**Product Name:** Isoflurane

**Chemical Family:** Halocarbon Anaesthetic

**Common Used Brand Names:** Forane, Aerrane

**Product Use:** Anaesthetic

**Company:**
Teva UK Limited
Ridings Point
Whistler Drive
Castleford
WF10 5HX

**Contains the following ingredients:**

1-chloro-2,2,2-trifluoroethyl difluoromethyl ether

**Emergency Telephone Number:**
01977 628 500 (9am-5pm)
0207 540 7000 (Out of hours)

**How Supplied:**
Liquid in 250ml glass bottles

Section 2. Composition & Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>RTECS No.</th>
<th>Concentration %</th>
<th>Empirical Formula</th>
<th>Molecular Weight</th>
<th>Symbol &amp; Risk-Phrases</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-chloro-2,2,2-trifluoroethyl difluoromethyl ether</td>
<td>26675-46-7</td>
<td>247-897-7</td>
<td>-</td>
<td>100%</td>
<td>C₃H₂ClF₅O</td>
<td>184.5</td>
<td>R36 R37 R38</td>
<td>50ppm 8-hr TWA (EH40/2005)</td>
</tr>
</tbody>
</table>

Section 3. Hazards Identification

**EMERGENCY OVERVIEW:**
CAUTION! Anaesthetic Agent..

**Inhalation:** Inhalation of isoflurane at a concentration of 0.5-3.0% can induce general anaesthesia in 7 to 10 minutes, with analgesia, muscle relaxation, and loss of consciousness. Isoflurane is mildly pungent and may cause coughing, laryngospasm and breath holding in an unconscious individual; secretions may be slightly stimulated and pharyngeal and laryngeal reflexes may be obtunded. Isoflurane is a severe respiratory depressant, causing a decreased tidal volume that may produce hypercapnia. Blood pressure is depressed with an initial decrease in systemic vascular resistance, heart rate and cardiac output, although rate and output may increase due to compensatory mechanisms. Arrhythmias can occur, and the myocardium may be slightly sensitized to epinephrine. Renal blood flow, glomerular filtration and urine flow are decreased without residual renal depression or renal injury following isoflurane anaesthesia. Isoflurane does not appear to produce liver injury when given for prolonged periods. Inhalation of higher concentrations may lead to death by medullary paralysis. Those recovering from exposure may exhibit shivering, nausea, vomiting, ileus, or excitement, and there may be a transient white blood count increase. A slight decrease in intellectual function may persist for 2-3 days, with small mood changes or symptoms possible for 6 days. Induction of general anaesthesia may cause malignant hyperthermia from hypermetabolism of skeletal muscles in susceptible individuals.

**Contact with Skin or Eyes:** May cause irritation.

**Ingestion:** No specific hazards other than therapeutic effects. See inhalation.

**Potential Health Hazards Acute and Chronic:**
Material Safety Data Sheet

ISOFLURANE

Section 4. First Aid Measures

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

**Skin:** In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops.

**Eyes:** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. 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.

Section 5. Fire Fighting Measures

**Extinguishing Media:**
Use foam or all purpose dry chemicals to extinguish.

**Unusual Fire and Explosion Hazard:**
Toxic vapours are released. Highly volatile liquid. On heating there is a risk of bursting due to internal pressure build up.

Section 6. Accidental Release Measures

**Spill & Leak Procedures**

**Small releases:** Evacuate personnel from immediate area. Allow spilled liquid to evaporate. Ensure adequate ventilation. Once liquid has evaporated and area clear of fumes wash affected area with water. Remove any broken packaging and dispose as hazardous waste.

**Large releases:** Evacuate personnel from immediate area. Ventilate area. Wearing appropriate PPE contain spill and absorb onto suitable inert absorbent material. Do not allow liquid to enter drains. Collect absorbent and place in plastic bags. Treat as hazardous waste. Contaminated area should be washed thoroughly with water. Collect broken contaminated packaging and treat as hazardous waste.

