

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

IBUPROFENUM

EN

FORM-06-14-01 (V00)

Page 1/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Ibuprofen
Ibuprofenum
Ibuprofen
Ibuprofène
Ibuprofen

N° CAS: 15687-27-1

N° EC: 239-784-6

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Repr. 1B	H360d

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302	Harmful if swallowed.
H360d	May damage the unborn child.

Precautionary statements:

P281	Use personal protective equipment as required.
------	--

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



IBUPROFENUM

P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy/while nursing.
P309+P311	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Ibuprofen
IUPAC name:	(2 <i>RS</i>)-2-[4-(2-Methylpropyl)phenyl]propanoic acid
Synonyms:	Brufen Motrin
N° CAS:	15687-27-1
N° EC:	239-784-6
Molecular Formula:	C ₁₃ H ₁₈ O ₂
Content:	98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing and shoes immediately. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). In case of respiratory distress, give oxygen. Keep the victim warm. Keep victim under observation. Make sure that medical personnel are aware of the substance (s) involved, and that protective precautions are taken.
After inhalation:	Place in fresh air. In case of breathlessness, oxygen may be required. Apply artificial respiration using a pocket mask with a one-way valve or other suitable respiratory medical device. Do not use mouth-to-mouth resuscitation if the victim has inhaled the substance. Seek medical attention if symptoms occur.
After skin contact:	Remove and isolate contaminated clothing and shoes. Wash off with warm water and soap. In case of slight skin contact, spreading of the material on unaffected skin should be avoided. If irritation develops and persists, seek medical attention.
After eye contact:	Immediately flush eyes with plenty of water for at least 15 minutes. Remove any contact lenses if this can be done easily. Seek medical attention if symptoms occur. Continue to rinse.
After ingestion:	Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupful of milk or water. In case of vomiting, keep the head low, so that stomach contents can't enter the lungs.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

IBUPROFENUM

EN

FORM-06-14-01 (V00)

Page 3/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



4.2 Most important symptoms and effects, both acute and delayed

Exposure to powder or dust may be irritating to the eyes, nose and throat.

4.3 Indication of any immediate medical attention and special treatment needed

In case of respiratory distress, give oxygen. Keep the victim warm. Keep victim under observation. Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, foam, dry chemical powder, carbon dioxide (CO₂).

Unsuitable extinguishing media: Do not use water jet as an extinguisher, as this will spread the fire.

5.2 Special hazards arising from the substance/mixture

Under fire conditions, it decomposes and emits toxic fumes.

5.3 Advice for firefighters

Surrounding fires: Keep containers exposed to heat cool with water and remove from the source of the fire if this can be done without risk. Vapors are heavier than air and may travel across the ground to a distant ignition source and then flare up suddenly. In case of fire and/or explosion do not breathe fumes. Containers exposed to flames must be cooled with water until well after the fire has been completely extinguished.

Protection against fire: Firefighters must use standard protective equipment such as a jacket made of fire-retardant material, helmet with full face shield, gloves, rubber boots and, if working in enclosed spaces, self-contained breathing apparatus. Structural protective clothing for firefighters offers only limited protection.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Remove all ignition sources. Avoid inhalation of vapors and spray mist. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

For emergency responders

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Keep upwind. Keep out of low areas. Avoid inhalation of vapors and spray mist. Wear suitable protective equipment and protective clothing during cleaning as indicated in section 8. Remove all ignition sources. Ventilate enclosed spaces before entering them.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Remove ignition sources. Ventilate the contaminated area. Prevent the spread of the spilled area (eg by containment or oil containment baffles). Prevent substance from entering

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

IBUPROFENUM

EN

FORM-06-14-01 (V00)

Page 4/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



waterways, sewers, basements or confined areas. In the event of spill or accidental discharge, notify the appropriate authorities and comply with all regulations in force.

6.3 Methods and material for containment and cleaning up

Remove ignition sources including sources of electrical, static or frictional sparks. Ventilate the contaminated area. Avoid dust formation. Wear suitable protective equipment and protective clothing during cleaning.

Large spills: Dike spilled material where possible. Cover with a piece of plastic to prevent spreading. Thoroughly clean the surface to remove residual contamination.

Small spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Thoroughly clean the surface to remove residual contamination.

