


SAFETY DATA SHEET

Section 1: Identification		
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Product	Ibuprofen Tablets, USP 300mg	
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	70512-794-90 (bottles of 90's)	
Section 2: Hazard(s) Identification		
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<u>According to Regulation NOM-018-STPS-2015</u>		
Classification of the product		
Acute Tox.	4 (oral)	Acute toxicity
Eye Dam./Irrit.	2A	Serious eye damage/eye irritation
STOT SE	3 (irritating to respiratory system)	Specific target organ toxicity — single exposure
Aquatic Acute	3	Hazardous to the aquatic environment - acute
Combustible Dust	Combustible Dust (1)	Combustible Dust
Label elements		
Pictogram:		
		
Signal Word:		
Warning		
Hazard Statement:		
H319	May form combustible dust concentration in air. Causes serious eye irritation.	
H302	Harmful if swallowed.	
H335	May cause respiratory irritation.	
H402	Harmful to aquatic life.	

Precautionary Statements (Prevention):

P271	Use only outdoors or in a well-ventilated area.
P280	Wear eye protection.
P261	Avoid breathing dust or fume.
P273	Avoid release to the environment.
P270	Do not eat, drink or smoke when using this product.
P264	Wash contaminated body parts thoroughly after handling.

Precautionary Statements (Response):

P312	Call a POISON CENTER or physician if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330	Rinse mouth
P337 + P313	If eye irritation persists: Get medical attention.

Precautionary Statements (Storage):

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Precautionary Statements (Disposal):

P501	Dispose of contents/container in accordance with local regulations.
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Hazards not otherwise classified

The product is under certain conditions capable of dust explosion.

Section 3: Composition/Information on Ingredients
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According to Regulation NOM-018-STPS-2015
Ibuprofen

CAS Number	15687-27-1
Content (W/W)	100.0%
Synonym	2-(4-Isobutylphenyl)propionic acid; Ibuprofen, Brufen

Section 4: First-Aid Measures
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Description of first aid measures
General advice:

First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). Immediately remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air, seek medical attention.

If on skin:

Wash thoroughly with soap and water

If in eyes:

Hold eyes open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing. If irritation develops, seek medical attention.

If swallowed:

Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: Overexposure may cause: vomiting, urticaria, coordination disorder, abdominal cramps, lethargy, tinnitus, nausea, itching, headache

Hazards: Causes adverse effects on the kidney and liver; causes effects on blood and blood forming organs.

Indication of any immediate medical attention and special treatment needed
Note to Physician

Treatment	Treat according to symptoms (decontamination, vital functions), no known specific antidote
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Section 5: Fire-Fighting Measures

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Extinguishing media

Suitable extinguishing media:

water spray, dry powder, carbon dioxide, foam

Unsuitable extinguishing media for safety reasons:

water jet

Additional information:

Avoid whirling up the material/product because of the danger of dust explosion.

Special hazards arising from the substance or mixture

Hazards during fire-fighting:

carbon oxides, harmful vapours

The substances/groups of substances mentioned can be released in case of fire. Dust explosion hazard.

Advice for fire-fighters

Protective equipment for fire-fighting:

Wear self-contained breathing apparatus and chemical-protective clothing.

Further information:

Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations. Cool endangered containers with water-spray. Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.

Impact Sensitivity

Remarks	Based on the chemical structure, there is no shock-sensitivity.
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Section 6: Accidental Release Measures

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Further accidental release measures:

Avoid dispersal of dust in the air (e.g. by clearing dusty surfaces with compressed air). Avoid the formation and build-up of dust - danger of dust explosion. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition.

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not breathe dust. Ensure adequate ventilation. Avoid contact with the skin, eyes and clothing. Use personal protective clothing. Information regarding personal protective measures, see section 8.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Contain with dust binding material and dispose of.

For large amounts: Sweep/shovel up.

Avoid raising dust. Dispose of absorbed material in accordance with regulations. Cleaning operations should be carried out only while wearing breathing apparatus.

Nonsparking tools should be used.

Section 7: Handling and Storage

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Precautions for safe handling

Avoid dust formation. Provide exhaust ventilation if dust is formed. Wear suitable protective clothing and eye/face protection. Avoid contact with the skin, eyes and clothing.

Protection against fire and explosion:

Avoid dust formation. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids (2013 Edition) for safe handling.

Dust explosion class: Dust explosion class 2 (Kst-value 200 up to 300 bar m s⁻¹).

Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Keep container tightly closed and dry.

Section 8: Exposure Controls / Personal Protection

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No substance specific occupational exposure limits known.

Advice on system design:

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection:

Respiratory protection in case of vapour/aerosol release. Wear a NIOSH-certified (or equivalent) respirator as necessary.

Hand protection:

Wear chemical resistant protective gloves.

Eye protection:

Wear safety goggles (chemical goggles) if there is potential for airborne dust exposures.

Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g. head protection, apron, protective boots, chemical-protection suit.

General safety and hygiene measures:

Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Do not breathe dust. Avoid contact with the skin, eyes and clothing. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately. Wash soiled clothing immediately.

