

Material Safety Data Sheet

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

DICLOFENACUM NATRICUM

EN

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

1.1 Product identifier

Product name:	Diclofenac sodium Diclofenacum natricum Natriumdiclofenac Diclofénac sodique Diclofenac-Natrium
N° CAS:	15307-79-6
N° EC:	239-346-4

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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. 2	H361
STOT RE 1	H372
Aquatic Chronic 2	H411

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Danger
Hazard statements:	
H302	Harmful if swallowed.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long-lasting effects.
Precautionary statements:	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P273	Avoid release to the environment.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Diclofenac sodium
IUPAC name:	Sodium [2-[2-(2,6-dichloroanilino)]phenyl]acetate
Synonyms:	Voltaren Solaraze
N° CAS:	15307-79-6
N° EC:	239-346-4
Molecular Formula:	$C_{14}H_{10}Cl_2NNaO_2$
Content:	99.0 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:	Instantly remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest provide artificial respiration.
After inhalation:	In case of unconsciousness bring patient into stable side position for transport.
After skin contact:	Instantly wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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After ingestion:

Do not induce vomiting; instantly call for medical help. Wash out mouth with water provided the patient is conscious.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

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:

CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol resistant foam.

Unsuitable extinguishing media:

Not available.

5.2 Special hazards arising from the substance/mixture

In case of fire be aware of formation of noxious fumes.

5.3 Advice for firefighters

Surrounding fires:

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

Protection against fire:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid causing dust. Wear personal protective clothing.

For emergency responders

Avoid causing dust. Wear personal protective clothing.

6.2 Environmental precautions

Do not allow product to enter soil.

6.3 Methods and material for containment and cleaning up

Collect mechanically while avoiding dust formation. Fill into marked containers with lids. Dispose of contaminated material as waste according to section 13. Ensure adequate ventilation. Wash the spill site with plenty of water.

6.4 Reference to other sections

For disposal considerations, see section 13.

SECTION 7: HANDLING AND STORAGE

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7.1 Precautions for safe handling

Precautions for safe handling:	Prevent formation of dust. Avoid all contact and inhalation of dust, mists and/or vapours associated with the material.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	The product is combustible. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container. Store only in the original container. Use only containers specifically permitted for this substance/product.
Conditions for safe storage, including any incompatibilities:	Store in a cool place under dry conditions.
Storage – away from:	Store protected from light and away from oxidising agents.

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

Appropriate engineering control

Keep away from foodstuffs, beverages, and food. Instantly remove any soiled and impregnated garments. Wash hands during breaks and at the end of the work. Store protective clothing separately.

Individual protection measures

Eye/face protection:	Tightly sealed safety glasses.
Skin protection:	Protective work clothing.
Hand protection:	Protective gloves. The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Respiratory protection:	In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or slightly yellowish, slightly hygroscopic, crystalline powder.
Odour:	Odourless
Odour threshold:	Not available.
pH:	7.0 – 8.5 (of 1% w/v solution in water)
Melting/freezing point:	283 – 285 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Product is flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in methanol, soluble in ethanol (96%), slightly soluble in acetone.
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Log(P) 13.4
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	The product is not explosive.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under normal temperatures and pressures.

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10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid exposure to light and excess moisture.

10.5 Incompatible materials

Strong oxidizing agents, strong bases and acid chlorine.

10.6 Hazardous decomposition products

Gives out toxic fumes of hydrogen chlorine, oxides of nitrogen, sodium, carbon dioxide and carbon monoxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 76.5 mg/kg Oral LD50 (mouse): 390 mg/kg Dermal LD50: 350 mg/kg Inhalation LC50: 4.8 mg/L
Skin corrosion/irritation:	Irritant for skin and mucous membranes.
Serious eye damage/irritation:	Irritant effect.
Respiratory/skin sensitisation:	No sensitizing effect known.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Causes damage to organs through prolonger or repeated exposure.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritant.
Skin contact:	Irritant.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed. Causes damage to organs through prolonger or repeated exposure.
Aspiration:	Not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

EC50: 14.5 mg/l (algae) (72h)

EC50: 22.4 mg/l (*Daphnia magna*) (48h)

LC50: 214 mg/l (fish) (96h)

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

Harmful to aquatic organisms.

Water hazard class 2 (Self-assessment): hazardous for water.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Disposal according to official regulations. Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811

IATA/ICAO (Air) :

14.2 UN proper shipping name

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

ADR: 2811 TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac sodium)
IMDG, IATA: TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac sodium)

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: No.

14.6 Special precautions for user

Warning: Toxic substances.
Kemler number: 60

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

Not applicable.

14.8 Additional transport information

ADR Limited quantities (LQ): LQ9

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.
R48 Danger of serious damage to health by prolonged exposure
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60 May impair fertility.
R61 May cause harm to the unborn child.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical help.
S27 Take off immediately all contaminated clothing.
S46 If swallowed, seek medical advice immediately and show this container or label.
S61 Avoid release to the environment.

15.2 Chemical safety assessment

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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

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

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(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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