

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Product Name	Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg
Manufacturer	Bausch Health Companies Inc. Quebec H7L 4A8 Canada
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Classification of the substance or mixture

GHS-US classification	Acute toxicity (oral), Category 4	H302
	Carcinogenicity, Category 2	H351
	Full text of H statements : see section 16	

Label elements GHS-US labelling

Hazard pictograms (GHS-US)



GHS07

GHS08

Signal word (GHS-US)

Warning

Contains

Ibuprofen; Titanium dioxide

Hazard statements (GHS-US)

H302 - Harmful if swallowed
H351 - Suspected of causing cancer (Inhalation)

Precautionary statements (GHS-US)

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear eye protection, protective gloves
P301+P312 - If swallowed: Call a doctor if you feel unwell
P308 + P313 - If exposed or concerned: Get medical advice/attention
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container to Collection point

Other hazards

No additional information available

Unknown acute toxicity (GHS US)

3% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal)
 3% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

Section 3: Composition/Information on Ingredients

Substances

Not applicable

Mixtures

Name	Product identifier	%	GHS-US classification
Ibuprofen (Main constituent)	(CAS No) 15687-27-1	70 - 83	Acute Tox. 4 (Oral), H302
Famotidine (Main constituent)	(CAS No) 76824-35-6	2 - 3	Not classified
Titanium dioxide	(CAS No) 13463-67-7	0.68 - 1.38	Carc. 2, H351

***Chemical name, CAS number and/or exact concentration have been withheld as a trade secret**

Full text of hazard classes and H-statements : see section 16

Section 4: First-Aid Measures

Description of first aid measures

First-aid measures general	Never give anything by mouth to an unconscious person. If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	Gently wash with plenty of soap and water.
First-aid measures after eye contact	In case of contact, immediately flush eyes with plenty of water.
First-aid measures after ingestion	Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	May cause cancer by inhalation.
Symptoms/injuries after skin contact	May cause slight irritation.
Symptoms/injuries after eye contact	May cause slight irritation.
Symptoms/injuries after ingestion	Harmful if swallowed.
Chronic symptoms	Long term exposure. Target organ(s). blood. lungs. central nervous system.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Section 5: Fire-Fighting Measures

Extinguishing Media.

Suitable extinguishing media	Carbon dioxide. Dry chemical. Foam. Water spray.
Unsuitable extinguishing media	Do not use a heavy water stream.

Special hazards arising from the substance or mixture

Fire hazard	Not flammable.
Explosion hazard	Dust may form explosive mixture in air.
Reactivity	No dangerous reactions known.
Advice for firefighters	
Firefighting instructions	Dike and collect water used to fight the fire.
Protection during firefighting	Wear a self-contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

General measures	Do not breathe dust.
For non-emergency personnel	
Protective equipment	Wear suitable protective clothing and gloves. Refer to section 8.
Emergency procedures	Evacuate unnecessary personnel
For emergency responders	
Protective equipment	Avoid release to the environment.
Emergency procedures	Wear suitable protective clothing and gloves. Refer to section 8.
Emergency procedures	Ventilate area.
Environmental precautions	Avoid release to the environment.
Methods and material for Containment and cleaning up	
For containment	Contain and collect as any solid
Methods for cleaning up	Large spills: Wipe up with absorbent material (for example cloth). Minimize generation of dust.
Reference to other sections	Section 7: safe handling. Section 8: personal protective equipment.

Section 7: Handling and Storage

Precautions for safe handling

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Avoid dust formation.
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.

Conditions for safe storage, including any incompatibilities

Storage conditions	Keep container tightly closed.
Heat and ignition sources	Keep away from heat, sparks and flame.

Storage area

Store in dry, cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Control parameters

Ibuprofen (15687-27-1)	Not applicable		
Famotidine (76824-35-6)	Not applicable		
Titanium dioxide (13463-67-7)	ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
	OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³

Exposure controls

Appropriate engineering controls

Ensure good ventilation of the work station.

Personal protective equipment

Avoid all unnecessary exposure.

Hand protection

Wear suitable gloves.

Eye protection

Chemical goggles or safety glasses.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. NIOSH. Approved respirator.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Tablets.
Colour	Blue
Odour	Odourless
Odour threshold	No data available
pH	No data available
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Relative evaporation rate (butylacetate=1)	No data available
Flammability (solid, gas)	No data available
Explosive limits	No data available
Explosive properties	No data available
Oxidising properties	No data available
Vapour pressure	No data available

Relative density	No data available
Relative vapour density at 20 °C	No data available
Solubility	No data available
Log Pow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Other information	No additional information available

Section 10: Stability and Reactivity

Reactivity	No dangerous reactions known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Conditions to avoid	Avoid creating or spreading dust. Heat.
Incompatible materials	None known
Hazardous decomposition products	None known

