

Material Safety Data Sheet

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

DICLOFENACUM DIETHYLAMINUM

EN

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

1.1 Product identifier

Product name: Diclofenac diethylamine
Diclofenacum diethylaminum
Diclofenac diéthylamine
Diclofénac diéthylamine
Diclofenac-diethylamin

N° CAS: 78213-16-8

N° EC: 616-599-2

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	H301+H311
Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Danger
Hazard statements:	
H301+H311	Toxic if swallowed or in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P405	Store locked up.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Diclofenac diethylamine
IUPAC name:	2-[2-(2,6-dichloroanilino)phenyl]acetic acid;N-ethylethanamine
Synonyms:	Diclofenac (diethylamine) Diethylammonium diclofenac
N° CAS:	78213-16-8
N° EC:	616-599-2
Molecular Formula:	C ₁₈ H ₂₂ Cl ₂ N ₂ O ₂
Content:	99.0% to 101.0% (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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After inhalation:	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
After skin contact:	Immediately wash skin soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
After eye contact:	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
After ingestion:	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel. If victim is not breathing perform mouth to mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful by inhalation or skin absorption. Toxic if swallowed. Hazardous in case of eye contact (irritant). To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use alcohol resistant foam, carbon dioxide, water spray or dry chemical spray.
Unsuitable extinguishing media:	A solid water stream may be inefficient.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Hazardous combustion products:	These products are carbon oxides (CO, CO ₂), nitrogen oxides (NO, NO ₂), halogenated compound.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid raising and breathing dust and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

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For emergency responders

Avoid raising and breathing dust and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental precautions

Take precautions to avoid release in to the environment, if safe to do so.

6.3 Methods and material for containment and cleaning up

Contain spill and collect, as appropriate.

Transfer to a chemical waste container for disposal in accordance with local regulation.

6.4 Reference to other sections

For information on safe handling, see section 7.

For information on individual protective measures, see section 8.

For disposal considerations, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid breathing dust/fumes/gas/mist/vapours/spray. Avoid contact with skin & eyes. Avoid prolonged or repeated exposure.
Personal protection:	Not available.
Technical protective measures:	Provide appropriate exhaust ventilation at places where dust is formed.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container. Store locked up.
Conditions for safe storage, including any incompatibilities:	Store at room temperature.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

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Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne level below recommended exposure limit.

Do not take internally.

Facilities storing or utilizing this material should be equipped with eyewash and a safety shower. Wash thoroughly after handling.

Individual protection measures

Eye/face protection: Tightly sealed goggles.

Skin protection: Lab coat.

Hand protection: Compatible chemical resistant gloves.

Respiratory protection: NIOSH approved respirator, as conditions warrant.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	A white to light beige, crystalline powder
Odour:	Odourless
Odour threshold:	Not available.
pH:	6.4 – 8.4 (1% w/v solution in ethanol 10%)
Melting/freezing point:	154 °C
Initial boiling point:	Decomposes.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	The product is not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in acetone, freely soluble in ethanol (96%) and in methanol, practically insoluble in 1 M NaOH.
Solubility in water:	Sparingly soluble in water.
Partition coefficient	Not available.

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(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: The product does not present an explosion hazard.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 318.13 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: The toxicological effects of this product have not been thoroughly studied.

Oral TDLO (women): 30 mg/kg 10D(intermittent)

Oral LD50 (rat): 53 mg/kg

Subcutaneous LD50 (rat): 83 mg/kg

Intraperitoneal LD50 (mouse): 74 mg/kg

Subcutaneous LD5 (mouse): 390 mg/kg

Oral LD50 (rabbit): 157 mg/kg

Oral TDLO (mouse): 8 mg/kg

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: Based on available data, the classification criteria are not met.

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Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
STOT-single exposure:	May cause respiratory irritation.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Toxic if in contact with skin. Causes skin irritation.
Inhalation:	May be irritating to the mucous membrane and upper respiratory tract. May be harmful by inhalation.
Ingestion:	Toxic if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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Waste from residues/unused products: Waste disposal must be in accordance with appropriate local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

Contaminated packaging: Do not re-use empty containers

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) : 2811

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : ADR: 2811 TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac Diethylamine)
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac Diethylamine), MARINE
POLLUTANT
IATA: TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac Diethylamine)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 6.1

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Marine pollutant: yes.

14.6 Special precautions for user

Warning: Toxic substances.

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

Not available.

14.8 Additional transport information

ADR Limited quantities (LQ): 5 kg.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R25 Toxic if swallowed

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Safety phrases:

R24/25 Toxic in contact with skin and if swallowed.

R36/R38 Irritating to eyes and skin.

S1 Keep locked up.

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

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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.).

S46 If swallowed, seek medical advice immediately and show this container or label.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

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

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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)

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.

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16.8 Department issuing MSDS

Quality Department

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