

SAFETY DATA SHEET

Section 1: Identification	
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Product	Ibuprofen Tablets USP 800mg
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-780-10 (bottles of 100's) 70512-781-50 (bottles of 500's)
Section 2: Hazard(s) Identification	
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Hazard classification of chemical mixture	
Physical:	Not hazardous
Health:	Eye irritant Category 2A specific, target organ toxicity, Category 3 (respiratory irritation)
Signal Word:	WARNING
Hazard Statement:	Harmful if swallowed. Suspected of damaging the unborn child. Causes serious eye irritation. May cause respiratory irritation.
Precautionary Statement:	Avoid breathing dust. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. 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.
Storage/Disposal:	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]
EU Classification:	Not available
US GHS Classification:	Not available

Section 3: Composition/Information on Ingredients

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Mixtures: Material does not meet the criteria of a substance according to the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and EU EINECS.

Composition			
Components (Chemical Name)	Identifiers (CAS Number)	% Composition	Classification according to regulations (US GHS / EU EINECS)
Ibuprofen	15687-27-1	*	Not available
Colloidal silicon dioxide	7631-86-9	*	Not available
Microcrystalline cellulose	9004-34-6	*	Not available
Pregelatinized starch	9005-25-8	*	Not available
Sodium Starch Glycolate	9063-38-1	*	Not available
Talc	14807-96-6	*	Not available
Magnesium Stearate	557-04-0	*	Not available
Opadry	N/A	*	Not available
Purified Water	N/A	*	Not available
Novomix GEN	N/A	*	Not available

Note: Percentage composition is not captured due to trade secret

Section 4: First-Aid Measures

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Inhalation

Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin

Wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash before reuse.

Eye

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 and effects both acute and delayed:

Symptoms

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.

Other hazards

Not available

UN GHS/EU EINECS

Not available

Effects

Not available

Indication of immediate medical attention and special treatment needed

Notes for the doctor

Immediate medical attention is recommended for overdose.

Special treatment

Not available

Section 5: Fire-Fighting Measures

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Suitable extinguishing media

Use carbon dioxide, dry chemical, or water spray

Unsuitable extinguishing media

Not available

Firefighting procedures

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

Unusual fire and explosion hazards

Not available

Hazardous combustion products

Formation of toxic gases is possible during heating or fire

Additional information

Not available

Section 6: Accidental Release Measures

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Personal precautions, protective equipment and emergency procedures

Personal precautions

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 clean-up. If dust is present, eliminate all sources of ignition.

Emergency procedure

Not available

Methods and material for containment and cleaning up

Containment/Cleanup measures

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.

Prohibited materials Not available			
Section 7: Handling and Storage			
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Precautions for safe handling			
Protective measures			
Safe handling If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.			
Fire prevention Not available			
Dust generation preventions Avoid the generation of dust.			
Environmental precautions Not available			
Conditions for safe storage, including any incompatibilities Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]			
Technical measure and storage condition Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]			
Special packaging materials Not available			
Requirement for storage rooms and assembly Not available			
Incompatible materials or ignition sources Not available			
Section 8: Exposure Controls / Personal Protection			
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Control parameters General ventilation normally adequate			
Exposure limits/guidelines: refer to the occupational exposure limits/guidelines for the individual product components.			
Component Name	Result	OSHA/TWA	Other agency information
Ibuprofen	TWA	Not available	200 ug/m ³ TWA Perrigo OEB1
Colloidal silicon dioxide	PEL/TWA	6mg/m ³ 15 mg/m (Total dust) 5 mg/m ³ (Respirable)	2mg/m ³
Microcrystalline cellulose	PEL/TWA	15 mg/m ³ (Total dust)	10 mg/m ³ (TWA)

		5 mg/m ³ (respirable fraction of dust)	
Pregelatinized starch	TWA ACGIH TLV/TWA OSHA PEL	10mg/m ³ 5 mg/m ³ (respirable) 15 mg/m ³ (total dust)	Not available
Sodium starch glycolate	TWAs	Not available	Not available
Talc	PEL/TWA	20 mppcf	2 mg/m ³
Magnesium stearate	TWA/PEL	5 mg/m ³ (Respirable fraction for nuisance dusts) 15 mg/m ³ Total dust	10 mg/m ³
Opadry	Not available	Not available	Not available
Purified Water	Not available	Not available	Not available
Novomix GEN	Not available	Not available	Not available

Exposure Controls

Engineering controls	General ventilation normally adequate
Personal protective equipment	
Hands	Not available
Eyes	Chemical safety goggles recommended for handling damaged tablets or tablets
Skin	Impervious gloves recommended for handling damaged tablets
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.
Special requirements for PPE	Not available

Section 9: Physical and Chemical Properties
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Information on physical and chemical properties

