

Baclofen

Safety Data Sheet

623148

Version: 3.1

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EC) No.

453/2010

Date of issue: 26/11/2014 Revision date 28/11/2019

Supersedes 26/09/2018

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

1.1. Product identifier

Product form	: Substance
Trade name	: Baclofen
IUPAC name	: 4-amino-3-(4-chlorophenyl)butanoic acid
EC-No.	: 214-486-9
CAS-No.	: 1134-47-0
Product code	: 623148
Synonyms	: B-(Aminomethyl)-4-chloronbenzenepropanic acid
Product group	: Raw material

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

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Industrial/Professional use spec	: Industrial For professional use only
Use of the substance/mixture	: Active Ingredient (Muscle relaxant agent)
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] show CLP information only

Acute toxicity (oral), Category 3	H301
Serious eye damage/eye irritation, Category 2	H319
Respiratory sensitisation, Category 1	H334
Skin sensitisation, Category 1	H317
Reproductive toxicity, Category 1B	H360

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to displayExtra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360 - May damage fertility or the unborn child.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Baclofen	(CAS-No.) 1134-47-0 (EC-No.) 214-486-9	≈ 100	Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1B, H360

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow affected person to breathe fresh air Allow the victim to rest Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Immediately call a POISON CENTER/doctor.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects	: Human systemic effects by ingestion: lowering blood pressure, coma, muscle weakness, decreased pulse rate, respiratory depression.
Symptoms/effects after inhalation	: Toxic if inhaled. Danger of serious damage to health by prolonged exposure through inhalation.
Symptoms/effects after skin contact	: Repeated exposure to this material can result in absorption through skin causing significant health hazard. Toxic in contact with skin.

Symptoms/effects after ingestion : Toxic if swallowed. Swallowing a small quantity of this material will result in serious health hazard.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam
Dry powder
Carbon dioxide
Water spray
Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Nitrogen oxides
Carbon dioxide
Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Use the personal protective equipment as indicated in chapter 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection. See Heading 13. Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice.
- Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed parts thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Store at room temperature
Keep container tightly closed.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct sunlight.
- Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Gloves material: Nitrilrubber (NBR) / thickness: 0,11mm / permeability cat 6 (> 480 minutes) / standard: EN 374

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 213.7 g/mol
Colour	: White to off-white.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ≈ 170 °C
Freezing point	: No data available
Boiling point	: 364 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.285 g/cm ³ bulk
Solubility	: Soluble in dilute solutions of alkali hydroxides.
Log Pow	: 1.31
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

High temperature.

10.5. Incompatible materials

Oxidizing agent.

10.6. Hazardous decomposition products

release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Human systemic effects by ingestion: lowering blood pressure, coma, muscle weakness, decreased pulse rate, respiratory depression.

Baclofen (1134-47-0)	
LD50 oral rat	145 mg/kg (Reference NIIRDN 6,576,82)
LD50 oral	200 mg/kg mouse

Skin corrosion/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Causes serious eye irritation.

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : May damage fertility or the unborn child.

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : May be harmful if inhaled

Additional information : Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Toxic if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Baclofen (1134-47-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Baclofen (1134-47-0)	
Log Pow	1.31
Bioaccumulative potential	Low bioaccumulation potential.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods



Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment. Hazardous waste due to toxicity.

HP Code : HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
14.3. Transport hazard class(es)	
6.1	6.1
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : T2

Special provisions (ADR) : 274, 614

Limited quantities (ADR) : 5kg

Excepted quantities (ADR) : E1

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Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : B3

Mixed packing provisions (ADR) : MP10

Portable tank and bulk container instructions (ADR) : T1

Portable tank and bulk container special provisions (ADR) : TP33

Tank code (ADR) : SGAH, L4BH

Tank special provisions (ADR) : TU15, TE19

Vehicle for tank carriage : AT

Transport category (ADR) : 2

Special provisions for carriage - Bulk (ADR) : VV9

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28

Special provisions for carriage - Operation (ADR) : S9

Hazard identification number (Kemler No.) : 60

Orange plates : 

Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

PCA Excepted quantities (IATA) : E1

PCA Limited quantities (IATA) : Y645

PCA limited quantity max net quantity (IATA) : 10kg

PCA packing instructions (IATA) : 670

PCA max net quantity (IATA) : 100kg

CAO packing instructions (IATA) : 677

CAO max net quantity (IATA) : 200kg

Special provisions (IATA) : A3, A5

ERG code (IATA) : 6L

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

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Baclofen is not on the REACH Candidate List

Baclofen is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1		Modified	Change of Logo
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
LD50	Median lethal dose

Data sources : Supplier. 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.

Other information : REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. None.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360	May damage fertility or the unborn child.

SDS EU (REACH Annex II) ducheфа nieuwe logo

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.