

Scientific Documentation

Baclofen, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Baclofen, USP (B1049)

Item Number	B1049
Item	Baclofen, USP
CAS Number	1134-47-0
Molecular Formula	C ₁₀ H ₁₂ ClNO ₂
Molecular Weight	213.66
MDL Number	
Synonyms	(RS)-Amino-3-(4-chlorophenyl)butyric Acid

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
WATER DETERMINATION		3.0 %
RESIDUE ON IGNITION		0.3 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES		
BACLOFEN RELATED COMPOUND A		1.0 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		2.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	B1049	Lot Number	4LD0031
Item	Baclofen, USP	Manufacturer Lot	BACL/017/21-22
CAS Number	1134-47-0	Manufacturer Code	13524
Molecular Formula	C ₁₀ H ₁₂ ClNO ₂	Molecular Weight	213.66

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	100.2 %
WATER DETERMINATION		3.0 %	0.1 %
RESIDUE ON IGNITION		0.3 %	<0.3 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES			.
BACLOFEN RELATED COMPOUND A		1.0 %	0.0 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %	0.0 %
TOTAL IMPURITIES		2.0 %	0.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
APPEARANCE			WHITE POWDER
EXPIRATION DATE			31-JAN-2027
DATE OF MANUFACTURE			01-FEB-2022
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
29-JUN-22 11:52:37

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BPATEL
Bhargavi Patel
29-JUN-22 12:14:38

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Medilux Laboratories Private Limited at Plot No. 98-99, Sector -1, Industrial Area, Pithampur, Dist. Dhar, Pithampur, Madhya Pradesh 454775, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 04/15/2015

Revision Date: 6/22/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: B1049
Product Name: BACLOFEN, USP

Other means of identification

Synonyms: Baclon
 Benzenepropanoic acid, beta-(aminomethyl)-4-chloro-(9CI)
 Hydrocinnamic acid, beta-(aminomethyl)-p-chloro-
 beta-(4-Chlorophenyl)gaba
 beta-(Aminomethyl)-4-chlorobenzenepropanoic acid
 beta-(Aminomethyl)-p-chlorohydrocinnamic acid
 beta-(p-Chlorophenyl)-gamma-aminobutyric acid
 gamma-Amino-beta-(p-chlorophenyl)butyric acid

CAS #: 1134-47-0
RTECS # MW5084200
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication. Drug.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 1A
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes serious eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
May damage fertility or the unborn child
May cause respiratory irritation



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Avoid breathing dust/fume/gas/mist/vapors/spray
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Use only outdoors or in a well-ventilated area
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

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 ON SKIN: Wash with plenty of water
Take off contaminated clothing and wash it before reuse
If skin irritation or rash occurs: Get medical advice/attention
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Baclofen	1134-47-0	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.
Skin Contact:	Wash off immediately with soap and plenty of water. Get medical attention. Consult a physician if necessary.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	Causes serious eye irritation Causes skin irritation May cause irritation of respiratory tract Drowsiness Dizziness May cause an allergic skin reaction May cause allergy or asthma symptoms or breathing difficulties if inhaled Toxic if swallowed
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides.
Specific hazards:	May be combustible at high temperatures.
<u>Special Protective Actions for Firefighters</u>	
Specific Methods:	No information available.
Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Do not let product enter drains. Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Baclofen	1134-47-0	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Baclofen	1134-47-0	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Baclofen	1134-47-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:

Safety glasses with side-shields or Goggles

Skin and body protection:

Long sleeved clothing
Gloves
apron

Respiratory protection:

Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures:

Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:

Solid

Appearance:

Powder.

Color:

White. Off-white.

Odor:

Odorless.

Taste

No information available.

Formula:

C10-H12-Cl-N-O2

Molecular/Formula weight:

213.66 g/mol

Flammability:

No information available

Flashpoint (°C/°F):

No information available.

