

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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Version: 2.0



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.
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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/m³ (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 <i>Skeletonema costatum</i>

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

12.2. Persistence and degradability

ibuprofen (15687-27-1)	
Persistence and degradability	Not readily biodegradable. Moderately biodegradable.

12.3. Bioaccumulative potential

Ibuprofen Tablets 200, 400, 600, 800mg	
Log Pow	3.3

ibuprofen (15687-27-1)	
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.
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ADR

Transport document description	: Not applicable
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Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

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

15.2. International regulations

CANADA

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WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

ibuprofen (15687-27-1)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	

EU-Regulations

ibuprofen (15687-27-1)	
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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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

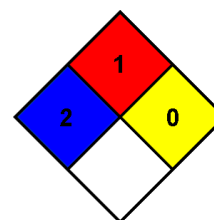
SECTION 16: Other information

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/ . Krister 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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