6.4 Reference to other sections

For disposal considerations, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Practice good personal hygiene. Avoid breathing dust/fume/gas/mist/vapor/spray. Avoid contact with eyes. Do not use in areas without adequate ventilation. Avoid prolonged exposure. "Empty" containers contain product residues (liquid or vapors) and can be dangerous. Do not reuse empty containers.
Personal protection:	Wear personal protective clothing.
Technical protective measures:	Take precautions against dust accumulation.
Handling:	Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Take measures against dust accumulation. Prevent electrostatic charge build-up by using regular bonding and grounding techniques.
Conditions for safe storage, including any incompatibilities:	Keep containers tightly closed in a dry, cool and well-ventilated place.
Storage – away from:	Store away from incompatible materials (see section 10). Keep away from heat, sparks and open flames.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits:

France - Threshold Limit Values - Exposure Limit Values in Workshops, INRS ED 984:

VME respirable fraction: 5 mg/m³

VME inhalable fraction: 10 mg/m³

Germany, DFG MAK (advisory):

TWA 8h inhalable dust: 4 mg/m³

TWA 8h respirable dust: 0.3 mg/m³

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



IBUPROFENUM

Germany - TRGS 900 - Exposure Limits in Workshops – TWAs:

AGW inhalable fraction: 10 mg/m³

AGW respirable fraction: 1.25 mg/m³

Switzerland SUVA limit values at the workplace: time-weighted average:

TWA 8h respirable dust: 3 mg/m³

TWA 8h inhalable dust: 10 mg/m³

UK EH40 - Occupational Exposure Limits (WELs):

TWA 8h respirable dust: 4 mg/m³

TWA 8h inhalable dust: 10 mg/m³

8.2 Exposure controls

Appropriate engineering control

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits.

Individual protection measures

Eye/face protection: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166 or NIOSH.

Skin protection: Wear appropriate protective clothing to prevent skin exposure.

Hand protection: Wear appropriate protective gloves to prevent skin exposure.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Wear suitable thermal protective clothing if necessary.

Environmental exposure control

Contain spilled product, prevent release of product and observe national regulations regarding emissions. Handle in accordance with good industrial hygiene and safety.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals.

Odour: Characteristic

Odour threshold: Not available.

pH: 5 - 6

Melting/freezing point: 75 – 78 °C

Initial boiling point: 154 °C at 5.32 hPa

319.6 °C at 760 mm Hg

Boiling range: Not available.

Flash point: 216.7 °C

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



IBUPROFENUM

Evaporation rate:	< ether
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	4.74 x10 ⁻⁵ mm Hg at 25 °C
Vapour density:	> air
Relative density:	Not available.
Solubility:	Freely soluble in acetone, in methanol, and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	3,97
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Avoid contact with oxidizing or reducing agents.

10.2 Chemical stability

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3 Possibility of hazardous reactions

No hazardous polymerization takes place.

10.4 Conditions to avoid

Incompatible materials, dust generation, excess heat.

10.5 Incompatible materials

Strong acids and bases, oxidising agents.

10.6 Hazardous decomposition products

Carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (mouse): 740 mg/kg
	Oral LD50 (rabbit): 1400 mg/kg
	Oral LD50 (rat): 636 mg/kg

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 7/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



IBUPROFENUM

Skin corrosion/irritation:	May cause skin irritation.
Serious eye damage/irritation:	Dust or powder can irritate the eye tissue.
Respiratory/skin sensitisation:	May cause sensitisation by skin contact.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	Suspected of damaging fertility or the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Target organs: kidneys. Prolonged or repeated exposure may cause gastrointestinal irritation and kidney damage. Adverse reproductive effects have been reported in humans.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Dust or powder can irritate the eye tissue.
Skin contact:	May cause skin irritation.
Inhalation:	May cause respiratory irritation. Long-term inhalation can be harmful.
Ingestion:	Harmful if swallowed. May cause gastrointestinal irritation with nausea, vomiting and diarrhoea. May cause kidney damage. Human fatalities have been reported from acute poisoning.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute:
Algae EC50: 26 mg/l (Algae)
Crustaceans EC50: 51.4 mg/l, 48h (Daphnia)
Chronic:
Algae NOEC: 0.01 mg/l (Algae)
Crustaceans NOEC: < 1.23mg/l, 48h (Daphnia)

12.2 Persistence and degradability

Not intrinsically biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Hardly mobile. Mobility in general: The product is practically insoluble in water.

12.5 Results of PBT and vPvB assessment

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

IBUPROFENUM

EN

FORM-06-14-01 (V00)

Page 8/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Residual waste: Dispose of in accordance with local regulations.

Contaminated packaging: Even when the package is empty, observe the warnings on the label, as empty packages may contain residues. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not reuse empty containers.

Methods of disposal/information on disposal: Dispose of in accordance with all applicable legal regulations. In the European Union, waste must be classified in accordance with regulations under Directive 91/689/EEC. Must be incinerated in a suitable incineration plant with a permit issued by the competent authorities. Do not allow this material to enter sewers/water supplies.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : CHEMICALS, N.O.S. - NO TRANSPORT REQUIREMENTS

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 9/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



IBUPROFENUM

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

R61 May cause harm to the unborn child.

Safety phrases:

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

IBUPROFENUM

EN

FORM-06-14-01 (V00)

Page 10/10

Publication: 15/02/2022

Revision: XX/XX/XXXX

Version: 00



The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be