Section 11: Toxicological Information

Information on toxicological effects

Likely routes of exposure Skin and eye contact; Inhalation; Ingestion

Acute toxicity Oral: Harmful if swallowed

Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg	
ATE US (oral)	766.265 mg/kg bodyweight
Ibuprofen (15687-27-1)	
LD50 oral rat	636 mg/kg ; 740 mg/kg mice; 1400 mg/kg rabbits
ATE US (oral)	636.000 mg/kg bodyweight
Famotidine (76824-35-6)	
LD50 oral rat	> 3000 mg/kg
Titanium dioxide (13463-67-7)	
LD50 oral rat	> 5000 mg/kg
LC50 inhalation rat (mg/l)	> 6.82 mg/l/4h

Skin corrosion/irritation Not classified

Serious eye damage/irritation Not classified

Respiratory or skin sensitisation	Not classified								
Germ cell mutagenicity	Not classified								
Carcinogenicity	Suspected of causing cancer (Inhalation).								
<table border="1"> <tr> <th colspan="2">Titanium dioxide (13463-67-7)</th> </tr> <tr> <td>NOAEL (chronic, oral, animal/ male, 2 years)</td> <td>5 mg/kg bodyweight rat</td> </tr> <tr> <td>Additional information</td> <td>Carcinogen Inhalation of dust</td> </tr> <tr> <td>IARC group</td> <td>2B - Possibly carcinogenic to humans, as dust</td> </tr> </table>		Titanium dioxide (13463-67-7)		NOAEL (chronic, oral, animal/ male, 2 years)	5 mg/kg bodyweight rat	Additional information	Carcinogen Inhalation of dust	IARC group	2B - Possibly carcinogenic to humans, as dust
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NOAEL (chronic, oral, animal/ male, 2 years)	5 mg/kg bodyweight rat								
Additional information	Carcinogen Inhalation of dust								
IARC group	2B - Possibly carcinogenic to humans, as dust								
Reproductive toxicity	Not classified								
Specific target organ toxicity (single exposure)	Not classified								
Specific target organ toxicity (repeated exposure):	Not classified								
Aspiration hazard	Not classified								
Symptoms/injuries after inhalation	May cause cancer by inhalation.								
Symptoms/injuries after skin contact	May cause slight irritation.								
Symptoms/injuries after eye contact	May cause slight irritation.								
Symptoms/injuries after ingestion	Harmful if swallowed.								
Chronic symptoms	Long term exposure. Target organ(s). blood. lungs. central nervous system.								

Section 12: Ecological Information

Toxicity

Ecology - general

No ecotoxicological data about this product are known.

Ibuprofen (15687-27-1)	
LC50 fish 1	173 mg/l sunfish, bluegill
EC50 Daphnia 1	9.06 mg/l Skeletonema costatum
EC50 other aquatic organisms 1	20.5 mg/l

Persistence and degradability

Ibuprofen and Famotidine Tablets, 800 mg / 26.6 mg	
Persistence and degradability	Not established.
Ibuprofen (15687-27-1)	
Persistence and degradability	Not readily biodegradable. Moderately biodegradable.

Bioaccumulative potential

Ibuprofen and Famotidine Tablets, 800 mg / 26.6 mg	
Bioaccumulative potential	Not established.
Ibuprofen (15687-27-1)	
Log Pow	3.87 (calculated)
Famotidine (76824-35-6)	
Log Pow	-0.64

Mobility in soil

Ibuprofen and Famotidine Tablets, 800 mg / 26.6 mg	
Ecology - soil	Not established.

Other adverse effects

Other information

No additional information available.

Section 13: Disposal Considerations**Waste treatment methods**

Waste disposal recommendations

Dispose in a safe manner in accordance with local/national regulations.

Section 14: Transport Information**Department of Transportation (DOT)**

In accordance with DOT

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Section 15: Regulatory Information**US Federal regulations**

This product or mixture does not contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

Ibuprofen (15687-27-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Titanium dioxide (13463-67-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

International regulations**CANADA****Ibuprofen (15687-27-1)**

Listed on the Canadian DSL (Domestic Substances List) inventory

Titanium dioxide (13463-67-7)

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)

Titanium dioxide (13463-67-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National regulations**Titanium dioxide (13463-67-7)**

Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on KECI (Korean Existing Chemicals Inventory)
Listed on Taiwan National Chemical Inventory
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on NZIoC (New Zealand Inventory of Chemicals)

US State regulations

California Proposition 65 - This product contains, or may contain, trace quantities of a substance(s) known to the state of California to cause cancer, developmental and/or reproductive harm

Titanium dioxide (13463-67-7)

U.S. - California - Proposition 65 -Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity – Female	U.S. - California - Proposition 65 - Reproductive Toxicity – Male	Non-significant risk level (NSRL)
Yes	No	No	No	

- U.S. - Minnesota - Hazardous Substance List
- U.S. - New Jersey - Right to Know Hazardous Substance List
- U.S. - New York - Right to Know List of Hazardous Substances
- U.S. - Washington - Permissible Exposure Limits - TWAs
- U.S. - Washington - Permissible Exposure Limits - STELs

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.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.