Material description	
Physical form	Tablets
Color	2005112 - White colored, round shaped biconvex film coated tablets engraved with "IBU 400" on one side 2005113 - White colored, oval shaped biconvex film coated tablets engraved with "IBU 600" on one side 2005214 - White colored, capsule shaped biconvex film coated tablets engraved with "IBU 800" on one side 2007895 - White to off - white powder
Odor	Not available
General properties	
Boiling point	Not available
Melting point	Not available

Water solubility	Not available
Specific gravity/relative density	Not available
pH	Not available
Decomposition temperature	Not available
Viscosity	Not available
Density	Not available
Partition coefficient	Not available
Volatility and flammability	Not available
Vapour pressure	Not available
Vapour density	Not available
Evaporation rate	Not available
Flash point	Not available
Upper exposure limit	Not available
Lower exposure limit	Not available
Flammability (solid, gas)	Not available

Section 10: Stability and Reactivity

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Reactivity	Not reactive under normal conditions of use
Chemical stability under normal ambient temperature	This product is expected to be stable
Possibility of hazardous reactions	Not available
Any stabilizer requirement on storage	Not available
Conditions to avoid	Not available
Incompatible materials	Avoid oxidizing agents
Hazardous decomposition products	Thermal decomposition may yield carbon dioxides

Section 11: Toxicological Information

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General Information

Handling of formulated product is not expected to cause any toxicological effects. The data pertains to the ingredient in formulations, rather than this specific formulation.

Components	CAS No.	Acute Toxicity			
		Species	Route	End Point	Dose
Ibuprofen	15687-27-1	Rat	Oral	LD50	636 mg/kg
Colloidal silicon dioxide	7631-86-9	Rat	Oral	LD50	3160 mg/kg
Microcrystalline cellulose	9004-34-6	Rabbit	Dermal	LD50	>2000 mg/kg
		Rat	Oral	LD50	>2000 mg/kg
Pregelatinized starch	9005-25-8	Mouse	Intra peritoneal	LD50	6600 mg/kg
Sodium Starch Glycolate	9063-38-1	Rat	Oral	LD50	>5000 mg/kg
Talc	14807-96-6	Rat	Oral	LD50	1600 mg/kg
Magnesium Stearate	557-04-0	Rat	Oral	LD50	>2000 mg/kg
		Rat	Inhalation	LC50	>2000 mg/kg
Opadry	N/A	Not available	Not available	Not available	Not available

Purified Water	N/A	Not available	Not available	Not available	Not available
Novomix GEN	N/A	Not available	Not available	Not available	Not available

Potential Health Effects

Inhalation

Acute (Immediate)	Inhalation of dust from damaged tablets may cause irritation of the mucous membranes and upper respiratory tract
Chronic (Delayed)	Not available

Skin

Acute (Immediate)	Contact may cause slight irritation
Chronic (Delayed)	Not available

Eye

Acute (Immediate)	Contact may cause irritation with redness and tearing. Ibuprofen is irritating to human eyes.
Chronic (Delayed)	Not available

Ingestion

Acute (Immediate)	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.
Chronic (Delayed)	Not available

Section 12: Ecological Information

Section 12, Ecological Information

Toxicity	Ibuprofen: LC50 fish (<i>Lepomis macrochirus</i>) 173 mg/L/96 hr; EC50 daphnia magna 29.6 mg/L/48 hr, NOEC daphnia magna 20mg/L/21 d; ErC50 algae (<i>Scenedesmus subspicatus</i>) 315 mg/L/72 hr.
Persistence and degradability	Ibuprofen: not readily biodegradable
Bio accumulative potential	Ibuprofen: log Kow 3.87
Mobility in soil	Not available
Other adverse effects	Not available

Section 13: Disposal Considerations

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Product waste

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

Packaging waste

Not available

Section 14: Transport Information

Section 14, Transport Information

UN number

Not available

UN shipper name

Not available

Transport hazard class

Non Hazardous

Environmental hazards

Not applicable

Transport in bulk according to Annex II or MARPOL 73/78 and the IBC Code

Non Hazardous

Section 15: Regulatory Information

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Components	CAS No.	CERCLA/SARA Emission Reporting
Ibuprofen	15687-27-1	Not listed
Colloidal silicon dioxide	7631-86-9	Not listed
Microcrystalline cellulose	9004-34-6	Not listed
Pregelatinized starch	9005-25-8	Not listed
Sodium Starch Glycolate	9063-38-1	Not listed
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Magnesium Stearate	557-04-0	Not listed
Opadry	N/A	Not listed
Purified Water	N/A	Not listed
Novomix GEN	N/A	Not listed

Note: Superfund Amendments and Reauthorization Act or Superfund or Comprehensive Environment Response, Compensation and Liability Act of 1980 (CERCLA)

Section 16: Other Information

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The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.