SAFETY DATA SHEETS

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Sixth revised edition

Version: 1.0

Creation Date: Aug 10, 2017

Revision Date: Aug 10, 2017

1. Identification

1.1 GHS Product identifier

Product name	diclofenac

1.2 Other means of identification

Product number	-
Other names	2-(2-((2,6-dichlorophenyl)amino)phenyl)acetic acid

1.3 Recommended use of the chemical and restrictions on use

Identified uses	For industry use only.
Uses advised against	no data available

2. Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 4

Reproductive toxicity, Category 2

Specific target organ toxicity – repeated exposure, Category 1

Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 2

2.2 GHS label elements, including precautionary statements

Pictogram(s)

Signal word	Danger
Hazard statement(s)	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 statement(s)	
Prevention	P264 Wash ... thoroughly after handling.
	P270 Do not eat, drink or smoke when using this product.
	P201 Obtain special instructions before use.
	P202 Do not handle until all safety precautions have been read and understood.
	P280 Wear protective gloves/protective clothing/eye protection/face protection.
	P260 Do not breathe dust/fume/gas/mist/vapours/spray.
	P273 Avoid release to the environment.
Response	P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/…if you feel unwell.
	P330 Rinse mouth.
	P308+P313 IF exposed or concerned: Get medical advice/ attention.
	P314 Get medical advice/attention if you feel unwell.
	P391 Collect spillage.
Storage	P405 Store locked up.

Disposal

P501 Dispose of contents/container to ...

2.3 Other hazards which do not result in classification

none

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
diclofenac	diclofenac	15307-86-5	none	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms/effects, acute and delayed

no data available

4.3 Indication of immediate medical attention and special treatment needed, if necessary

/SRP:/ Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR if necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on the left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. /Poisons A and B/

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Specific hazards arising from the chemical

no data available

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use.Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Diclofenac sodium 1% gel and diclofenac epolamine transdermal system should be stored at 25°C but may be exposed to temperatures ranging from 15-30°C. Diclofenac gel should not be frozen.

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8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique(without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and

dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

Wear dust mask when handling large quantities.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state	White to yellowish crystalline powder
Colour	Crystals from ether-petroleum ether
Odour	no data available
Melting point/ freezing point	158°C(dec.)(lit.)
Boiling point or initial boiling point and boiling range	83°C/0.7mmHg(lit.)
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available
Flash point	58°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	no data available
Partition coefficient n-octanol/water (log value)	no data available
Vapour pressure	1.07E-09mmHg at 25°C
Density and/or relative density	1.431 g/cm3
Relative vapour density	no data available
Particle characteristics	no data available

10. Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

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11. Toxicological information

Acute toxicity

- Oral: LD50 Monkey oral 3200 mg/kg /Diclofenac sodium/
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

AEROBIC: Diclofenac degradation in a freshwater inoculum from Lake Geifense, Swizterland and incubated for 37 days was found to be negligible(1). At low concentrations (3-35 uM), the compound was biodegraded when incubated in a river sediment consortia from the creek Muenzbach (Freiberg/Saxony), as indicated by the metabolite p-benzoquinone imine of 5-hydroxydiclofenac; concentrations of up to 260uM proved toxic(2). Diclofenac, present at 50 mg/L, reached 1.1% of its theoretical BOD in 75 days using a wastewater inoculum from the Jyvaskyla, Finland sewage treatment plant in the 301F Manometric respirometry test(3).

12.3 Bioaccumulative potential

An estimated BCF of 3 was calculated for diclofenac(SRC), using a log Kow of 4.51(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic

organisms is low(SRC), provided the compound is not altered physically or chemically once released into the environment.

12.4 Mobility in soil

Using an agricultural soil from Corrstown, County Dublin, Ireland a log Koc of 2.39 was measured(1), corresponding to a Koc of 245(SRC). According to a classification scheme(2), this estimated Koc value suggests that diclofenac is expected to have moderate mobility in soil. The pKa of diclofenac is 4.15(3), indicating that this compound will exist almost entirely in the dissociated form in the environment and anions generally do not adsorb more strongly to organic carbon and clay than their neutral counterparts(4). Adsorption to sediments from Lake Greifensee, Switzerland was found to be negligible(5). When 500 ng/L diclofenac was mixed with one liter of lake water and 1 g sediment/L water, the aqueous phase showed no decrease in concentration following centrifugation and removal of sediment particles(5).

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: UN2811 IMDG: UN2811 IATA: UN2811

14.2 UN Proper Shipping Name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S.
IMDG: TOXIC SOLID, ORGANIC, N.O.S.
IATA: TOXIC SOLID, ORGANIC, N.O.S.

14.3 Transport hazard class(es)

ADR/RID: 6.1 IMDG: 6.1 IATA: 6.1

14.4 Packing group, if applicable

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: yes IMDG: yes IATA: yes

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

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15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
diclofenac	diclofenac	15307-86-5	none
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Not Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Listed.

Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)	Not Listed.

16. Other information

Information on revision

Creation Date	Aug 10, 2017
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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB - Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemIDplus, website:

http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA - European Chemicals Agency, website: https://echa.europa.eu/
