



Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 12/03/2019

Reviewed on 12/03/2019

1 Identification

· Product Identifier

· **Trade Name:** Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

· **Relevant identified uses of the substance or mixture and uses advised against:**

· **Product Description:**

Tablets: 200 mg, Orange Colored, Round, Bi-Convex, Film-Coated, Debossed with '115' on one side and plain on the other side.

Caplets: 200 mg, Orange Colored, Capsule-Shaped, Bi-Convex, Film-Coated, Debossed with '120' on one side and plain on the other side.

· **Application of the substance / the mixture:** Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

· **Details of the Supplier of the Safety Data Sheet:**

· **Manufacturer/Supplier:**

Marksans Pharma Ltd.

Plot No. L-82 & L-83

Verna Industrial Estate

Verna, Goa, India, 403722

Phone: +91 (0832) 6721900

Fax: +91 (0832) 2782071

E-mail: Marksanspharma@vsnl.net

Web: <http://www.marksanspharma.com>

· **Emergency telephone number:** +91 (0832) 6721900

2 Hazard(s) Identification

· **Classification of the substance or mixture:**



Acute Tox. 4 H302 Harmful if swallowed.

· **Label elements:**

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labeling:**

Ibuprofen

· **Hazard statements:**

H302 Harmful if swallowed.

· **Precautionary statements:**

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Unknown acute toxicity:**

6.3 % of the mixture consists of component(s) of unknown toxicity.

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Trade Name: Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

Classification system:

NFPA ratings (scale 0 - 4)



Health = 1
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 1
Fire = 0
Physical Hazard = 0

Hazard(s) not otherwise classified (HNOC): None known

*** 3 Composition/Information on Ingredients**

Chemical characterization: Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Dangerous Components:

15687-27-1	Ibuprofen ◇ Acute Tox. 4, H302	70.2%
9004-34-6	Microcrystalline Cellulose	Proprietary%
9005-25-8	Starch ◇ STOT SE 3, H335; Combustible Dust	Proprietary%
99439-28-8	Colloidal Silicon Dioxide ◇ Acute Tox. 4, H312	Proprietary%
13463-67-7	Titanium Dioxide ◇ Carc. 2, H351	Proprietary%
14807-96-6	Talc ◇ Carc. 2, H351; ◇ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%

4 First-Aid Measures

Description of first aid measures

General information:

First aid is generally not required if product is used correctly and according to the recommended dosages established by this manufacturer.

Symptoms of poisoning may occur after exposure to dust, fumes or particulates; seek medical attention if feeling unwell.

After inhalation:

The product does not irritate with inhalation.

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in the side position for transportation.

After skin contact:

Generally, the product does not irritate the skin.

Wash with soap and water.

If skin irritation occurs, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water.

If eye irritation occurs, consult a doctor.

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· **After swallowing:**

Product generally does not present an ingestion hazard if used correctly and according to the recommended dosages established by this manufacturer.

· **Information for doctor**

Signs and symptoms of Ibuprofen overdose may include ringing in the ears, blurred vision, diarrhea, heartburn, nausea, stomach pain, vomiting, little to no urine production, difficult or slow breathing, wheezing, headache, agitation, incoherence, confusion, coma, drowsiness, seizures, dizziness, unsteadiness, rash or sweating. Treatment should be started as soon as possible after overdose.

· **Most important symptoms and effects, both acute and delayed:** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed:**

No further relevant information available.

5 Fire-Fighting Measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **For safety reasons unsuitable extinguishing agents:** No further relevant information is available.

· **Special hazards arising from the substance or mixture:**

If incinerated, product may release the following toxic gases: Oxides of Carbon, Nitrogen (NO_x), Sodium, Silicon and Magnesium.

· **Advice for firefighters**

· **Special protective equipment for firefighters:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures:** Not required.

· **Environmental precautions:** Do not allow to enter sewers/surface or ground water.

· **Methods and material for containment and cleaning up:**

Pick up mechanically.

Dispose of the collected material according to regulations.

· **Reference to other sections:**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

9002-89-5	Poly(vinyl alcohol)	24 mg/m ³
13463-67-7	Titanium Dioxide	30 mg/m ³
25322-68-3	Polyethylene Glycol	30 mg/m ³

· **PAC-2:**

9002-89-5	Poly(vinyl alcohol)	270 mg/m ³
13463-67-7	Titanium Dioxide	330 mg/m ³
25322-68-3	Polyethylene Glycol	1,300 mg/m ³

· **PAC-3:**

9002-89-5	Poly(vinyl alcohol)	1,600 mg/m ³
13463-67-7	Titanium Dioxide	2,000 mg/m ³
25322-68-3	Polyethylene Glycol	7,700 mg/m ³

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7 Handling and Storage

- **Handling**
- **Precautions for safe handling:** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
Store away from strong acids, strong bases, strong oxidizing agents and strong reducing agents.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in the original container.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** No further relevant information available.

* 8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

9004-34-6 Microcrystalline Cellulose

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

9005-25-8 Starch

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

13463-67-7 Titanium Dioxide

PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³

14807-96-6 Talc

PEL	Long-term value: 20 mppcf ppm (containing <1% Quartz)
REL	Long-term value: 2* mg/m ³ *respirable dust; and <1% Quartz
TLV	Long-term value: 2* mg/m ³ *as respirable fraction; E

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

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- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not necessary under normal conditions.
- **Protection of hands:** Not necessary under normal conditions.
- **Material of gloves:** Not required.
- **Penetration time of glove material:** Not applicable.
- **Eye protection:** Not necessary under normal conditions.

