

SAFETY DATA SHEETS

This SDS packet was issued with item:

078946668

N/A

SAFETY DATA SHEET

Isoflurane, USP

1. IDENTIFICATION

Product Identifier:	Isoflurane, USP
Synonyms:	I-chloro-2,2,2-trifluoroethyl difluoromethyl ether
National Drug Code (NDC):	59399-106-01
Recommended Use:	Veterinary Product. Isoflurane, USP is used for induction and maintenance of general anesthesia in horses and dogs.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Acute Toxicity, Oral	Category 5
	Acute Toxicity, Dermal	Category 5
	Serious Eye Damage/Eye Irritation	Category 2B
	Specific Target Organ Toxicity – Single Exposure (Narcotic Effects)	Category 3
	Specific Target Organ Toxicity – Repeated Exposure (Inhalation)	Category 2



Symbol(s):

Signal Word:

Warning.

Hazard Statement(s):

- H303 May be harmful if swallowed.
- H313 May be harmful if in contact with skin.
- H320 Causes eye irritation.
- H336 May cause drowsiness or dizziness.

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Precautionary Statement(s):

- H373 May cause damage to organs (Cardio-vascular system, Central nervous system) through prolonged or repeated exposure if inhaled.
- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P264 Wash hands and other exposed areas thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
+ Wear protective gloves/protective clothing/eye protection/face protection.
- P280
- P301 IF SWALLOWED: Immediately call a POISON CENTER or doctor / physician.
+
P310
- P302 IF ON SKIN: Wash with plenty of soap and water.
+
P352
- P332 If skin irritation occurs: Get medical advice/attention.
+
P313
- P304 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
+
P340
- P312 Call a POISON CENTRE/doctor/physician if you feel unwell.
- P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
+
P351
+
P338
- P337 If eye irritation persists: Get medical advice/attention.
+
P313
- P314 Get medical advice/attention if you feel unwell.
- P362 Take off contaminated clothing and wash before Reuse.
+
P364
- P403 Store in a well-ventilated place. Keep container tightly closed.
+
P404
- P405 Store locked up.

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified:
Supplementary Information:

Not classifiable.
None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Isoflurane	1-chloro-2,2,2-trifluoroethyl difluoromethyl ether	26675-46-7	C ₃ H ₂ ClF ₅ O	184.5	100%

4. FIRST AID MEASURES

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

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Signs and Symptoms:

Cardiovascular effects may include fluctuations in heart rate, changes in blood pressure, chest pain. Respiratory effects may include shortness of breath, bronchospasms, laryngospasms, and 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.

Medical Conditions Aggravated by Exposure:

Individuals who have shown hypersensitivity to this material and individuals with heart conditions and impaired kidney and/or liver functions may be more susceptible to toxicity in cases of over exposure.

Notes to Physician:

Treat supportively and symptomatically. Due to possible disturbances of cardiac rhythm, catecholamine drugs, such as epinephrine, should be considered only as a last resort in life-threatening emergencies.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or water spray.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products:

Combustion may produce hydrogen fluoride, other fluorinated products, oxides of carbon, and other irritating or toxic gases. May include oxides of chlorine and hydrogen chloride.

Other Specific Hazards:

Not flammable. Fine particles (such as mists) may fuel fires/explosions. Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Small spills: Allow to evaporate. Isolate area until gas has dispersed. Large Spills: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal

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regulations. Wipe working area surfaces to dryness, and then wash with soap and water.

Environmental Precautions:

Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling:

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

Store at room temperature 15° to 30°C (59° to 86°F). Protect against physical damage. Keep container tightly closed in a dry and well-ventilated location

Specific End Use:

Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Sevoflurane	TWA	60 ppm

TWA: Time Weighted Average.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Avoid contact with eyes. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

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Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear, colorless liquid.
Odor:	Slightly pungent.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	48.5°C.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	300 mmHg @ 20°C.
Vapor Density:	>1.
Relative Density:	1.5.
Solubility(ies):	Negligible.
Partition Coefficient (n-octanol/water):	log Pow: 2.271.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials:	Alkali metals, powdered Aluminum, powdered Magnesium, powdered Zinc.
Hazardous Decomposition Products:	May emit toxic fumes under fire conditions: Hydrofluoric Acid, Hydrogen Chloride gas, Carbonyl Fluoride.

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11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	Based on components, inhalation may cause irritation, headache, drowsiness, dizziness, nausea, vomiting, diarrhea, dehydration, and symptoms of drunkenness. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.
Ingestion:	May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause additional affects as listed under "Inhalation."
Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Sevoflurane	Rat	Inhalation	LC ₅₀	15,300 ppm, 3h
Sevoflurane	Mouse	Inhalation	LC ₅₀	16,800 ppm, 3h
Sevoflurane	Rat	Oral	LD ₅₀	4,770 mg/kg
Sevoflurane	Mouse	Oral	LD ₅₀	5,080 microliters/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
Isoflurane	9 week(s)	Mouse	Inhalation	0.5% (MTC)	NOAEL	No effects at maximum dose

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Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Isoflurane	Reproductive & Fertility-Females	Mouse	Inhalation	0.4%	NOAEL	No effects at maximum dose
Isoflurane	Reproductive & Fertility-Males	Mouse	Inhalation	0.4%	NOAEL	No effects at maximum dose

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

Nervous system, heart, liver.

Systemic Effects:

No data available.

Reproductive Effects:

Pregnancy Category C. 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.

Carcinogenicity:

No data available.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Mobility in Environment:

No data available.

Other Adverse Effects:

No data available.

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13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Aviation regulated liquid n.o.s. (Sevoflurane)	UN3334	9	III

International Air Transport Association (IATA):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Aviation regulated liquid n.o.s. (Isoflurane)	UN3334	9	III

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Isoflurane	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

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U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Isoflurane	Listed	Listed	Not Listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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