

# Ibuprofen Tablets 200, 400, 600, 800mg

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Product name. : Ibuprofen Tablets 200, 400, 600, 800mg

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

Dr. Reddy's Laboratories Ltd.  
8-2-337 Road No. 3, Banjara Hills  
Hyderabad 500-034, - India  
T +91-40-49002900 - F +91-40-49002999

#### 1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Acute Tox. 4 (Oral) H302

#### 2.2. Label elements

##### GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) : Warning  
Hazard statements (GHS-US) : H302 - Harmful if swallowed  
Precautionary statements (GHS-US) : P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P301+P312 - If swallowed, call a doctor if you feel unwell  
P330 - If swallowed, rinse mouth  
P501 - Dispose of contents/container in accordance with local and national regulations

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS-US)

No data available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixture

Only components with health hazards above the applicable thresholds are shown. Specific composition withheld as trade secret.

Full text of H-phrases: see section 16

Name	Product identifier	%	GHS-US classification
Ibuprofen (main constituent)	(CAS No) 15687-27-1	80 – 90	Acute Tox. 4 (Oral), H302

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical advice/attention.

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First-aid measures after inhalation	: If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after skin contact	: Wash skin with mild soap and water.
First-aid measures after eye contact	: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Rinse mouth. Call a POISON CENTER/doctor/physician if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: Inhalation may cause: irritation, coughing, shortness of breath.
Symptoms/injuries after skin contact	: No significant signs or symptoms indicative of any health hazard are expected to occur as a result of skin contact.
Symptoms/injuries after eye contact	: May cause slight irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed. May be harmful if swallowed in large quantities. Follow all instructions given by your doctor or physician. Symptoms of overexposure may include: asthma, edema, hives, headache, and dizziness.

### 4.3. Indication of any immediate medical attention and special treatment needed

All treatments should be based on observed signs and symptoms of distress in the patient.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Carbon dioxide. Dry powder. Foam. Water spray.
Unsuitable extinguishing media	: None known.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: No specific fire or explosion hazard.
Explosion hazard	: Product is not explosive.
Reactivity	: No dangerous reactions known.

### 5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid creating or spreading dust. Avoid contact with eyes and skin.
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#### 6.1.1. For non-emergency personnel

Protective equipment	: Wear suitable protective clothing and gloves. In case of inadequate ventilation wear respiratory protection.
Emergency procedures	: Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment	: Wear suitable protective clothing and gloves. Chemical goggles or safety glasses.
Emergency procedures	: Ventilate area.

### 6.2. Environmental precautions

Do not discharge into drains or the environment.

### 6.3. Methods and material for containment and cleaning up

For containment	: Absorb and/or contain spill with inert material, then place in suitable container. Avoid generating dust.
Methods for cleaning up	: Minimize generation of dust. Take up in non-combustible absorbent material and shovel into container for disposal.

### 6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling	: Provide good ventilation in process area to prevent formation of dust. Use personal protective equipment as required.
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Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed.  
Storage conditions : Keep only in the original container in a cool well ventilated place. Keep container closed when not in use. Do not store near food, foodstuffs, drugs, or potable water supplies.  
Incompatible products : Strong oxidizers. Strong bases. Strong acids.  
Incompatible materials : Sources of ignition.

### 7.3. Specific end use(s)

Pharmaceuticals.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Ibuprofen (15687-27-1)

Dr. Reddy's OEL 1300 µg/m<sup>3</sup> (8-hr TWA)

### 8.2. Exposure controls

Appropriate engineering controls : Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Provide local exhaust or general room ventilation to minimize exposure to dust.  
Personal protective equipment : Avoid all unnecessary exposure.  
Hand protection : Wear dust impervious gloves.  
Eye protection : Chemical goggles or safety glasses.  
Respiratory protection : Where excessive dust may result, use approved respiratory protection equipment. Use an air-purifying respirator equipped with particulate filtering cartridges.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Tablets.  
Colour : White.  
Odour : No data available  
Odour threshold : No data available  
pH : No data available  
Relative evaporation rate (butylacetate=1) : No data available  
Melting point : 75 - 77 °C  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Self ignition temperature : No data available  
Decomposition temperature : No data available  
Flammability (solid, gas) : No data available  
Vapour pressure : No data available  
Relative vapour density at 20 °C : No data available  
Relative density : No data available  
Solubility : No data available  
Log Pow : 3.3  
Log Kow : No data available  
Viscosity, kinematic : No data available  
Viscosity, dynamic : No data available  
Explosive properties : Product is not explosive. Dust may form explosive mixture in air.  
Oxidising properties : No oxidizing properties.  
Explosive limits : No data available

### 9.2. Other information

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No dangerous reactions known.

