

## 1. Identification

**Product identifier** **Baclofen**  
**Other means of identification**  
**Chemical name** Butanoic acid, 4-amino-3-(4-chlorophenyl)-

**Company name** Triova Pharmaceuticals LLC  
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 Tulsa, OK 74103

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 Canada

## 2. Hazard(s) identification

**Physical hazards** Not Classified  
**Health hazards** Acute toxicity, oral Category 3  
 Sensitization, skin Category 1  
 Reproductive toxicity Category 1  
 Specific target organ toxicity, single exposure Category 3 narcotic effects  
**Environmental hazards** Not classified.  
**OSHA defined hazards** Not classified.

### Label elements



**Signal word** Danger  
**Hazard statement** Toxic if swallowed. May cause an allergic skin reaction. May cause drowsiness or dizziness. May damage fertility or the unborn child.

### Precautionary statement

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If exposed or concerned: Get medical advice/attention.

**Storage** Store in a well-ventilated place. Keep container tightly closed. Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** Not classified.

**Other hazards which do not result in classification** None known.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Baclofen		1134-47-0	100

### 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	May cause allergic skin reaction. Narcotic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment of overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as an aqueous slurry, unless contraindicated. For seizures, administer IV benzodiazepines. For uncontrollable or recurring seizures, administer barbiturates. For hypotension, infuse 10 to 20 mL/kg isotonic fluid. If unresponsive, administer dopamine or norepinephrine. For bradycardia, administer atropine. Monitor heart and respiratory functions. Hemodialysis may be effective. [Poisindex 2006; Meditext 2006]
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

### 8. Exposure controls/personal protection

#### Exposure limit values

Industrial Use Material	Type	Value
Baclofen (CAS 1134-47-0)	TWA	0.4 mg/m <sup>3</sup>

**Biological limit values** No biological exposure limits noted for the ingredient(s).

<b>Appropriate engineering controls</b>	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White to off-white crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Nearly odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	402.8 - 406.4 °F (206 - 208 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Slightly soluble.
<b>Partition coefficient (n-octanol/water)</b>	-0.96
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Benzene derivative.
<b>Molecular formula</b>	C10H12ClNO2
<b>Molecular weight</b>	213.66
<b>Solubility (other)</b>	Soluble in dilute mineral acids and in dilute solutions of alkali hydroxides; very slightly soluble in methanol; practically insoluble in acetone and in ether; insoluble in chloroform.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Strong oxidizing agents. Nitric acid.
<b>Hazardous decomposition products</b>	Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Toxic if swallowed.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	May cause an allergic skin reaction.
<b>Eye contact</b>	Due to lack of data the classification is not possible.

**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.

**Delayed and immediate effects of exposure** Ovarian cysts. Low blood pressure. Coma.

**Medical conditions aggravated by exposure** Active alcoholism. Peptic ulcer. Psychiatric disorders. Epilepsy. Diabetes mellitus. Porphyria. Impaired kidney function. Impaired liver function. Impaired pulmonary function.

**Acute toxicity** Toxic if swallowed.

Product	Species	Test Results
Baclofen (CAS 1134-47-0)		
<b>Oral</b>		
LD50	Mouse	200 mg/kg
	Rat	145 mg/kg
<b>Skin corrosion/irritation</b>	Due to lack of data the classification is not possible.	
<b>Serious eye damage/eye irritation</b>	Due to lack of data the classification is not possible.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	May cause an allergic skin reaction.	
<b>Germ cell mutagenicity</b>	Due to lack of data the classification is not possible.	
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.	
	< 500 mg/kg/day Carcinogenicity study Result: No evidence of carcinogenicity. Species: Rat Test Duration: 2 years	
<b>Reproductive toxicity</b>	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.	
<b>Reproductivity</b>	12.5 mg/kg/day Reproductivity study Result: No increase in birth defects. Species: Rat 15 mg/kg/day Reproductivity study Result: No increase in birth defects. Species: Mouse	
<b>Specific target organ toxicity - single exposure</b>	Narcotic effects.	
<b>Specific target organ toxicity - repeated exposure</b>	Due to lack of data the classification is not possible.	
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.	

## 12. Ecological information

<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available.
<b>Mobility in soil</b>	Not available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Not available.
<b>Hazardous waste code</b>	Not regulated.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	
<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Baclofen)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>IATA</b>	
<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Baclofen)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed.
<b>Cargo aircraft only</b>	Allowed.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not available.
<b>DOT; IATA</b>	



## 15. Regulatory information

<b>US federal regulations</b>	CERCLA/SARA Hazardous Substances - Not applicable.  One or more components are not listed on TSCA.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes**SARA 313 (TRI reporting)**  
Not regulated.**Other federal regulations****Safe Drinking Water Act (SDWA)** Not regulated.**Food and Drug Administration (FDA)** Not regulated.**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**US. California Proposition 65**

Not Listed.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 01/01/2017**Revision date** 01/01/2017**Version #** 00**Further information** Not available.

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