

# **SAFETY DATA SHEET**

Version 6.7 Revision Date 07/18/2025 Print Date 07/19/2025

### **SECTION 1. IDENTIFICATION**

1.1 Product identifiers

Product name : Diclofenac Sodium (200 mg)

Product Number : 1188800

Brand : US Pharmacopeia CAS-No. : 15307-79-6

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

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Inc.

3050 SPRUCE ST ST. LOUIS MO 63103 UNITED STATES

Telephone : +1 314 771-5765 Fax : +1 800 325-5052

1.4 Emergency telephone number

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-

: Category 1

527-3887 CHEMTREC (International) 24

Hours/day; 7 Days/week

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 3

Reproductive toxicity : Category 2

Specific target organ

toxicity - repeated

exposure

Long-term (chronic) : Category 2

aquatic hazard

US Pharmacopeia - 1188800

Page 1 of 14



### Other hazards

None known.

### **GHS** label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H301 Toxic 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 : **Prevention:** 

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have

been read and understood. P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this

product.

P273 Avoid release to the environment.

P280 Wear protective gloves, protective clothing, eye

protection and face protection.

Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call

a POISON CENTER/ doctor. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical

advice/ attention. P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved

waste disposal plant.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Substance

US Pharmacopeia - 1188800

Page 2 of 14

### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
2-[(2,6- dichlorophenyl)amino]- phenylacetic acid monosodium salt	15307-79-6*	>= 80 - <= 100	TSC

<sup>\*</sup> Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

# **SECTION 4. FIRST AID MEASURES**

General advice : Show this safety data sheet to the doctor in

attendance.

If inhaled : After inhalation: fresh air. Call in physician.

In case of skin contact : In case of skin contact: Take off immediately all

contaminated clothing. Rinse skin with water/ shower.

Consult a physician.

In case of eye contact : After eye contact: rinse out with plenty of water.

Call in ophthalmologist. Remove contact lenses.

If swallowed: give water to drink (two glasses at

most). Seek medical advice immediately. In

exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administer activated charcoal (20 - 40 g in a 10% slurry) and

consult a doctor as quickly as possible.

Most important

symptoms and effects, both acute and delayed

: The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in

section 11

Protection of first-aiders : For personal protection see section 8.

Notes to physician : No data available

# **SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing

media

: Water

Foam

Carbon dioxide (CO2)

Dry powder

US Pharmacopeia - 1188800

Page 3 of 14

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada



Unsuitable extinguishing media

: For this substance/mixture no limitations of

extinguishing agents are given.

Specific hazards during

: Combustible.

fire fighting

Development of hazardous combustion gases or

vapours possible in the event of fire.

Hazardous combustion

: Carbon oxides

products

Nitrogen oxides (NOx)

Hydrogen chloride gas

Sodium oxides

Specific extinguishing

methods

: No data available

Further information

: Suppress (knock down) gases/vapours/mists with a

water spray jet.

Prevent fire extinguishing water from contaminating

surface water or the ground water system.

Special protective equipment for fire-

fighters

: Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

# **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid generation and inhalation of dusts in all

circumstances.

Avoid substance contact. Ensure adequate ventilation.

Evacuate the danger area, observe emergency

procedures, consult an expert. Advice for emergency responders: For personal protection see section 8.

Environmental

: Do not let product enter drains.

US Pharmacopeia - 1188800

Page 4 of 14

precautions

Methods and materials for containment and

cleaning up

: Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7

and 10).

Take up carefully. Dispose of properly. Clean up

affected area.

Avoid generation of dusts.

# **SECTION 7. HANDLING AND STORAGE**

For precautions see section 2.2.

Advice on safe handling : Work under hood. Do not inhale substance/mixture.

Further information on storage conditions

: Tightly closed.

Dry.

Keep in a well-ventilated place.

Keep locked up or in an area accessible only to

qualified or authorised persons.

Storage class : 6.1C, Combustible, acute toxic Cat.3 / toxic

compounds or compounds which causing chronic

effects

Recommended storage

temperature

: Recommended storage temperature see product label.

# **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

### Personal protective equipment

Respiratory protection : required when dusts are generated.

Our recommendations on filtering respiratory

protection are based on the following standards: DIN

EN 143, DIN 14387 and other accompanying

standards relating to the used respiratory protection

system.

Recommended Filter

type:

: Filter type P3

The entrepeneur has to ensure that maintenance, cleaning and US Pharmacopeia - 1188800

Page 5 of 14

testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Hand protection

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.11 mm
Protective index : Full contact

Manufacturer : KCL 741 Dermatril® L

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.11 mm
Protective index : Splash contact

Manufacturer : KCL 741 Dermatril® L

Remarks : This recommendation applies only to the product

stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-

36124 Eichenzell, Internet: www.kcl.de).

Eye protection : Use equipment for eye protection tested and

approved under appropriate government standards

such as NIOSH (US) or EN 166(EU).