**Waste:** Unwanted product, contaminated packaging and spill clean-up materials should be treated as hazardous waste. Waste must be removed by a licensed waste contractor and destroyed preferably by incineration

Section 7. Handling & Storage

**GENERAL PRECAUTIONS**
Avoid breathing vapour. Store and use in well ventilated areas.
Handling Precautions:
Wash thoroughly after handling.

Storage Conditions:
Keep container tightly closed. Keep in a dry, cool well ventilated place. Store between 15-30C.

Section 8. Exposure Controls – Personal Protection

Respiratory Protection
Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits implement a respiratory protection programme including respiratory protection that is in accordance with local regulations.

Hand Protection:
Use chemical resistant, impervious gloves.

Eye Protection:
Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

Skin Protection:
Wear 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 Control & Work Hygienic Practices:
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 anaesthesia equipment (combined with good general room ventilation) is important in limiting the exposures of all personnel.

Section 9. Physical & Chemical Properties

Drug Product Appearance, Physical State and Colour:
Clear colourless mobile liquid with characteristic ethereal odour.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>48.5°C</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Insoluble in cold water</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Oxidising Properties</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative Vapour Density</td>
<td>&gt;1 (Air = 1)</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>330mm Hg (@20°C)</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.50 (water = 1)</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Section 10. Stability & Reactivity

Stability:
The product is stable under recommended storage conditions

Conditions to avoid:
Section 11. Toxicological Information

**Acute toxicity**: 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).

**Corrosivity/irritation** (eye, skin, respiratory tract): Non corrosive. May cause eye and skin irritation.

**Sensitisation** (skin, respiratory): No data available

**Mutagenicity**: No data available

**Carcinogenicity**: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data.

**Reproductive toxicity** (fertility, developmental): No impairment to fertility based on animal data. May be fetotoxic at high doses based on animal data. Epideiological studies suggest higher than normal incidences of problem pregnancies (particularly spontaneous abortions) among exposed personnel.

Section 12. Ecological Information

**All work practices must be aimed at eliminating environmental contamination.**

**Ecotoxicity**: No data available

Section 13. Disposal Considerations

**Methods of Disposal**: All contaminated waste (including and spill cleanup materials) must be disposed of by a licensed waste contractor preferably by incineration.

Section 14. Transport Information

**Transport information according to EU Guidelines**

**UN Number**: UN3334

**Hazard Class**: 9

**Proper Shipping Name**: Aviation regulated liquid n.o.s. (Isoflurane)

**Packing Group**: 

Do not store above 30C

**Materials to avoid**: Peroxides

**Hazardous Decomposition Products**: Hydrofluoric and hydrochloric acids, phosgene

**Hazardous Polymerisation**: Will not occur
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**ISOFLURANE**

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<tr>
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<tbody>
<tr>
<td><strong>Marine Pollutant:</strong></td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td><strong>Other applicable information:</strong></td>
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<tr>
<td>None</td>
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</table>

#### Section 15. Regulatory Information

Labelling Directive (1999/45/EC) and REACH (EC1907/2006) do not apply to medicinal products for human use

<table>
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<tr>
<th>Hazard Symbols:</th>
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<tbody>
<tr>
<td><strong>Classification</strong></td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td><strong>Risk Phrases:</strong></td>
</tr>
<tr>
<td>R36  - Irritating to eyes.</td>
</tr>
<tr>
<td>R37  - Irritating to respiratory system.</td>
</tr>
<tr>
<td>R38  - Irritating to skin.</td>
</tr>
<tr>
<td><strong>Safety Phrases:</strong></td>
</tr>
<tr>
<td>None</td>
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#### Section 16. Other Information

This MSDS conforms to: 91/155/EEC; 93/112/EC; 2001/58/EC and EC1907/2006.

<table>
<thead>
<tr>
<th>MSDS Creation Date: August 2009</th>
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### Disclaimer

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