

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name

Diclofenac Sodium EP

Product no.

37256

REACH registration number

-

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

Relevant identified uses of the substance or mixture

NA

Uses advised against

-

The full text of any mentioned and identified use categories are given in section 16

1.3. Details of the supplier of the safety data sheet

Company and address

Caldic Ingredients A/S

Valhoejs Allé 183

2610 Roedovre

Denmark

Phone: +45 36 72 26 26

Mail: info@caldic.dk

Contact person

Ragnhild Emilie Sørensen

E-mail

j.norby@caldic.dk

SDS date

2017-03-20

SDS Version

2.0

1.4. Emergency telephone number

Contact The National Poisons Information Service (dial 111, 24 h service). See section 4 "First aid measures".

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Acute Tox. 3; H301 + H311 + H331

Repr. 2; H361

STOT RE 2; H373

Aquatic Chronic 3; H412

; DGEBE

See full text of H-phrases in section 2.2.

2.2. Label elements

▼ Hazard pictogram(s)



Signal word

Danger

▼ Hazard statement(s)

Toxic if swallowed, in contact with skin or if inhaled. (H301 + H311 + H331)

Suspected of damaging fertility or the unborn child. (H361)

May cause damage to organs through prolonged or repeated exposure. (H373)

Harmful to aquatic life with long lasting effects. (H412)

Do not use in paint spraying equipment. (DGEBE)

▼ Safety statement(s)

General

Prevention

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Avoid breathing dust. (P261).

Wash hands/exposed areas/exposed skin/hands and exposed skin thoroughly after handling. (P264).

Wear protective clothing/protective gloves/eye protection/face protection. (P280).

Response

Specific treatment (see instructions on this label). (P321).

IF INHALED: Remove person to fresh air and keep comfortable for breathing. (P304+P340).

Storage

Store in a well-ventilated place. Keep container tightly closed. (P403+P233).

Disposal

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Identity of the substances primarily responsible for the major health hazards

sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate. CAS no.: 15307-79-6

▼ 2.3. Other hazards

This product contains teratogenic substances, which may cause long-term adverse effects to the unborn foetus.

This product contains substances that may cause adverse effects to the reproductive system.

Additional labelling

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Additional warnings

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VOC

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SECTION 3: Composition/information on ingredients

3.1/3.2. Substances/Mixtures

NAME:	sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate
IDENTIFICATION NOS.:	CAS-no: 15307-79-6 EC-no: 239-346-4
CONTENT:	95-100%
CLP CLASSIFICATION:	Acute Tox. 3, STOT RE 2, Repr. 2, Aquatic Chronic 3 H301, H361, H373, H412

(*) See full text of H-phrases in chapter 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

ATEmix(inhale, vapour) = 2,4 - 3,6
 ATEmix(inhale, dust/mist) = 0,4 - <= 0.5
 ATEmix(inhale, gas) = 560 - 840
 ATEmix(Dermal) = 240 - 360
 ATEmix(oral) = 80 - 120
 N chronic (CAT 3) Sum = $\text{Sum}(\text{Ci}/\text{M}(\text{chronic}) \cdot 25 \cdot 0.1 \cdot 10^4 \text{CATi}) = 3,2 - 4,8$

SECTION 4: First aid measures

4.1. Description of first aid measures

▼ General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. The doctor can contact The National Poisons Information Service (dial 111, 24 h service). Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

▼ Inhalation

Bring the injured person into fresh air. Make sure the injured person is continuously monitored. Prevent shock by keeping the injured person warm and calm. If breathing ceases, give mouth-to-mouth resuscitation. If unconscious, roll the injured person into recovery position. Call an ambulance.

▼ Skin contact

Remove contaminated clothing and shoes immediately. Ensure to wash exposed skin thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

▼ Eye contact

Remove contact lenses. Flush eyes immediately with plenty of water or isotonic water (20-30°C) for at least 15 minutes and continue until irritation stops. Make sure to flush under upper and lower eyelids. If irritation continues, contact a doctor. Continue flushing during transport.

