Perrigo Pharmaceuticals Co.
U.S. Pharmaceuticals Division

MATERIAL SAFETY DATA SHEET
NDC Product(s) Code(s): 0121-4774-05
0121-4774-10

Product Name: **Ibuprofen Oral Suspension 100mg/5mL**

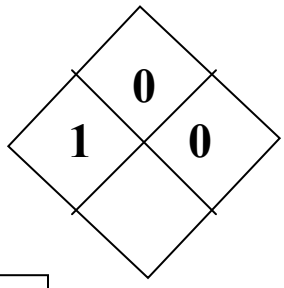
Revision No. 01

1. Manufacturer:
Perrigo Pharmaceuticals Co.

Poison Control Center
Phone: 1-800-222-1222

2. Product Identification

Product Name:	**Ibuprofen Oral Suspension**
Product NDC Code:	0472-1270-94
Chemical Family:	Mixture
Synonyms:	Motrin® Ibuprofen Suspension
Product Category:	Anti-Inflammatory (NSAID)



Hazard Rating
4-Extreme
3-Serious
2-Moderate
1-Slight
0-Minimal

3. Composition/Ingredient Information

Ingredient	Common Name	% By Weight	CAS #	Exposure Limit(s)	Other Information
1.	Ibuprofen	100 mg/5ml	15687-27-1	Not Established	Possible allergic reaction to material if inhaled, ingested or in contact with skin.
2.	Water	used as base ingredient	7732-18-5	N/A	N/A

Other Ingredients: Citric Acid, Glycerin, Polysorbate 80, Hypromellose, Sodium Benzoate, Corn Syrup, Xanthan Gum, Sorbitol, Propylene Glycol, Butylparaben, FD&C Yellow #6 and FD&C Red #33, Artificial flavor, and Purified Water. (Refer to MSDSs of all the ingredients for more details.)

4. Physical and Chemical Properties

Appearance/Physical State:	Orange-colored, berry-flavored suspension
pH Range:	3.6-4.6
Boiling Point:	N/D
Evaporation Rate:	N/D
Specific Gravity (water=1):	1.10-1.20
Vapor Density (air):	N/D
Vapor Pressure:	N/D
Volatility:	N/D

5. Stability and Reactivity

Stability:	Stable
Physical Conditions to Avoid:	None
Incompatibility with Other Materials:	None
Hazardous Decomposition Products:	None
Hazardous Polymerization:	Does Not Occur

6. Hazards Identification

Primary Routes of Exposure:	Ingestion.
Overdosage:	The toxicity of ibuprofen overdose is dependent upon the amount of drug instead and the time elapsed since ingestion, though 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 included 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.

7. Emergency and First Aid Measures

Skin Contact: Remove contaminated clothing and shoes immediately. Wash affected area with soap and large amounts of water.
Eye Contact: Immediately flush eyes with water and continue washing for several minutes. Obtain medical attention if discomfort persists.
Inhalation: Remove to fresh air.
Ingestion: Obtain medical attention or contact poison control center.

8. Fire Fighting Measures

This product does not pose a fire hazard.

Flash Point:	N/D
Lower Explosion Limit (LEL):	N/D
Upper Explosion Limit (UEL):	N/D
Extinguishing Media:	Water Spray, Multipurpose Dry Chemical, Carbon dioxide or Foam as appropriate for the surrounding fire or materials.
Fire Fighting Procedures:	Use self-contained breathing apparatus and protective clothing.
Unusual Fire or Explosion Hazards:	None
Hazardous Combustion Products:	Oxides of carbon.

9. Pharmacology

Physicochemical Characteristics:	Molecular Weight = 206.28; Ibuprofen is a member of the propionic acid group of nonsteroidal anti-inflammatory drugs. Ibuprofen is a racemic mixture of [+]S- and [-]R-enantiomers.
Mechanism of action/Effect:	Its mode of action, like that of other NSAIDSs, is not completely understood, but may be related to prostaglandin synthetase inhibition. After absorption of the racemic ibuprofen, the [-]R-enantiomer undergoes interconversion to the [+]S-form. The biological activities of ibuprofen are associated with the [+]S- enantiomer.

Half-life:	Elimination: 1.8-2 hours
Onset of Action:	Pain: 0.5 hours
Time to Peak Effect:	Fever: 2-4 hours
Duration of Action:	Fever: 5mg/kg dose – 6 hours and 10mg/kg dose-8 hours or more Pain: 4-6 hours
Metabolism:	Following oral administration, the majority of the dose was recovered in the urine with 24 hours as the hydroxy-(25%) and carboxypropyl-(37%) phenylpropionic acid metabolites. The percentages of free and conjugated ibuprofen found in the urine were approximately 1% and 14%, respectively. The remainder of the drug was found in the stool as both metabolites and unabsorbed drug.
Elimination:	Ibuprofen is rapidly metabolized and eliminated in the urine. The excretion of ibuprofen is virtually complete 24 hours after the last dose.

10. Toxicological Information

Acute Studies:

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

Other Studies:

Pregnancy:	Teratogenic Effects: Pregnancy Category B: Reproductive studies conducted in rats and rabbits at doses somewhat less than the maximum 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 the pregnancy only if clearly needed. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus ateriosus), use during late pregnancy should be avoided. Administration of this drug 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 the rats. Administration of this drug is not recommended during labor and delivery.
Breast-feeding:	In limited studies, an assay capable of detecting 1ug/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 newborns, this drug is not recommended for use in nursing mothers.
Pediatrics:	The safety and effectiveness in pediatric patients below the age of 6 months has not been established. Dosing of this drugs in children 6 months or older should be guided by their bodyweight.
Geriatrics	Certain side effects, such as confusion, swelling of 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.

11. Spill and Leak Procedures

Steps to be taken in case material is released or spilled: 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.

12. Waste Disposal Method

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

13. Storage and Handling Precautions

Federal law prohibits dispensing without prescription. As with any drug/medicine, keep this drug out of reach of the children. Store at controlled room temperature 15-30 ˚C (59-86˚F). Shake well before using. Use the dosage as recommended by the physician.

14. Process Handling Precautions

Avoid all contact and inhalation of dust, mists, and/or vapors associated with the materials. Wear proper protective equipment to avoid any overexposure. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. Wash thoroughly after handling.

15. Personal Protection/Exposure Controls (Bulk Handling)

Respiratory Protection:	NIOSH approved respirator
Ventilation:	Local exhaust
Protective Gloves:	Rubber Gloves
Eye Protection:	Safety glasses with side shields

16. Shipping Regulations (Ref: 49CFR § 172.101)

Proper Shipping Name:	Not Regulated
Hazard Class:	None
UN/NA Number:	None Listed
Subsidiary Risk:	None
US DOT Emergency Response Guide:	N/A
Transportation Label Required:	None

17. Other Information

Labeling: This product (drug/medicine) is subject to the labeling requirements of FDA and therefore, is exempt form the labeling requirements of OSHA Hazardous Communication Standard (29 CFR 1910.1200).

18. Disclaimer

The contents of this MSDS are believed to be accurate, but should only be used as a guide. Perrigo Pharmaceutical Company disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.