


Section 1: Identification

Common Name/Trade Name	BACLOFEN USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	C10-H12-Cl-N-O2, "benzenepropanoic acid, beta-(aminomethyl)-4-chloro-", "beta-(aminomethyl)-4-chlorobenzenepropanoic acid", "hydrocinnamic acid, beta-(aminomethyl)-p-chloro-", "beta-(aminomethyl)-p-chlorohydrocinnamic acid", "gamma-amino-beta-(p-chlorophenyl)butyric acid", "beta-(p-chlorophenyl)gammaaminobutyric acid", beta-(4-chlorophenyl)GABA, "4-amino-3-(3-4-chlorophenyl)butanoic acid", BA-34647, C-34647BA, "Ciba Ba 34647", Lioresal, Baclofen, "muscle relaxant"	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute Toxicity Category 3, Eye Irritation Category 2A, Reproductive Toxicity Category 1B, Respiratory Sensitizer Category 1, Skin Corrosion/Irritation Category 2, Skin Sensitizer Category 1, STOT - SE Category 3	
Signal Word	Danger	
Hazard Statement(s)	H301 H315 H317 H319 H334 H335 H360	Toxic if swallowed Causes skin irritation May cause an allergic skin reaction Causes serious eye irritation May cause allergy or asthma symptoms or breathing difficulties if inhaled May cause respiratory irritation May damage fertility or the unborn child
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P261 P264 P270 P271 P272 P280 P281 P285 P301+P310 P302+P352 P304+P340 P304+P341 P305+P351+P338 P308+P313 P312 P330 P333+P313 P337+P313 P342+P311 P363 P403+P233 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF ON SKIN Wash with soap and water. IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF INHALED If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. IF exposed or concerned Get medical advice/attention. Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. If skin irritation or a rash occurs Get medical advice/attention. If eye irritation persists Get medical advice/attention. If experiencing respiratory symptoms Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Store in a well ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data Available	
Ingredient(s) with Unknown Toxicity	No data Available	

Section 3: Composition/Information on Ingredients

Chemical Name	Baclofen
Common Name	Baclofen
CAS Number	1134-47-0
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	NOTES TO PHYSICIAN Treat symptomatically. For poisons (where specific treatment regime is absent): Basic Treatment: Establish a patent airway with suction where necessary. Watch for signs of respiratory insufficiency and assist ventilation as necessary. Administer oxygen by non-rebreather mask at 10 to 15 L/min. Monitor and treat, where necessary, for pulmonary oedema. Baclofen is rapidly absorbed from the gastrointestinal tract and is primarily excreted unchanged in the urine.
If Inhaled	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
In Case of Skin Contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
In Case of Eye Contact	If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. Transport to hospital or doctor without delay.
If Swallowed	Give slurry of activated charcoal in water to drink. NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK. At least 3 tablespoons in a glass of water should be given. Although induction of vomiting may be recommended (IN CONSCIOUS PERSONS ONLY), such a first aid measure is dissuaded due to the risk of aspiration of stomach contents. (i) It is better to take the patient to a doctor who can decide on the necessity and method of emptying the stomach. (ii) Special circumstances may however exist; these include non-availability of charcoal and the ready availability of the doctor. NOTE: If vomiting is induced, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
Most Important Symptoms and Effects	Inhaled: Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. Ingestion: Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual. Side effect of skeletal muscle relaxants may include: Sedation, drowsiness, Blurred or double vision, constipation or diarrhea, Impairment of mental and physical abilities required for driving or operating hazardous machinery. Skin Contact: Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twentyfour hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur. Chronic: Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. There is sufficient evidence to provide a strong presumption that human exposure to the material may result in developmental toxicity.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Foam, Dry chemical powder, BCF (where regulations permit). Carbon dioxide.
Special Hazards Arising From the Substance/Mixture	Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC). Combustion products include: carbon monoxide (CO) carbon dioxide (CO2) hydrogen chloride phosphene nitrogen oxides (NOx) other pyrolysis products typical of burning organic material May emit poisonous fumes. FIRE INCOMPATIBILITY Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
Special PPE and/or Precautions for Firefighters	FIRE FIGHTING Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves for fire only. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Wear full body protective clothing with breathing apparatus.
Methods and Materials Used for Containment	MINOR SPILLS Clean up all spills immediately. Avoid contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. MAJOR SPILLS Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Prevent, by any means available, spillage from entering drains or water course. Wear full body protective clothing with breathing apparatus.
Cleanup Procedures	MINOR SPILLS Clean up all spills immediately. Avoid contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. MAJOR SPILLS Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Prevent, by any means available, spillage from entering drains or water course. Wear full body protective clothing with breathing apparatus.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. Establish good housekeeping practices. Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Conditions for Safe Storage	Avoid reaction with oxidising agents. Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Baclofen: CAS: 1134-47-0 (No OEL data Available at present).
Appropriate Engineering Controls	To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. An air-purifying respirator should be worn by all personnel in the immediate area in cases where nonventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.
PPE - Eye/Face Protection	For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: Chemical goggles Face shield. Full face shield may be required for supplementary but never for primary protection of eyes Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent].
PPE - Skin Protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves 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. Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
PPE - Body Protection	HANDS/FEET The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. Contaminated gloves should be replaced. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as: Frequency and duration of contact, Chemical resistance of glove material, Glove thickness and Dexterity. Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. PVC gloves. Protective shoe covers [AS/NZS 2210]. Change gloves frequently and when contaminated, punctured or torn. BODY/OTHER MEANS OF PROTECTION For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
PPE - Respiratory Protection	Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent). Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option). Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory. These may be government mandated or vendor recommended. Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.