▼ Ingestion

In the case of ingestion, contact a doctor immediately and bring safety data sheet or label. If the person is conscious, give them water. DO NOT try to induce vomiting, unless this is recommended by a doctor. Hold head facing down to prevent vomit returning mouth and throat. Prevent shock by keeping the injured person warm and calm. Initiate immediate resuscitation if breathing stops. If unconscious, roll the injured person into recovery position. Call an ambulance.

Burns

Not applicable

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

No special

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

IF exposed or concerned:

Get immediate medical advice/attention.

Information to medics

Bring this safety data sheet.

SECTION 5: Firefighting measures

▼ 5.1. Extinguishing media

Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Waterjets should not be used, since they can spread the fire.



▼ 5.2. Special hazards arising from the substance or mixture

If the product is exposed to high temperatures, e.g. in the event of fire, dangerous catabolic substances are produced. These are: Carbon oxides. Fire will result in dense black smoke. Exposure to combustion products may harm your health. Fire fighters should wear appropriate protection equipment. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

▼ 5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact The National Poisons Information Service (dial 111, 24 h service) in order to obtain further advice.

SECTION 6: Accidental release measures

▼ 6.1. Personal precautions, protective equipment and emergency procedures

Avoid direct contact with spilled substances.

▼ 6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of leakage to the surroundings, contact local environmental authorities. It is recommended to install waste collection trays in order to prevent emissions to the waste water system and surrounding environment.

▼ 6.3. Methods and material for containment and cleaning up

Collect spills carefully. Moist the material with water in order to prevent the formation and propagation of dust. To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.

▼ 6.4. Reference to other sections

See section on "Disposal considerations" in regard of handling of waste. See section on 'Exposure controls/personal protection' for protective measures.

SECTION 7: Handling and storage

▼ 7.1. Precautions for safe handling

Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms. It is recommended to install waste collection trays in order to prevent emissions to the waste water system and surrounding environment. See section on 'Exposure controls/personal protection' for information on personal protection. Avoid direct contact with the product.

▼ 7.2. Conditions for safe storage, including any incompatibilities

Store locked up. The room and chemical closet shall be provided with warning sign for toxic substances. Always store in containers of the same material as the original container. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature

No data available.

▼ 7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

▼ OEL

No substances are listed in The Control of Substances Hazardous to Health Regulations with an occupational exposure limit.

▼ DNEL / PNEC

No data available

8.2. Exposure controls

▼ Control is unnecessary if the product is used as intended.

General recommendations

▼ Observe general occupational hygiene standards.

Exposure scenarios

In the event exposure scenarios are appended to the safety data sheet, the operational conditions and risk management measures in these shall be complied with.

▼ Exposure limits

Occupational exposure limits have not been defined for the substances in this product.

▼ Appropriate technical measures

Apply standard precautions during use of the product. Avoid inhalation of gas or dust.

▼ Hygiene measures

In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Always wash hands, forearms and face.

▼ Measures to avoid environmental exposure

Keep damming materials near the workplace. If possible, collect spillage during work.

Individual protection measures, such as personal protective equipment



Generally

Use only CE marked protective equipment.

▼ Respiratory Equipment

Recommended: S/SL. P2 . White

▼ Skin protection

Dedicated work clothing should be worn. Wear a protective suit in the event of prolonged periods of work with the product.

▼ Hand protection

Recommended: 4H/Barrier

▼ Eye protection

Wear face shield alternatively safety glasses with side shields.

SECTION 9: Physical and chemical properties

▼ 9.1. Information on basic physical and chemical properties

Form	Powder
Colour	White
Odour	None
pH	7,5
Viscosity (40°C)	No data available.
Density (g/cm ³)	0,851

▼ Phase changes

Melting point (°C)	280
Boiling point (°C)	No data available.
Vapour pressure	No data available.

▼ Data on fire and explosion hazards

Flashpoint (°C)	No data available.
Ignition (°C)	No data available.
Self-ignition (°C)	No data available.
Explosion limits (Vol %)	No data available.

▼ Solubility

Solubility in water	Insoluble
n-octanol/water coefficient	No data available.

▼ 9.2. Other information

Solubility in fat (g/L)	No data available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

▼ 10.2. Chemical stability

The product is stable under the conditions, noted in the section "Handling and storage".