Safety glasses

Skin and body protection : protective clothing

Hygiene measures : Immediately change contaminated clothing. Apply

preventive skin protection. Wash hands and face

after working with substance.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : solid

Color : white

Odor : No data available

Odor Threshold : No data available pH : No data available

US Pharmacopeia - 1188800

Page 6 of 14

Melting point/ range : 541 - 545 °F / 283 - 285 °C

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Flammability (liquids) : No data available

Burning rate : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapour density : No data available

Relative density : No data available

: No data available Density

Solubility(ies)

Water solubility : 21.3 g/l (77 °F / 25 °C)

pH: 8

Partition coefficient: n-

octanol/water

: No data available

: No data available Autoignition temperature

Decomposition temperature

: No data available

: No data available Viscosity, dynamic

Viscosity, kinematic : No data available

: No data available Flow time

Explosive properties : No data available

Oxidizing properties : No data available

US Pharmacopeia - 1188800



Molecular weight : 318.1 g/mol

Particle characteristics

Particle size : No data available

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : The following applies in general to flammable organic

> substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion

potential may generally be assumed.

Chemical stability : The product is chemically stable under standard

ambient conditions (room temperature) .

Possibility of hazardous

reactions

: Caution! In contact with nitrites, nitrates, nitrous acid

possible liberation of nitrosamines! Violent reactions possible with:

strong oxidising agents

Conditions to avoid : no information available

: No data available Incompatible materials

products

Hazardous decomposition : In the event of fire: see section 5

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## 11.1 Information on toxicological effects

### **Acute toxicity**

LD50 Oral - Rat - 53 mg/kg

Remarks: Behavioral:Altered sleep time (including change in righting reflex).

Behavioral: Ataxia.

Lungs, Thorax, or Respiration: Respiratory stimulation.

Inhalation: No data available Dermal: No data available

No data available

**Skin corrosion/irritation** Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available US Pharmacopeia - 1188800

Page 8 of 14



## 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.

NTP: No component of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

# **Reproductive toxicity**

Suspected of damaging the unborn child.

# Specific target organ toxicity - single exposure

No data available

# Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### **Aspiration hazard**

No data available

#### 11.2 Additional Information

Repeated dose toxicity - Rat - Oral

Gastrointestinal disturbance, Nausea, Dizziness, Headache, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Stomach - Irregularities - Based on Human Evidence

Stomach - Irregularities - Based on Human Evidence

### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

### **Components:**

# 2-[(2,6-dichlorophenyl)amino]-phenylacetic acid monosodium salt:

Toxicity to fish : Remarks: No data available

# **Ecotoxicology Assessment**

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

# Persistence and degradability

### **Components:**

# 2-[(2,6-dichlorophenyl)amino]-phenylacetic acid monosodium salt:

Biodegradability : aerobic

Concentration: 20 mg/l

US Pharmacopeia - 1188800

Page 9 of 14

Result: Not readily biodegradable.

Biodegradation: 28 % Exposure time: 28 d

Method: OECD Test Guideline 301E

## **Bioaccumulative potential**

## **Components:**

# 2-[(2,6-dichlorophenyl)amino]-phenylacetic acid monosodium salt:

Bioaccumulation : Remarks: No data available

# Mobility in soil

# **Components:**

# 2-[(2,6-dichlorophenyl)amino]-phenylacetic acid monosodium salt:

Stability in soil : Remarks: No data available

### Other adverse effects

### **Product:**

Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part

82 Protection of Stratospheric Ozone - CAA Section

602 Class I Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR

82, Subpt. A, App.A + B).

## **Components:**

## 2-[(2,6-dichlorophenyl)amino]-phenylacetic acid monosodium salt:

Additional ecological

information

: No data available

# **SECTION 13. DISPOSAL CONSIDERATIONS**

### **Disposal methods**

Waste from residues : Waste material must be disposed of in accordance

with the national and local regulations. Leave

chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product

itself.

# **SECTION 14. TRANSPORT INFORMATION**

## **International Regulations**

US Pharmacopeia - 1188800

Page 10 of 14

IATA-DGR

UN/ID No. : UN 2811

Proper shipping name : Toxic solid, organic, n.o.s.

(2-[(2,6-dichlorophenyl)amino]-phenylacetic acid

monosodium salt)

Class : 6.1 Packing group : III

Labels : Division 6.1 - Toxic substances

Packing instruction (cargo: 677

aircraft)

Packing instruction : 670

(passenger aircraft)

IMDG-Code

UN number : UN 2811

Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.

(2-[(2,6-dichlorophenyl)amino]-phenylacetic acid

monosodium salt)

Class : 6.1
Packing group : III
Labels : 6.1
EmS Code : F-A, S-A
Marine pollutant : yes

# Transport in bulk according to IMO instruments

Not applicable for product as supplied.

## **National Regulations**

49 CFR Road

UN/ID/NA number : UN 2811

Proper shipping name : Toxic solids, organic, n.o.s.

(2-[(2,6-dichlorophenyl)amino]-phenylacetic acid

monosodium salt)

Class : 6.1 Packing group : III

Labels : Division 6.1 - Toxic substances

ERG Code : 154 Marine pollutant : no

Poison Inhalation Hazard : No

## Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

US Pharmacopeia - 1188800

A

Page 11 of 14

### **SECTION 15. REGULATORY INFORMATION**

## **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

# **SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 : Acute Health Hazard
Hazards : Chronic Health Hazard

**SARA 313** : This material does not contain any chemical

components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by

SARA Title III, Section 313.

### **Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **US State Regulations**

## **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

## **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

## **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

# The components of this product are reported in the following inventories:

US Pharmacopeia - 1188800

Page 12 of 14

inventory.

### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA -International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO -International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO -International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA -Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Decomposition Temperature; SARA Superfund Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

US Pharmacopeia - 1188800

Page 13 of 14



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

Revision Date : 07/18/2025

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.

US / EN

US Pharmacopeia - 1188800



Page 14 of 14