

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number DX21625

Product Name Indomethacin

Synonyms Indocin;

Pure substance/mixture Substance

Contains 2-[1-(4-chlorobenzoyl)-5-methoxy-2-methylindol-3-yl]acetic acid

Molecular weight 357.8

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

Recommended Use Laboratory chemical

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL

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STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

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STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone		- §45 - ((EC)1272/2008	
F				440

Europe 112

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 01-Mar-2023 Revision Number 2

73942 - Indomethacin

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 2 - (H300)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitization	Category 1 - (H317)
Germ cell mutagenicity	Category 2 - (H341)
Reproductive toxicity	Category 1B - (H360)
Specific target organ toxicity (single exposure)	Category 3 - (H335)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)
Chronic aquatic toxicity	Category 4 - (H413)

2.2. Label elements

200-186-5

Contains 2-[1-(4-chlorobenzoyl)-5-methoxy-2-methylindol-3-yl]acetic acid



Signal word Danger

Hazard statements

Hazard statements

- H300 Fatal if swallowed
- H317 May cause an allergic skin reaction
- H318 Causes serious eye damage
- H335 May cause respiratory irritation
- H341 Suspected of causing genetic defects
- H360 May damage fertility or the unborn child
- H373 May cause damage to organs through prolonged or repeated exposure
- H413 May cause long lasting harmful effects to aquatic life

Precautionary Statements - EU (§28, 1272/2008)

- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor
- P280 Wear eye protection/ face protection
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P310 Immediately call a POISON CENTER or doctor
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P201 Obtain special instructions before use
- P202 Do not handle until all safety precautions have been read and understood
- P308 + P313 IF exposed or concerned: Get medical advice/attention
- P260 Do not breathe dust/fume/gas/mist/vapors/spray
- P314 Get medical advice/attention if you feel unwell
- P501 Dispose of contents/container to industrial incineration plant



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 01-Mar-2023 Revision Number 2

73942 - Indomethacin

Additional information
This product requires child resistant fastenings if supplied to the general public This product requires tactile warnings if supplied to the general public

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonyms

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
2-[1-(4-chlorobenzoyl)-5-methoxy-2-methylindol-3-yl]acetic acid	200-186-5	53-86-1	100	Acute Tox. 2 (H300) Muta. 2 (H341) Repr. 1 (H360) STOT RE 2 (H373) Eye Dam. 1 (H318) Skin Sens. 1 (H317) STOT SE 3 (H335) Aquatic Chronic 4 (H413)	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance.

Inhalation Get medical attention immediately if symptoms occur. Remove to fresh air. IF exposed or

concerned: Get medical advice/attention.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an

allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Ingestion Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

and drink afterwards plenty of water. Never give anything by mouth to an unconscious

person.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

Symptoms Burning sensation. Itching. Rashes. Hives.

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

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

surrounding environment.

Unsuitable Extinguishing Media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Product is or contains a sensitizer. May cause sensitization by skin contact.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Keep people away from and upwind of spill/leak.

Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas.

Other Information Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Environmental precautions Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning upTake up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Take off contaminated clothing and wash before reuse. Avoid contact with skin, eyes or

clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient

ventilation, wear suitable respiratory equipment.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS). Keep

out of the reach of children. Store locked up.

7.3. Specific end use(s)

Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Page 5/13



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Tight sealing safety goggles.

Hand protection Wear suitable gloves.

Skin and body protectionWear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Solid

AppearanceNo information availableColorNo information availableOdorNo data availableOdor thresholdNo data available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pHNo data availableNone knownMelting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlash pointNo data availableNone knownEvaporation rateNo data availableNone known

Flammability (solid, gas) Product is not flammable.



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Flammability Limit in Air None known

Upper flammability limit:No data availableLower flammability limit:No data available

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityNo data availableNone knownSolubility(ies)DMF: >20.2 mg/mL; DMSO: >17.8None known

mg/mL; PBS pH 7.2: <50 μg/mL;

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Explosive propertiesNo information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 357.8

Molecular formula C19H16CINO4

VOC Content (%)
Liquid Density
No information available
No information available
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None. 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Page 7/13



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon dioxide (CO2). Carbon monoxide. Hydrogen chloride gas. Nitrogen oxides (NOx).

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Severely irritating to eyes.

Causes serious eye damage. May cause burns. May cause irreversible damage to eyes.

Skin contact May cause irritation. May cause sensitization by skin contact. Specific test data for the

substance or mixture is not available. Repeated or prolonged skin contact may cause

allergic reactions with susceptible persons. (based on components).

Ingestion Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Specific test

data for the substance or mixture is not available. Fatal if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness. Itching. Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 5.01 mg/kg

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

Page 8/13



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
2-[1-(4-chlorobenzoyl)-5-methox y-2-methylindol-3-yl]acetic acid	5 5 ,		
	,		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause skin irritation.			
Product Information	luct Information			
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes burns. Risk of serious			
	damage to eyes.			
Product Information				
Respiratory or skin sensitization	May cause sensitization by skin contact.			
Product Information				
Germ cell mutagenicity	Classification based on data available for ingredients. Contains a known or suspected			
D d t. f	mutagen.			
Product Information				
Carcinogenicity	No information available.			
Product Information	The information available.			
r roads mornadon				
Reproductive toxicity	Classification based on data available for ingredients.			
	Product Information			
STOT - single exposure	May cause respiratory irritation.			
Product Information				
STOT - repeated exposure	May cause damage to organs.			
Product Information				
Aspiration hazard	No information available.			

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Page 9/13



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Ecotoxicity May cause long lasting harmful effects to aquatic life.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

Section 14: TRANSPORT INFORMATION

Note: Transport in accordance with local, state, and federal regulations. When sold in quantities

of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging

does not have to be labeled as Dangerous Goods/Excepted Quantity.



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 01-Mar-2023 Revision Number 2

IMDG

14.1 UN Number UN2811

14.2 UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (Indomethacin)

14.3 Transport hazard class(es) 6.1 Toxic substances

14.4 Packing Group

14.5 Marine pollutant Not applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

73942 - Indomethacin

Code

RID

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

ADR

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

IATA

14.1 UN Number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Indomethacin)

14.3 Transport hazard class(es) 6.1 Toxic substances

14.4 Packing Group

14.5 Environmental hazard Not applicable

14.6 Special Provisions None

Section 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

H2 - ACUTE TOXIC

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

Complies **TSCA DSL/NDSL** Complies **EINECS/ELINCS** Complies Complies **ENCS IECSC** Does not comply **KECL** Complies **PICCS** Complies Complies **AICS**

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H300 - Fatal if swallowed

H317 - May cause an allergic skin reaction

H318 - Causes serious eve damage

Page 12/13



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73942 - Indomethacin

Revision Date 01-Mar-2023 Revision Number 2

H335 - May cause respiratory irritation

H341 - Suspected of causing genetic defects

H360 - May damage fertility or the unborn child

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

H413 - May cause long lasting harmful effects to aquatic life

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Revision Date 01-Mar-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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