

SAFETY DATA SHEETS

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

Version: 1.0

Creation Date: Aug 12, 2017

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1. Identification

1.1 GHS Product identifier

Product name indometacin

1.2 Other means of identification

Product number -

Other names Lausit

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 2

Skin sensitization, Category 1

Reproductive toxicity, Category 1B

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word	Danger
Hazard statement(s)	<p>H300 Fatal if swallowed</p> <p>H317 May cause an allergic skin reaction</p> <p>H360 May damage fertility or the unborn child</p>
Precautionary statement(s)	
Prevention	<p>P264 Wash ... thoroughly after handling.</p> <p>P270 Do not eat, drink or smoke when using this product.</p> <p>P261 Avoid breathing dust/fume/gas/mist/vapours/spray.</p> <p>P272 Contaminated work clothing should not be allowed out of the workplace.</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P201 Obtain special instructions before use.</p> <p>P202 Do not handle until all safety precautions have been read and understood.</p>
Response	<p>P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...</p> <p>P321 Specific treatment (see ... on this label).</p> <p>P330 Rinse mouth.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water/...</p> <p>P333+P313 If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P362+P364 Take off contaminated clothing and wash it before reuse.</p> <p>P308+P313 IF exposed or concerned: Get medical advice/ attention.</p>

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
indometacin	indometacin	53-86-1	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

SYMPTOMS: May cause gastrointestinal discomfort and possibly ulcerations. May aggravate psychiatric disturbances, epilepsy, and parkinsonism. May cause

drowsiness and headache. ACUTE/CHRONIC HAZARDS: Very toxic. Hazardous decomposition products. May aggravate central nervous system disorders. Suspected teratogen.

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

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Specific hazards arising from the chemical

Excerpt from ERG Guide 154 [Substances - Toxic and/or Corrosive (Non-Combustible)]: Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes. Some are oxidizers and may ignite combustibles (wood, paper, oil, clothing, etc.). Contact with metals may evolve flammable hydrogen gas. Containers may explode when heated. For electric vehicles or equipment, ERG Guide 147 (lithium ion batteries) or ERG Guide 138 (sodium batteries) should also be consulted. (ERG, 2016)

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

ACCIDENTAL RELEASE MEASURES: Personal precautions, protective equipment and emergency procedures: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust; Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains; Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. 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

Keep container tightly closed in a dry and well-ventilated place. Keep in a dry place.

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 crystalline powder
Colour	Pale-yellow to yellow-tan, crystalline powder
Odour	Odorless, or has slight odor
Melting point/ freezing point	112°C(lit.)
Boiling point or initial boiling point and boiling range	125°C
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available

Flash point	6°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	9.89X10 ⁻¹¹ mm Hg at 25°C (est)
Density and/or relative density	1.32g/cm ³
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

Light. Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

A weak organic acid.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Incompatible materials: Strong bases

10.6 Hazardous decomposition products

Special hazards arising from the substance or mixture: Carbon oxides, nitrogen oxides (NO_x), Hydrogen chloride gas

11. Toxicological information

Acute toxicity

- Oral: LD50 Rat oral 12 mg/kg
- 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: Indomethacin, present at 100 ug/L, exhibited biodegradation half-lives of 430 and 410 hours using the DOC river die-away test. Inoculum were obtained from the Tamiya and Tsumeta rivers, Tokushima City, Japan. 31% Biodegradation was obtained using batch-activated sewage treatment for 6 hours(1).

12.3 Bioaccumulative potential

A pKa of 4.50(1) indicates indomethacin will exist almost entirely in the anion form at pH values of 5 to 9 and, therefore, bioconcentration is not expected to be an important fate process(SRC). Anions do not bioconcentrate(SRC).

12.4 Mobility in soil

Using an Eliot silt loam soil (2.2% organic carbon, pH 6.6), a Koc of 1300 was reported(1). A log Koc of 2.95 (Kd = 32 L/kg), corresponding to a Koc of 891 , was measured using an agricultural soil (pH 6.3) from Corrstown, Co Dublin, Ireland(2). According to a classification scheme(3), these Koc values suggest that indomethacin is expected to have low mobility in soil. The pKa of indomethacin is 4.50(4), indicating that this compound will exist almost entirely in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts(5). A Kd value of 214 L/kg was reported using a digester sludge from wastewater treatment plant, Dublin Ireland (pH 6.3)(2). Koc values of 160, 160 and 400 were reported using river sediments from the Akui, Tamiya and Tataro rivers, Japan, respectively(1).

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: I IMDG: I IATA: I

14.5 Environmental hazards

ADR/RID: no IMDG: no IATA: no

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

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
indometacin	indometacin	53-86-1	none
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.

16. Other information

Information on revision

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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/>

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