Section 9: Physical and Chemical Properties

Appearance	White or creamy-white, odourless, crystalline powder
Upper/Lower Flammability or Explosive Limits	Not Available
Odor	No data available
Vapor Pressure	Negligible
Odor Threshold	No data available
Vapor Density	No data available
pH	Not Applicable
Relative Density	Not Applicable
Melting Point/Freezing Point	Melting/freezing range (°C) 206-208
Solubility	Does not mix well with water. Soluble in dilute mineral acids and alkali hydroxides. Solubility in water (g/L) Partly miscible
Initial Boiling Point and Boiling Range	Not applicable
Flash Point	Not available
Evaporation Rate	Not applicable
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	Not Available
Decomposition Temperature	Not Available
Viscosity	Not Applicable

Section 10: Stability and Reactivity

Reactivity	Stable under normal conditions.
Chemical Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal conditions.
Conditions to Avoid	Moisture. Heat.
Incompatible Materials	Strong oxidizers. Nitric acid
Hazardous Decomposition Products	When heated to decomposition, emits dangerous fumes. Carbon monoxide. Chlorides. Carbon dioxide. Nitrogen oxides. Hazardous polymerization : Will not occur.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral - rat- 145 mg/kg
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	May cause sensitization by inhalation and skin contact.
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No data available.
Carcinogenicity ACGIH	No data available.
Carcinogenicity NTP	No data available.
Carcinogenicity OSHA	No data available.
Reproductive Toxicity	Toxic for reproduction : unborn child: Category 3: Substances which cause concern for humans owing to possible developmental toxic effects.
Specific Target Organ Toxicity - Single Exposure	No data available.
Specific Target Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise: If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, and then puncture containers, to prevent re-use, and bury at an authorized landfill. Where possible retain label warnings and MSDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. A Hierarchy of Controls seems to be common - the user should investigate: Reduction. DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material) Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. According to the European Waste Catalogue, Waste Codes are not product specific but application specific. Waste Codes should be assigned by the User based on the application in which the product is used.
Waste Treatment Methods Packaging	Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise: If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, and then puncture containers, to prevent re-use, and bury at an authorized landfill. Where possible retain label warnings and MSDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. A Hierarchy of Controls seems to be common - the user should investigate: Reduction. DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for Disposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material) Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. According to the European Waste Catalogue, Waste Codes are not product specific but application specific. Waste Codes should be assigned by the User based on the application in which the product is used.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	2811
UN Proper Shipping Name	TOXIC SOLID, ORGANIC N.O.S. (Contains Baclofen).
Transport Hazard Class(es)	6.1
Packaging Group	III
Environmental Hazards	No data available.

Section 15: Regulatory Information

BACLOFEN (CAS: 106266-06-2) is found on the following regulatory lists; "European Customs Inventory of Chemical Substances (English)" This safety data sheet is in compliance with the following EU legislation and its adaptations as far as applicable - : 1907/2006/EC, (EC) No 1272/2008, 67/548/EEC, 1999/45/EC, 76/769/EEC, 98/24/EC, 92/85/EEC, 94/33/EC, 91/689/EEC, 1999/13/EC, OSHA 29 CFR 1910.1200 as well as the following British legislation: - The Control of Substances Hazardous to Health Regulations (COSHH) 2002 - COSHH Essentials - The Management of Health and Safety at Work Regulations 1999

Section 16: Other Information

Additional Information	Unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
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