

Diclofenac sodium

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 23/02/2012 Revision date: 23/02/2017

621293

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Diclofenac sodium
IUPAC name : Sodium 2-[(2,6-dichlorophenyl)amino]phenylacetate
EC No : 239-346-4
CAS No : 15307-79-6
Product code : 621293
Formula : C₁₄H₁₀Cl₂NO₂ · Na
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3 H301
Specific target organ toxicity — Single exposure, Category 3, H335
Respiratory tract irritation

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)

:



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed
H335 - May cause respiratory irritation

Precautionary statements (CLP)

: P261 - Avoid breathing dust
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Diclofenac sodium	(CAS No) 15307-79-6 (EC No) 239-346-4	99 - 101	Acute Tox. 3 (Oral), H301 STOT SE 3, H335

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air. Seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Drink plenty of water. Induce vomiting if person is conscious. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Nausea. Dizziness. Headache. Vomiting. Exposure may produce an allergic reaction. Sleepiness. Irritation of the respiratory tract and the other mucous membranes. Nervous system disorder. Can affect blood cell formation. Damage to kidneys and liver.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Fire hazard : This product is flammable. On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Chlorine.
Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Wear appropriate mask. Dustmask with filtertype P2

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 318.1 g/mol
Colour	: White. Slightly yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: 6.5 - 8.5
pH solution	: 1 g/l in H ₂ O, 20°C
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ca. 280 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0.6 g/cm ³ 20°C
Solubility	: Soluble in : Methanol. Water: 1.5 g/l
Log Pow	: 1.56

Diclofenac sodium

621293

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available

Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Light (daylight). Moisture.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides. Chlorine.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Toxic if swallowed.

Diclofenac sodium (15307-79-6)	
LD50 oral rat	53 mg/kg

Skin corrosion/irritation : Not classified
pH: 6.5 - 8.5

Serious eye damage/irritation : Not classified
pH: 6.5 - 8.5

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Diclofenac sodium (15307-79-6)	
LC50 fish 1	214 mg/l 96 h
EC50 Daphnia 1	70 mg/l 48 h

12.2. Persistence and degradability

Diclofenac sodium (15307-79-6)	
Persistence and degradability	Biodegradable.
Biodegradation	55 %

12.3. Bioaccumulative potential

Diclofenac sodium (15307-79-6)	
Log Pow	1.56
Bioaccumulative potential	Weak.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available


SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : T2

Excepted quantities (ADR) : E1

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Hazard identification number (Kemler No.) : 60

Orange plates :



Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Diclofenac sodium is not on the REACH Candidate List

Diclofenac sodium is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Respiratory protection	Modified	Added additional information (type of clothing related to concentration levels)

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Diclofenac sodium

621293

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed
H335	May cause respiratory irritation

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product