10.3. Possibility of hazardous reactions

No special

10.4. Conditions to avoid

No special

▼ 10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

▼ Acute toxicity

Substance	Species	Test	Route of exposure	Result
sodium [2-[(2,6-dichlorophenyl...	Rat	LD50	Oral	76,5 mg/kg
sodium [2-[(2,6-dichlorophenyl...	Mouse	LD50	Dermal	215 mg/kg
sodium [2-[(2,6-dichlorophenyl...	Mouse	LC50	Inhalation	2,8 mg/l

▼ Skin corrosion/irritation

No data available.

Serious eye damage/irritation

No data available.

Respiratory or skin sensitisation

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

STOT-single exposure

No data available.

▼ STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

No data available.

▼ Long term effects

Reproductive toxicity: This product contains teratogenic substances, which may produce anomalies and/or developmental defects to the human offspring. Adverse effects include: death, growth retardation, congenital disorders, delayed mental development, and functional disorders.

Reproductive toxicity: This product contains reprotoxic substances, which may harm the reproductive capacity. Adverse effects include: sterility, effects on the sexual function, lowered effective fertility and dysfunctional menstrual cycle.

SECTION 12: Ecological information

12.1. Toxicity

Substance	Species	Test	Duration	Result
sodium [2-[(2,6-dichlorophenyl...	Algae	EC50	72h	14,5 mg/l
sodium [2-[(2,6-dichlorophenyl...	Daphnia	EC50	48h	22,4 mg/l
sodium [2-[(2,6-dichlorophenyl...	Fish	LC50	96h	214 mg/l

12.2. Persistence and degradability

Substance	Biodegradability	Test	Result
sodium [2-[(2,6-dichlorophenyl...	No	No data available	No data available

12.3. Bioaccumulative potential

Substance	Potential bioaccumulation	LogPow	BCF
No data available.			

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

▼ 12.6. Other adverse effects

This product contains substances, which due to poor biodegradability, may cause adverse long-term effects to the aquatic environment,

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

Product is covered by the regulations on hazardous waste.

Waste

EWC code

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Specific labelling

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▼ Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: Transport information**14.1 – 14.4**

This product is within scope of the regulations of transport of dangerous goods.

ADR/RID

14.1. UN number	2811
14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. (Diclofenac Sodium)
14.3. Transport hazard class(es)	6.1
14.4. Packing group	III
Notes	-
Tunnel restriction code	-

IMDG

UN-no.	2811
Proper Shipping Name	OXIC SOLID, ORGANIC, N.O.S. (Diclofenac Sodium)
Class	6.1
PG*	III
EmS	F-A, S-A
MP**	no
Hazardous constituent	-

▼ IATA/ICAO

UN-no.	2811
Proper Shipping Name	OXIC SOLID, ORGANIC, N.O.S. (Diclofenac Sodium)
Class	6.1
PG*	III

14.5. Environmental hazards

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14.6. Special precautions for user

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

No data available

(*) Packing group
(**) Marine pollutant

SECTION 15: Regulatory information

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

▼ Restrictions for application

People under the age of 18 shall not be exposed to this product cf. Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work.

Industrial use only.

Pregnant women and women breastfeeding must not be exposed to this product. The risk, and possible technical precautions or design of the workplace needed to eliminate exposure, must be considered.

Demands for specific education

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Additional information

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Sources

COUNCIL DIRECTIVE 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP).
EC regulation 1907/2006 (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

▼ Full text of H-phrases as mentioned in section 3

H301 - Toxic if swallowed.

H361 - Suspected of damaging fertility or the unborn child.

H373 - May cause damage to organs through prolonged or repeated exposure.

H412 - Harmful to aquatic life with long lasting effects.

The full text of identified uses as mentioned in section 1

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Other symbols mentioned in section 2

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Other

In accordance with Regulation (EC) No. 1272/2008 (CLP) the evaluation of the classification of the mixture is based on:

The classification of the mixture in regard of health hazards are in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP)

The classification of the mixture in regard of environmental hazards are in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP) It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The safety data sheet is validated by

Jan Skov Nørby

Date of last essential change

(First cipher in SDS version)

2015-07-20

Date of last minor change

(Last cipher in SDS version)

2015-07-20