



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ibuprofen Oral Suspension
CAS No: 15687-27-1
Chemical Name: (±)-2-p-Isobutylhydratropic acid
Chemical Formula: $C_{13}H_{18}O_2$
Molecular Weight: 206.29
Product Use: To control pain and Inflammation

Manufacturer's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Ibuprofen (100mg/5mL) active ingredient

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

Primary Route of Entry: Ingestion.

Overdoseage: The toxicity of ibuprofen overdose is dependent upon the amount of drug instead and the time elapsed since ingestion, through individual response may vary. Although uncommon, serious toxicity and death have been reported in the medical literature with ibuprofen overdosage. The most frequently reported symptoms of ibuprofen overdose include abdominal pain, nausea, vomiting, lethargy and drowsiness. Other central nervous system symptoms include headache, tinnitus, CNS depression and seizures. Cardiovascular toxicity, including hypotension, bradycardia, tachycardia and atrial fibrillation, also have been reported.

Medical Conditions Aggravated by Exposure: Hypersensitivity to ibuprofen, existing medical problems especially Hepatitis, Kidney disease, Heart disease, Rectal problems, Asthma, Parkinson's disease, Hemorrhoids, Sugar diabetes, Intestinal problems may get worse.

4. FIRST AID MEASURES

Eye Exposure: Immediately flush eyes with water and continue washing for several minutes. Obtain medical attention if discomfort persists.

Skin Exposure: Remove contaminated clothing and shoes immediately. Wash affected area with soap and large amounts of water.

Inhalation: Remove to fresh air.

Ingestion: Obtain medical attention or contact poison control center.

Special Protection Information

Ventilation: Not required under normal conditions of therapeutic use.

Respiratory Protection: Not required under normal conditions of therapeutic use.

Protective Gloves and Clothing: Not required under normal conditions of therapeutic use.

Eye Protection: Safety glasses recommended.

5. FIRE AND EXPLOSION HAZARD

This product does not pose a fire hazard.

Flash Point: Not determined.

Extinguishing Media: Water spray, multipurpose dry chemical, carbon dioxide or foam as appropriate for the surrounding fire or material.

Fire Fighting Procedures: Use self contained breathing apparatus and protective clothing.

Hazardous Combustion Products: Oxides of carbon.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released: Use proper personal protective equipment to avoid overexposure. Small spills can be absorbed with appropriate material, e.g. rags, paper towels. Large spills should be contained and vacuumed and placed in a suitable container. Dispose of the spilled material in compliance with federal, state and local regulations.

7. HANDLING AND STORAGE

Handling: Observe good industrial hygiene practices. Shake well before using.

Storage: Store at controlled temperature of 15° to 30°C (59° to 86°F). Keep out of reach from children.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits: None

Engineering Controls: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Personal Protection: Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Orange-colored, berry-flavored suspension
Melting Point (deg. C): Not determined.
Boiling Point (deg. C): Not determined.
Solubility: Insoluble.
pH Range: 3.6-4.6

10. STABILITY AND REACTIVITY

Chemical Stability: Stable
Conditions to Avoid: None
Incompatibility: None
Hazardous Decomposition: None
Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Studies:

Oral LD50 (rat): 636 mg/kg
Oral LD50 (mouse): 740 mg/kg

Other Studies:

Pregnancy: Teratogenic Effects — Pregnancy Category B: Reproductive studies conducted in rats and rabbits at doses somewhat less than the maximal clinical dose did not demonstrate evidence of developmental abnormalities. However, animal reproduction studies are not always predictive of human response. As there are no adequate and well-controlled studies in pregnant women, this drug should be used during pregnancy only if clearly needed. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during late pregnancy should be avoided. Administration of ibuprofen is not recommended during pregnancy.

Labor and Delivery: As with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia and delayed parturition occurred in rats. Administration of ibuprofen is not recommended during labor and delivery.

- Nursing Mothers: In limited studies, an assay capable of detecting 1 mcg/mL did not demonstrate ibuprofen in the milk of lactating mothers. Because of the limited nature of these studies, however, and the possible adverse effects of prostaglandin inhibiting drugs on neonates, ibuprofen is not recommended for use in nursing mothers.
- Pediatrics: The safety and efficacy in pediatric patients below the age of 6 months has not been established. Dosing of this drug in children 6 months or older should be guided by their body weight.
- Geriatrics: Certain side effects, such as confusion, swelling of the face, feet or lower legs or sudden decrease in the amount of urine, may be especially likely to occur in older patients who are usually more sensitive to the effects of nonsteroidal anti-inflammatory drugs. Also, elderly people are more likely than younger adults to get very sick if these nonsteroidal anti-inflammatory drugs cause stomach problems.

12. ECOLOGICAL INFORMATION

Environmental Effects: Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.

At Home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

FDA: Ibuprofen is an approved prescription medication.

Inventory Status: The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: June 2009

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION