


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	BACLOFEN, USP
PRODUCT CODE	3209
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Acute Toxicity - Dermal (Category 3) Toxic to Reproduction (Category 2) Sensitization - Skin (Category 1) Specific Target Organ Toxicity - Single Exposure (Category 3) - (Narcotic effects) Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Toxic in contact with skin. Irritating to eyes, skin and respiratory system. Suspected of damaging fertility or the unborn child. May cause an allergic skin reaction. May cause drowsiness or dizziness. Toxic to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable

PRECAUTIONARY STATEMENT(S)	Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Do not handle until all safety precautions have been read and understood. Avoid breathing dust, fume, gas, mist, vapors, spray. Contaminated work clothing must not be allowed out of the workplace. Obtain, read and follow all special instructions before use. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Use only outdoors or in a well-ventilated area. Avoid release to the environment.		
	Response	IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth. IF ON SKIN (HAIR): Wash with plenty of water; Immediately call a poison center or medical professional. Take off immediately all contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell. IF EXPOSED OR CONCERNED: Get medical advice.		
	Storage	Store locked up. Store in a well-ventilated place. Keep container tightly closed.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	HMIS CLASSIFICATION	Health Hazard	3	Flammability
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Butanoic acid, 4-amino-3-(4-chlorophenyl)-								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	C ₁₀ H ₁₂ ClNO ₂								
CHEMICAL FAMILY	Benzene derivative								
CAS NUMBER	1134-47-0								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	213.6628								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>BACLOFEN</td> <td>1134-47-0</td> <td>214-486-9</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	BACLOFEN	1134-47-0	214-486-9	100
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BACLOFEN	1134-47-0	214-486-9	100						

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable.

FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: **BACLOFEN** CAS #: **1134-47-0**

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial use: TWA: 0.4 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White to off-white, crystalline powder. Is odorless or practically so.

SOLUBILITY

Slightly soluble in water; very slightly soluble in methanol; insoluble in chloroform; practically insoluble in acetone and in ether. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.

ODOR

Practically odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	364°C, 687.2°F (760mmHg)	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	174°C, 345.2°F
log P (OCTANOL-WATER)	1.31	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(206 - 208)°C, (402.8-406.4)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Nitric acid.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 145 Dermal: Rat LD50: (mg/kg): 115 Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Causes irritation.
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Causes irritation.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	May cause an allergic skin reaction. Suspected skin sensitizer: CAESAR skin sensitization model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA BACLOFEN is not listed.

NTP BACLOFEN is not listed.

IARC BACLOFEN is not evaluated.

California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.

< 500 mg/kg/day Carcinogenicity study; Result: No evidence of carcinogenicity.; Species: Rat; Test Duration: 2 years.

Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity; ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (moderate reliability)

REPRODUCTIVE TOXICITY

May cause congenital malformation in the fetus. Presumed human reproductive toxicant.

May damage fertility or the unborn child. One study showed skeletal abnormalities in offspring of rats given 19 times the maximum human dose of baclofen. Offspring of mice given doses 17 to 34 times the maximum human dose and rabbits given 7 times the maximum human dose of baclofen had reduced weights and delayed skeletal maturation.

Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability)

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Narcotic effects.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Ovarian cysts. Low blood pressure. Coma.

Symptoms related to the physical, chemical, and toxicological characteristics:

Drowsiness Confusion Dizziness. Weakness. Trembling. Headache. Hallucinations. Excitement. Slurred speech. Ringing in ears. Fainting. Visual disturbances. Convulsions. Nausea. Stomach pain. Constipation. Vomiting. Weight gain. Loss of appetite. Urinary problems. Blood in urine. Diarrhea. Muscle pain. Chest pain. Numbness of extremities. Stuffy nose. Difficulty sleeping.

Medical conditions aggravated by exposure:

Active alcoholism. Peptic ulcer. Psychiatric disorders. Epilepsy. Diabetes mellitus. Porphyria. Impaired kidney function. Impaired liver function. Impaired pulmonary function.

POTENTIAL HEALTH EFFECTS

Inhalation Harmful if inhaled. Causes respiratory tract irritation.

Ingestion Toxic if swallowed.

Skin Toxic in contact with skin. Causes skin irritation. May cause an allergic skin reaction.

Eyes Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia Magna (mg/L): 4.42* LC50: 96 Hr: Fish: (mg/L): 9.64** LC50: 96 Hr: Fish: Fathead Minnow (mg/L): 82.45*** EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is Possible NON Readily Biodegradable (moderate reliability);The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable
BIOACCUMULATIVE POTENTIAL	Low: LogPow: 1.31
MOBILITY IN SOIL	Slightly soluble in water. Water Solubility: 2090 mg/L (25°C) Vapor Pressure: 2.36E-09mm Hg (25°C) Henry's Law Constant: 5.94E-12atm-m ³ /mole (25°C)
OTHER ADVERSE EFFECTS	Suspected hazardous to the aquatic environment. This product is not intended to be released into the environment.
NOTES	*VEGA (Q)SAR platform prediction (moderate reliability). **Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (moderate reliability). *** (EPA) in VEGA (Q)SAR platform prediction (moderate reliability).

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III
AUSTRALIA HAZCHEM	2X
EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A Appendix B		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
BACLOFEN 1134-47-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
BACLOFEN 1134-47-0	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
BACLOFEN 1134-47-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES
ABBREVIATIONS AND ACRONYMS

Available upon request

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

02/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.