#### 10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

#### 10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

#### 10.4. Conditions to avoid

Avoid creating or spreading dust. Keep away from sources of ignition.

#### 10.5. Incompatible materials

Strong oxidizers. Strong bases. Strong acids. Alkali.

#### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Ibuprofen Tablets 200, 400, 600, 800mg	
ATE (oral)	500.000 mg/kg bodyweight

ibuprofen (15687-27-1)	
LD50 oral rat	636 mg/kg
LD50 oral mice	740 mg/kg
LD50 oral rabbit	1400 mg/kg
ATE (oral)	636.000 mg/kg bodyweight

Skin corrosion/irritation	: Not classified Ibuprofen - Non-irritating to the skin.
Serious eye damage/irritation	: Not classified Ibuprofen - Slightly irritating to the eyes.
Respiratory or skin sensitisation	: Not classified Ibuprofen - Non-sensitizing in the guinea pig.
Germ cell mutagenicity	: Not classified Ibuprofen - Not mutagenic in the Ames test. Weakly positive in the mouse micronucleus assay.
Carcinogenicity	: Not classified Ibuprofen – Not carcinogenic.
Reproductive toxicity	: Not classified Ibuprofen - Not teratogenic or embryotoxic in rats and rabbits. No effects on male or female fertility in rats.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Inhalation may cause: irritation, coughing, shortness of breath.
Symptoms/injuries after skin contact	: No significant signs or symptoms indicative of any health hazard are expected to occur as a result of skin contact.
Symptoms/injuries after eye contact	: May cause slight irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed. May be harmful if swallowed in large quantities. Follow all instructions given by your doctor or physician. Symptoms of overexposure may include: asthma, edema, hives, headache, and dizziness.

### SECTION 12: Ecological information

#### 12.1. Toxicity

ibuprofen (15687-27-1)	
LC50 fishes 1	173 mg/l sunfish, bluegill
EC50 Daphnia 1	9.06 mg/l Skeletonema costatum

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<b>ibuprofen (15687-27-1)</b>	
EC50 other aquatic organisms 1	20.5 mg/l

### 12.2. Persistence and degradability

<b>ibuprofen (15687-27-1)</b>	
Persistence and degradability	Not readily biodegradable. Moderately biodegradable.

### 12.3. Bioaccumulative potential

<b>Ibuprofen Tablets 200, 400, 600, 800mg</b>	
Log Pow	3.3
<b>ibuprofen (15687-27-1)</b>	
Log Pow	3.87 (calculated)

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Sewage disposal recommendations	: Do not dispose of waste into sewer.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Dispose of container in a licensed facility.

## SECTION 14: Transport information

In accordance with DOT

Not considered a dangerous good for transport regulations

### Additional information

Other information : No supplementary information available.

### ADR

Transport document description : Not applicable

### Transport by sea

No additional information available

### Air transport

No additional information available

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

<b>ibuprofen (15687-27-1)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

### 15.2. International regulations

#### CANADA

<b>Ibuprofen Tablets 200, 400, 600, 800mg</b>	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects
<b>ibuprofen (15687-27-1)</b>	
Listed on the Canadian DSL (Domestic Substances List) inventory.	

#### EU-Regulations

<b>ibuprofen (15687-27-1)</b>	
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances) substances.	

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

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Full text of H-phrases: see section 16

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### Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R22

#### 15.2.2. National regulations

No additional information available

#### 15.3. US State regulations

No additional information available

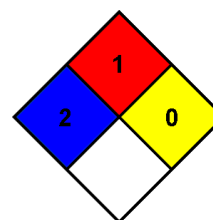
### SECTION 16: Other information

- Indication of changes : GHS classification information. Revised sections: 1 - 16.
- Data sources : ACGIH 2000.  
European Chemicals Agency (ECHA) Registered Substances list. Accessed at <http://echa.europa.eu/>.  
Kriester Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition.  
National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition.  
OSHA 29CFR 1910.1200 Hazard Communication Standard.  
TSCA Chemical Substance Inventory. Accessed at <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>.
- Abbreviations and acronyms : CLP: Classification, Labelling, Packaging.  
ATE: Acute Toxicity Estimate.  
CAS (Chemical Abstracts Service) number.  
EC50: Environmental Concentration associated with a response by 50% of the test population.  
GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).  
LD50: Lethal Dose for 50% of the test population.  
OSHA: Occupational Safety & Health Administration.  
TSCA: Toxic Substances Control Act.

Full text of H-phrases: see section 16:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H302	Harmful if swallowed

- NFPA health hazard : 2 - Intense or continued exposure could cause temporary incapacitation or possible residual injury unless prompt medical attention is given.
- NFPA fire hazard : 1 - Must be preheated before ignition can occur.
- NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



SDS US (GHS HazCom 2012)

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