

SAFETY DATA SHEETS

This SDS packet was issued with item:

078683294

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078337737

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078683039 078683088



70903

Material Safety Data Sheet**Ibuprofen, UF 200 MG, 400 MG, 600 MG, 800 MG TAB**

Creation Date: July 10, 2012

Revision Date:

1. Substance/preparation and Company identification

<u>Company</u> Dr. Reddy's Laboratories 8800 Line Avenue Shreveport, Louisiana 71106, USA	<u>24 Hour Emergency Response Information</u> CHEMTREC: 1-800-424-9300
----------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------

2. Composition information on the Ingredients

Chemical Name (active pharmaceutical ingredient)	CAS Number	Content (W/W)
Ibuprofen	15678-27-1	≥80% - ≤100%
Chemical Name (Other Ingredients)	CAS Number	
Croscarmellose sodium	74811-65-7 (≥1% - ≤5%)	
Microcrystalline cellulose	9004-34-6 (≥1% - ≤5%)	
Titanium dioxide	13463-67-7 (≥0.1% - ≤1.5%)	

3. Hazard IdentificationEmergency Overview

WARNING: Causes eye irritation

HARMFUL IF SWALLOWED

MAY CAUSE RESPIRATORY TRACT IRRITATION

MAY CAUSE SKIN IRRITATION

Avoid contact with skin, eyes or clothing

Avoid inhalation of dusts

Wear chemical resistant protective gloves

Wear NIOSH-certified chemical goggles

Wear NIOSH-certified (or equivalent) particulate respirator

Eye wash fountains and safety showers must be easily accessible

Potential Health Effects

Routes of entry for solids include eye and skin contact, ingestion and inhalation.

Acute Toxicity (Ibuprofen)

Harmful if swallowed

Irritation (Ibuprofen)

May cause slight irritation to the skin. Irritating to the eyes. Irritating to the respiratory system.

Sensitization (Ibuprofen)

May cause sensitization by inhalation and skin contact. Not a skin sensitizer when tested in animals.

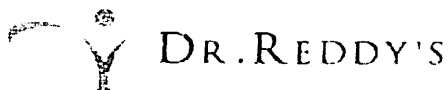
Repeated Dose Toxicity

Common effects include skin rash, heartburn, nausea, vomiting, dizziness and headache

Medical Conditions Aggravated by Overexposure

Individuals with ulcers, aspirin hypersensitivity and other drug allergies may have increased susceptibility to overexposure. Inhalation of dusts could aggravate existing respiratory conditions.

See MSDS Section 11 – Toxicological Information



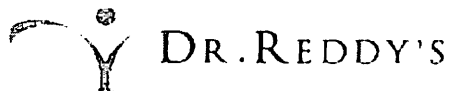
Material Safety Data Sheet

Ibuprofen, UF 200 MG, 400 MG, 600 MG, 800 MG TAB

Creation Date: July 10, 2012

Revision Date:

4. First-Aid Measures
<u>General Advice</u> Remove contaminated clothing
<u>If Inhaled</u> Remove the individual into fresh air and keep the person calm. Assist in breathing if necessary. Immediate medical attention required.
<u>If on the Skin</u> Wash affected areas thoroughly with soap and water. If irritation develops, seek medical attention.
<u>If in the Eyes</u> In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention.
<u>If Swallowed</u> Rinse mouth and then drink plenty of water. Never induce vomiting or give anything by mouth of the person is unconscious or having convulsions. Immediate medical attention required.
<u>Note to Physician</u> Possible symptoms of overexposure include asthma, edema, hives, headache and dizziness. Can cause adverse effects on the kidney and liver. Can affect blood or blood forming organs. Possible allergic reaction to dust if inhaled, ingested or in contact with skin.
5. Fire-Fighting Measures
Flash point – no data available Autoignition – no data available
<u>Suitable Extinguishing Media</u> Water, fog, foam, dry extinguishing media, gaseous extinguishing media, carbon dioxide
<u>Hazards During Firefighting</u> No particular hazards known
<u>Protective Equipment for Fire-Fighting</u> Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.
6. Accidental-Release Measures
<u>Personal Precautions</u> Wear appropriate respiratory equipment. Use personal protective clothing. Ensure adequate ventilation.
<u>Environmental Precautions</u> This product is not regulated by RCRA. Do not discharge into drains, surface water or groundwater.
<u>Cleanup</u> Spills should be contained and placed in suitable containers for disposal. Follow applicable State and Federal Regulations.



Material Safety Data Sheet

Ibuprofen, UF 200 MG, 400 MG, 600 MG, 800 MG TAB

Creation Date: July 10, 2012

Revision Date:

7. Handling and Storage

Handling (General Advice)

Provide good ventilation of working area (local exhaust ventilation if necessary). Ensure adequate ventilation. Avoid formation of dust. Wear suitable protective clothing and gloves.

Protection against fire and explosion

No explosion proofing is necessary. Containers should be grounded against electrostatic charge. Take precautionary measures against static discharges. Dust can form an explosive mixture with air. Avoid dust formation.

Storage (General Advice)

Keep only in the original container in a cool, dry, well-ventilated place away from ignition sources, heat or flame. Keep away from food, drink and animal feeding stuffs.

Storage (Incompatibility)

Segregate from oxidizing agents. Segregate from strong acids. Segregate from strong bases.