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
 - **Form:** Tablets or Caplets
 - **Color:** Orange
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
 - **Melting point/Melting range:** Not determined.
 - **Boiling point/Boiling range:** Not determined.
- **Flash point:** None
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:** Not applicable
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density:**
 - **Relative density:** Not determined.
 - **Vapor density:** Not applicable.
 - **Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with:**
 - **Water:** Partly soluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - **Dynamic:** Not applicable.
 - **Kinematic:** Not applicable.

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· Solvent content:

Organic solvents: 0.0 %

Solids content: 100 %

Other information: No further relevant information available.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** Strong acids, strong bases, strong oxidizing agents and strong reducing agents.
- **Hazardous decomposition products:** Oxides of Carbon, Nitrogen (NOx), Sodium, Silicon and Magnesium.

*11 Toxicological Information

· Information on toxicological effects:

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

15687-27-1 Ibuprofen

Oral	LD50	636 mg/kg (Rat)
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9004-34-6 Microcrystalline Cellulose

Oral	LD50	>5,000 mg/kg (Rat)
Dermal	LD50	>2,000 mg/kg (Rabbit)

99439-28-8 Colloidal Silicon Dioxide

Oral	LD50	5,000 mg/kg (Rat)
Dermal	LD50	2,000 mg/kg (Rat)

13463-67-7 Titanium Dioxide

Oral	LD50	>10,000 mg/kg (Rat)
Dermal	LD50	>10,000 mg/kg (Rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (Rat)

· Primary irritant effect:

· **On the skin:** No irritating effect.

· **On the eye:** No irritating effect.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

· Carcinogenic categories:

· IARC (International Agency for Research on Cancer):

Group 1 - Carcinogenic to humans

Group 2A - Probably carcinogenic to humans

Group 2B - Possibly carcinogenic to humans

Group 3 - Not classifiable as to its carcinogenicity to humans

Group 4 - Probably not carcinogenic to humans

9002-89-5	Poly(vinyl alcohol)	3
13463-67-7	Titanium Dioxide	2B

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Trade Name: Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

14807-96-6	Talc	3
2783-94-0	FD&C Yellow #6	3

· **NTP (National Toxicology Program):**

None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

*12 Ecological Information

· **Toxicity:**

· **Aquatic toxicity:**

99439-28-8 Colloidal Silicon Dioxide

EC50 10,000 mg/l (Trout)

13463-67-7 Titanium Dioxide

EC50 >1,000 mg/l (Water flea)

· **Persistence and degradability:** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential:** No further relevant information available.

· **Mobility in soil:** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment:**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects:** No further relevant information available.

13 Disposal Considerations

· **Waste treatment methods**

· **Recommendation:**

Smaller quantities can be disposed of with household waste.

Observe all federal, state and local environmental regulations when disposing of this material.

· **Uncleaned packaging**

· **Recommendation:** Dispose of as unused product.

14 Transport Information

· **UN-Number:**

· **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material

· **UN proper shipping name:**

· **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material

· **Transport hazard class(es):**

· **DOT, ADR/ADN, ADN, IMDG, IATA**

Non-Regulated Material

· **Class:**

Non-Regulated Material

· **Packing group:**

Non-Regulated Material

· **DOT, ADR/ADN, IMDG, IATA**

Not applicable.

· **Environmental hazards:**

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Trade Name: Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

* 15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

- **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

15687-27-1	Ibuprofen	ACTIVE
9004-34-6	Microcrystalline Cellulose	ACTIVE
9005-25-8	Starch	ACTIVE
9002-89-5	Poly(vinyl alcohol)	ACTIVE
557-04-0	Magnesium Stearate	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE
25322-68-3	Polyethylene Glycol	ACTIVE
14807-96-6	Talc	ACTIVE
2783-94-0	FD&C Yellow #6	ACTIVE

- **Hazardous Air Pollutants**

None of the ingredients are listed.

- **California Proposition 65:**



WARNING: This product can expose you to chemicals including the listed chemicals which are known to the State of California to cause cancer, birth defects and/or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

- **Chemicals known to cause cancer:**

13463-67-7 Titanium Dioxide

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

- **New Jersey Right-to-Know List:**

9004-34-6 Microcrystalline Cellulose

13463-67-7 Titanium Dioxide

25322-68-3 Polyethylene Glycol

14807-96-6 Talc

- **New Jersey Special Hazardous Substance List:**

14807-96-6 Talc

CA

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Trade Name: Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

· Pennsylvania Right-to-Know List:

9004-34-6	Microcrystalline Cellulose
9005-25-8	Starch
13463-67-7	Titanium Dioxide
25322-68-3	Polyethylene Glycol
14807-96-6	Talc

· Pennsylvania Special Hazardous Substance List:

None of the ingredients are listed.

· Carcinogenic categories:

EPA (Environmental Protection Agency):
None of the ingredients are listed.

· TLV (Threshold Limit Value established by ACGIH):

9005-25-8	Starch	A4
13463-67-7	Titanium Dioxide	A4
14807-96-6	Talc	A4

· NIOSH-Ca (National Institute for Occupational Safety and Health):

13463-67-7	Titanium Dioxide
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· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms:



· Signal word: Warning

· Hazard-determining components of labeling:

Ibuprofen

· Hazard statements:

H302 Harmful if swallowed.

· Precautionary statements:

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· National regulations:

None of the ingredients are listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· Date of last revision/ revision number: 12/03/2019 / 2

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Trade Name: Ibuprofen Tablets, USP 200 mg (Orange Tablets & Caplets)

Abbreviations and acronyms:

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
Carc. 2: Carcinogenicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

*** Data compared to the previous version altered.**

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