SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: IBUPROFEN 50mg INFANT DF SUSPENSION
Synonyms: 255

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

Label Elements:
Warning!

Hazard statement(s)
Suspected of damaging the unborn child.

Precautionary statement(s)
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective clothing and gloves.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Ibuprofen	15687-27-1	<5%
Anhydrous Citric Acid	77-92-9	Proprietary
Artificial Mixed Fruit Flavor	Proprietary	Proprietary
Butylparaben	94-26-8	Proprietary
Propylene Glycol	57-55-6	Proprietary
Glycerin	56-81-5	Proprietary
Hypromellose	9004-65-3	Proprietary
Polysorbate 80	9005-65-6	Proprietary

Purified Water	7732-18-5	Proprietary
Sodium Benzoate	532-32-1	Proprietary
Sorbitol Solution	50-70-4	Proprietary
Sucrose	57-50-1	Proprietary
Xanthan Gum	11138-66-2	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: First aid is not generally required for skin contact. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdoasage.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding, ulceration and heart attack and stroke. Suspected to cause adverse reproductive effects.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for large unintended ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: This product is not a fire hazard but may burn under fire conditions after the water has evaporated

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Caution – spilled liquid may present a slip hazard.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect liquid with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Ibuprofen	2000 ug/m3 Perrigo OEL
Anhydrous Citric Acid	None Established
Artificial Mixed Fruit Flavor	None Established
Butylparaben	None Established
Propylene Glycol	10 mg/m3 TWA AIHA WEEL
Glycerin	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Hypromellose	None Established
Polysorbate 80	None Established
Purified Water	None Established
Sodium Benzoate	None Established
Sorbitol Solution	None Established
Sucrose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Xanthan Gum (as PNOC)	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: None required for normal use. Impervious gloves recommended for bulk handling.
Eye protection: None required for normal use. Chemical safety goggles recommended for bulk handling.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Opaque suspension
Odor: Mixed fruit

Odor threshold: Not available	**pH:** 3.6-4.6
Melting point/freezing point: Not available	**Boiling Point:** Not available
Flash point: None	**Evaporation rate:** Not available
Flammability (solid, gas): Not applicable	**VOC:** Not available
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not available	**Vapor density:** Not available
Relative density: Not available	**Solubility(ies):** Completely soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not available

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing amounts above the recommended dosage may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding and ulceration.
Skin contact: Contact may cause slight irritation.
Eye contact: Contact may cause slight irritation with redness and tearing.
Chronic Effects: NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.
Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Ibuprofen was not mutagenic in in-vitro bacterial reverse mutation assay.
Reproductive Toxicity: Reproductive studies conducted with ibuprofen in rats and rabbits have not demonstrated evidence of developmental abnormalities. Ibuprofen is a member of the nonsteroidal antiinflammatory drug (NSAID) drug class. Usage in late pregnancy is associated with a significant increase in the risk of premature closure of the ductus arteriosus.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 12,500 mg/kg
Ibuprofen: LD50 oral rat 636 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard

DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA hazard classification.
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1* Flammability = 0 Physical Hazard = 0

SDS Revision History: Updated CAS No. in section 3.
Date of preparation: September 6, 2023

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).