SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Ibuprofen 200mg Tablets
Synonym: 517, 074

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 – pain reliever/fever reducer
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not Hazardous	Eye Irritant Category 2A Specific Target Organ Toxicity Category 3 (respiratory irritation)

Label Elements:

WARNING:

Hazard statement(s)

Causes serious eye irritation.
May cause respiratory irritation.

Precautionary statement(s)

Avoid breathing dust.
Wash hands thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear eye protection.

Precautionary statement(s)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
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	50-65%
Microcrystalline Cellulose	9004-53-9	Proprietary

Corn Starch	9005-25-8	Proprietary
Colloidal Silicon Dioxide	112945-52-5	Proprietary
Croscarmellose Sodium	74811-65-7	Proprietary
Iron Oxide Red	Proprietary	Proprietary
Iron Oxide Yellow	51274-00-1	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Polyvinyl Alcohol	9002-89-5	Proprietary
Stearic Acid	57-11-4	Proprietary
Titanium Dioxide (bound in tablet)	13463-67-7	Proprietary
Talc	14807-96-6	Proprietary
FD&C Red #40 Aluminum Lake	68583-95-9	Proprietary
FD&C Yellow #6 Aluminum Lake	15790-07-5	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: Wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Get medical attention if irritation persists**.**
Ingestion: Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if large amount is ingested or if symptoms develop.

Most important symptoms/effects, acute and delayed: Causes eye irritation. May cause mild skin irritation. Breathing dust may cause respiratory tract 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.
Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended for overdose.

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: Tablets are not a fire hazard but may burn under fire conditions. Fine dust from crushed tablets will present a dust explosion hazard.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If tablets are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

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 using methods that avoid the generation of dust and damage to tablets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. 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 TWA Perrigo OEB1
Microcrystalline Cellulose	5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL 10 mg/m3 TWA ACGIH TLV
Corn Starch	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Colloidal Silicon Dioxide	80 mg/m3/%SiO2 TWA OSHA PEL
Croscarmellose Sodium	None Established
Iron Oxide Red	None Established
Iron Oxide Yellow	10 mg/m3 TWA OSHA PEL (as fume) 5 mg/m3 (respirable) TWA ACGIH TLV
Polyethylene Glycol	None Established
Polyvinyl Alcohol	None Established
Stearic Acid	None Established
Titanium Dioxide	15 mg/m3 TWA OSHA PEL 10 mg/m3 TWA ACGIH TLV
Talc	20 mppcf TWA OSHA PEL 2 mg/ m3 (respirable) TWA ACGIH TLV
FD&C Red #40 Aluminum Lake	None Established
FD&C Yellow #6 Aluminum Lake	None Established

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: Impervious gloves recommended for handling damaged tablets.
Eye protection: Chemical safety goggles recommended for handling damaged tablets or tablets.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Orange tablets.
Odor: No odor

Odor threshold: Not applicable	**pH:** Not applicable
Melting point/freezing point: Not applicable	**Boiling Point:** Not applicable

Flash point: Not applicable	**Evaporation rate:** Not applicable
Flammability (solid, gas): Not flammable	**VOC:** Not applicable
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not applicable	**Vapor density:** Not applicable
Relative density: Not available	**Solubility(ies):** Not available
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not applicable

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 dust from damaged tablets 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 irritation with redness and tearing. Ibuprofen is irritating to human eyes.
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: None of the components are reproductive toxins. Reproductive studies conducted with ibuprofen in rats and rabbits have not demonstrated evidence of developmental abnormalities.

Carcinogenicity: Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). The titanium dioxide is bound in the coating matrix and no inhalation exposure will occur during the handling of these tablets. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 2500 mg/kg
Ibuprofen: LD50 oral rat 1600 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values:
Ibuprofen: LC50 fish (lepomis macrochirus) 173 mg/L/96 hr; EC50 daphnia magna 29.6 mg/L/48 hr, NOEC daphnia magna 20 mg/L/21 d.; ErC50 algae (scenedesmus subspicatus) 315 mg/L/72 hr.
Persistence and degradability: Ibuprofen: not readily biodegradable.
Bioaccumulative potential: Ibuprofen: log Kow 3.87
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): Acute Health

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 = 1 Instability = 0
HMIS Rating: Health = 2 Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS.
Date of preparation: April 23, 2016

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).