8. Exposure Controls and Personal Protection

Components with Workplace Control Parameters

Microcrystalline cellulose – OSHA PEL 5 mg/m³ (respirable fraction); PEL 15 mg/m³ (total dust)

Microcrystalline cellulose – ACGIH TWA 10 mg/m³

Titanium dioxide – OSHA PEL 15 mg/m³ (total dust)

Titanium dioxide – ACGIH TWA 10 mg/m³

Ibuprofen – Dr. Reddy's Occupational Exposure Limit (TWA) 3 mg/m³

Advice on system design: Provide local exhaust ventilation to control dust.

Personal Protective Equipment

Respiratory protection – Breathing protection if dusts are formed. Wear a NIOSH-certified (or equivalent) particulate respirator.

Hand protection – Chemical resistant protective gloves

Eye protection – Tightly fitting safety goggles (chemical goggles)

General safety and hygiene measures – Avoid inhalation of dust. Wear protective clothing as necessary to minimize contact. Wash soiled clothing immediately.

9. Physical and Chemical Properties

Form – Tablets

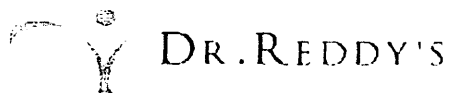
Odor – Characteristic faint odor

Color – White

pH value – No data available

Melting point – 75-77°C (1 ATM)

Partition coefficient (n-octanol/water log Pow) – 3.3



Material Safety Data Sheet

Ibuprofen, UF 200 MG, 400 MG, 600 MG, 800 MG TAB

Creation Date: July 10, 2012

Revision Date:

10. Stability and Reactivity

Conditions to avoid: Avoid dust formation. Avoid all sources of ignition, heat, sparks, and open flame.

Substances to avoid: Strong alkalis, oxidizing agents, strong acids

Hazardous reactions: This product is chemically stable.

Decomposition products: Carbon monoxide (hazardous), carbon dioxide

Thermal decomposition: No data available.

Corrosion to metals: No corrosive effect on metal.

11. Toxicological Information

Acute Toxicity

Oral (ibuprofen): Rat oral LD50 – 1,600 mg/kg

Inhalation LC50 (ibuprofen) – Not available

Dermal: Rabbit dermal LD50 (ibuprofen) – Not available

Skin Irritation (ibuprofen) – Slightly irritating

Eye Irritation (ibuprofen) – Irritant

Sensitization (ibuprofen) – Non-sensitizing in the guinea pig maximization test (OECD Guideline 406)

Carcinogenicity (titanium dioxide) – IARC (International Agency for Research on Cancer) has classified this substance as a group 2B carcinogen (agent is possible carcinogenic to humans)

12. Ecological Information

Environmental Fate and Transport

Stability in water: No data available

Bioaccumulation: No data available

Environmental Toxicity

Acute and prolonged toxicity to fish: No data available.

Toxicity to aquatic plants: No data available.

Toxicity to terrestrial plants: No data available.

13. Disposal Considerations

Waste disposal of substance: Do not discharge substance/product into the sewer system. Dispose of according with national, state, and local regulations.

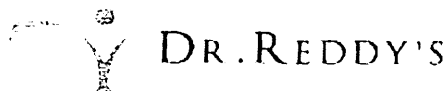
Container disposal: Dispose of in a licensed facility. Recommend crushing, puncturing, or other means to prevent authorized use of used containers.

14. Transport Information

Land transport: Not classified as dangerous goods under transport regulations

Sea transport: Not classified as dangerous goods under transport regulations

Air transport (IATA/ICAO): Not classified as dangerous goods under transport regulations



Material Safety Data Sheet

Ibuprofen, UF 200 MG, 400 MG, 600 MG, 800 MG TAB

Creation Date: July 10, 2012

Revision Date:

15. Regulatory Information

The information included below is an overview of the major regulatory information. It should not be considered an exhaustive summary. Local regulations should be consulted for additional requirements.

Federal Regulations

Registration status: TSCA – exempt (ibuprofen)

OSHA hazard category (titanium dioxide): IARC 2B; NIOSH-Ca; TLV-A4

CERCLA – Not listed

SARA (EPCRA 311/312) – Acute, Chronic

State Regulations (Right to Know)

Microcrystalline cellulose – MA, PA

Titanium dioxide – MA, NJ, PA

CA Prop 65 – This product contains a chemical known to the State of California to cause cancer.

European Union Classification and Labeling System (CL & P) – R22 Acute Oral Toxicity (Symbol – Harmful)

GHS Classification and Labeling (GHS) – H302; Acute Oral Toxicity Category 4 (Symbol – Exclamation mark; Signal word – Warning; Hazard Statement – Harmful if swallowed;

16. Other Information

HMIS Rating

Health: 2 Flammability: 1 Physical Hazard: 0

HMIS used a numbering scale ranging from 0 to 4 to indicate the degree of hazard. A value of zero means that the substance possesses essentially no hazard, a rating of 4 indicated high hazard.

Corporate Disclaimer: Dr. Reddy's Laboratories Louisiana, LLC. Provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a brief summary and general guide to the appropriate precautionary handling of this material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for any particular purpose. DR. REDDY'S LABORATORIES LOUISIANA, LLC. MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, DR. REDDY'S LABORATORIES LOUISIANA, LLC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.