

Safety Data Sheet

Ibuprofen 50

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Version: 2.0

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(30076166/SDS_GEN_DO/EN)

1. Identification

Product identifier used on the label

Ibuprofen 50

Recommended use of the chemical and restriction on use

Recommended use*: Pharmaceutical agent

Unsuitable for use: Not intended for sale to or use by the general public.

* The "Recommended use" identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:

BASF Dominicana S.A
Av. Winston Churchill
Acropolis Center Tower
8vo Piso. SPATIUM
Pinatini, 10148
Santo Domingo, República Dominicana
Telephone: (1) 809 334-1026

Emergency telephone number

24 Hour Emergency Response Information

CHEMTREC 1-703-527-3887
Or call 911

Other means of identification

Molecular formula: C(13)H(18)O(2)
Synonyms: 2-(4-Isobutylphenyl)propionic acid; Ibuprofen, Brufen

2. Hazards Identification

According to Regulation NOM-018-STPS-2015

Classification of the product

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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.
H302	Causes serious eye irritation.
H335	Harmful if swallowed.
H402	May cause respiratory irritation.
	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.

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3. Composition / Information on Ingredients

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

4. First-Aid Measures

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.

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:

water spray, dry powder, carbon dioxide, foam

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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.

6. Accidental release measures

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.

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7. Handling and Storage

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.

8. Exposure Controls/Personal Protection

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

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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.

9. Physical and Chemical Properties

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	

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Evaporation rate: The product is a non-volatile solid.

10. Stability and Reactivity

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.
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Chemical stability

The product is stable if stored and handled as prescribed/indicated.

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 alkalis

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.

11. Toxicological information

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.

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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

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

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

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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.

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.

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

15. Regulatory Information

Federal Regulations

Not applicable

NFPA Hazard codes:

Health: 2 Fire: 1 Reactivity: 0 Special:

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

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

16. Other Information

SDS Prepared by:
BASF NA Product Regulations
SDS Prepared on: 2022/10/27

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our operations on society and the environment during production, storage, transport, use and disposal of our products.

This information is considered accurate but is not exhaustive and shall only be used as a guideline based on current knowledge of the chemical substance or mixture. Safety precautions suitable for the product must be applied.

END OF DATA SHEET