Section 9: Physical and Chemical Properties

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Form:	crystalline, powder	
Odour:	almost odourless	
Odour threshold:	not determined	
Colour:	white	
pH value:	substance/mixture is non-soluble (in water)	
melting range:	75 - 77 °C (1,013 hPa) Literature data.	
Freezing point:	No data available	
Boiling range:	154 - 157 °C (5.32 hPa) Literature data.	(other)
Boiling point:	(1,013 hPa) The substance / product decomposes therefore not determined.	
Flash point:	not applicable, the product is a solid	
Flammability:	not highly flammable	(UN Test N.1 (ready combustible solids))
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Vapour pressure:	< 0.001 hPa (25 °C) Literature data.	
Density:	1.18 g/cm ³ (20 °C) Literature data.	(other)
Relative density:	1.18 (20 °C) Literature data.	(other)

Bulk density:	200 - 600 kg/m ³ Literature data.
Vapour density:	The product is a non-volatile solid.
Partitioning coefficient n-octanol/water (log Pow):	3.87 (25 °C) Literature data.
Self-ignition temperature:	Based on its structural properties the product is not classified as self-igniting.
Thermal decomposition:	No decomposition if stored and handled as prescribed/indicated.
Viscosity, dynamic:	not applicable, the product is a solid
Viscosity, kinematic:	No data available.
Particle size:	No data available.
Solubility in water:	0.01139 g/l (25 °C) Literature data.
Molar mass:	206.28 g/mol
Evaporation rate:	The product is a non-volatile solid.

Section 10: Stability and Reactivity

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Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals:

No corrosive effect on metal.

Oxidizing properties:

Based on its structural properties the product is not classified as oxidizing. (other)

Dust explosion class:

Dust explosion class 2 (Kst-value 200 up to 300 bar m s ⁻¹) (St 2)		
Formation of flammable gases:	Remarks:	Forms no flammable gases in the presence of water.

Possibility of hazardous reactions

The product is chemically stable.

Dust explosion hazard.

Conditions to avoid

Avoid electro-static discharge. Avoid all sources of ignition: heat, sparks, open flame.

Incompatible materials

oxidizing agents, strong alkalies

Hazardous decomposition products

Decomposition products:

Hazardous decomposition products: No hazardous decomposition products if stored and handled as prescribed/indicated.

Thermal decomposition:

No decomposition if stored and handled as prescribed/indicated.

Section 11: Toxicological Information

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Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Of moderate toxicity after single ingestion.

Oral

Type of value: LD50

Species: rat

Value: 1,600 mg/kg

Inhalation

No data available.

Dermal

No data available.

Assessment other acute effects

Assessment of STOT single:

Causes temporary irritation of the respiratory tract.

Irritation / corrosion

Assessment of irritating effects: May cause slight irritation to the skin. Eye contact causes irritation.

Skin

Species: human

Result: non-irritant

Eye

Species: human

Result: Irritant.

Sensitization

Assessment of sensitization: Skin sensitizing effects were not observed in animal studies.

Guinea pig maximization test

Species: guinea pig

Result: Non-sensitizing.

Method: OECD Guideline 406

Aspiration Hazard

not applicable

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: The substance may cause damage to the kidney after repeated ingestion of high doses, as shown in animal studies.

Genetic toxicity

Assessment of mutagenicity: The substance was not mutagenic in bacteria.

Carcinogenicity

Assessment of carcinogenicity: In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed.

Reproductive toxicity

Assessment of reproduction toxicity: The results of animal studies gave no indication of a fertility impairing effect.

Teratogenicity

Assessment of teratogenicity: No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Section 12: Ecological Information

Section 12, Ecological Information

Toxicity

Aquatic toxicity

Assessment of aquatic toxicity:

Acutely harmful for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish

LC50 (96 h) 173 mg/l, *Lepomis macrochirus* (Screening test, static)

Nominal concentration.

Aquatic invertebrates

EC50 (48 h) 35.79 mg/l, *Daphnia magna* (Daphnia test acute)

Aquatic plants

EC50 (72 h) 342.2 mg/l (growth rate), *Desmodesmus subspicatus* (Guideline 92/69/EEC, C.3, static)

The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to fish

No observed effect concentration (33 d) > 3 mg/l, *Pimephales promelas* (OECD Guideline draft, Flow through.)

The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to aquatic invertebrates

No observed effect concentration (21 d) 5.36 mg/l, aquatic mollusc (other, Flow through.)
Nominal concentration.

Microorganisms/Effect on activated sludge

Toxicity to microorganisms

soil
bacteria/EC50 (20 min): 120.1 mg/l

Persistence and degradability

Assessment biodegradation and elimination (H2O)

Not readily biodegradable (by OECD criteria). Moderately/partially biodegradable.

Elimination information

20 - 60 % BOD of the ThOD (28 d) (OECD 301D; EEC 92/69, C.4-E) (aerobic, activated sludge)

Assessment of stability in water

According to structural properties, hydrolysis is not expected/probable.

Bioaccumulative potential

Assessment bioaccumulation potential

No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Mobility in soil

Assessment transport between environmental compartments

The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is not expected.

Additional information

Other ecotoxicological advice:
No data available.

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Waste disposal of substance:

Observe national and local legal requirements.

Container disposal:

Dispose of in accordance with national, state and local regulations.

Section 14: Transport Information

Section 14, Transport Information

Land transport TDG	Not classified as a dangerous good under transport regulations
Sea transport IMDG	Not classified as a dangerous good under transport regulations
Air transport IATA/ICAO	Not classified as a dangerous good under transport regulations

Section 15: Regulatory Information

Section 15, Regulatory Information

Federal Regulations

Not applicable

NFPA Hazard codes:

Health: 2 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 2 Flammability: 1 Physical hazard: 0

Assessment of the hazard classes according to UN GHS criteria (most recent version):

Acute Tox.	4 (oral)	Acute toxicity
Skin Corr./Irrit.	3	Skin corrosion/irritation
STOT SE	3 (irritating to respiratory system)	Specific target organ toxicity — single exposure
Aquatic Acute	3	Hazardous to the aquatic environment - acute
Eye Dam./Irrit.	2A	Serious eye damage/eye irritation

Section 16: Other Information

Section 16, Other Information

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.