Flash Point Tested according to:

Not available

Autoignition Temperature (°C/°F):

No information available

Lower Explosion Limit (%):

No information available

Upper Explosion Limit (%):

No information available

Melting point/range(°C/°F):

207°C/ 404.6°F

Decomposition temperature(°C/°F):

No information available

Boiling point/range(°C/°F):

No information available

Bulk density:

No information available

Density (g/cm3):

No information available

Specific gravity:
No information available

pH:
No information available

Vapor pressure @ 20°C (kPa):
No information available

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

**Partition coefficient
(n-octanol/water):**
No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Partially soluble in cold water
Very slightly soluble in Methanol
Insoluble in Acetone
Very slightly soluble in alcohol
Insoluble in Chloroform
Dissolves in dilute mineral acids and in
dilute solutions of alkali hydroxides

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Oxidizing agents

**Hazardous decomposition
products:** Carbon oxides. Nitrogen oxides (NO_x).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Baclofen

CAS-No. 1134-47-0

LD50/oral/rat = 145 mg/kg Oral LD50 Rat

LD50/oral/mouse = 200 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 145 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 200 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation Inhalation of dust or powder may cause respiratory tract irritation.

Ingestion Harmful if swallowed. May cause dry mouth, excessive salivation, taste alterations, increased sweating, skin rashes, pruritus, nausea, vomiting, hypermotility, diarrhea or constipation, tinnitus, muscular pain and weakness, paraesthesias. May affect behavior/central nervous system (drowsiness, somnolence, dizziness, lassitude, headache, lightheadedness, confusion, fatigue, slurred speech, ataxia, seizures/convulsions, hallucinations, depression, aggression, insomnia, delirium, tremors, increase in spasticity, coma), vision/eyes (visual disturbances - blurred vision, pupils are often dilated with sluggish or no reaction to light, nystagmus (involuntary eye movement)), respiration (respiratory depression), brain, urinary system (urinary retention/incontinence, cardiovascular system (hypotension, pulse rate change (bradycardia or tachycardia), cardiovascular depression), liver (alterations in liver function values), respiration (dyspnea, respiratory depression),. It may also cause blood sugar changes.

Aspiration hazard No information available.

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

Chronic Toxicity Prolonged or repeated ingestion may cause weight loss. Prolonged or repeated inhalation may affect the bone marrow (changes in bone marrow). Medical Conditions Aggravated by Exposure: Peptic ulcer; renal impairment; porphyria; respiratory disorders.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Baclofen	1134-47-0	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity May damage fertility or the unborn child

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Baclofen	1134-47-0	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.(baclofen)
Hazard Class: 6.1
Subsidiary Class: No information available
Packing group: III
Emergency Response Guide Number: 154
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No Information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.(baclofen)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No information available
EMS: F-A
Special Provisions: 223, 274
Description: UN2811, Toxic solid, organic, n.o.s. (BACLOFEN), 6.1, III

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ICAO

UN-No: UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III
Special Provisions A3, A5

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Baclofen	1134-47-0	Not Listed	Present KE-01454	Not present	Not present	Not present	Present	Present 214-486-9

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Baclofen	1134-47-0	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Baclofen	1134-47-0	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Baclofen	1134-47-0	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

Product code: B1049

Product name: BACLOFEN, USP

WHMIS 2015 Hazard Classification
Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class
D1B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Baclofen	1134-47-0	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Baclofen	1134-47-0	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Baclofen	1134-47-0	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Baclofen	1134-47-0	

EU - CLP (1272/2008)

R-phrases(s)

R25 - Toxic if swallowed.

R43 - May cause sensitization by skin contact.

S -phrase(s)

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Baclofen	1134-47-0		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T - Toxic

T



16. OTHER INFORMATION

Preparation Date: 04/15/2015
Revision Date: 6/22/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
B1049	Baclofen, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

B1049, Baclofen, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Baclofen, USP (Cat# B1049)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Arsenic	As	1	< 1.5 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 ppm
Lithium	Li	3	< 55 ppm
Antimony	Sb	3	< 120 ppm
Copper	Cu	3	< 300 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Baclofen, USP (Cat# B1049)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

DANGER

• Toxic if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • May cause drowsiness or dizziness • May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled • May damage fertility or the unborn child.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection, protective gloves, protective clothing • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

FIRST AID: 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 attention. IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth. If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

B1049

SIZ SY

Baclofen

USP

CAS 1134-47-0

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solid, organic, n.o.s. (baclofen), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{10}H_{12}ClNO_2$ F.W. 213.66

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Anhydrous Basis) 98.0-102.0%
MAXIMUM LIMITS

Water Determination 3.0%
Residue on Ignition 0.3%
Elemental Impurities As reported
Organic Impurities:
Baclofen Related Compound A 1.0%
Any Unspecified Impurity 0.10%
Total Impurities 2.0%
Residual Solvents To pass test

Store at Room Temperature: Keep tightly closed.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

Repackaged by Spectrum as:

B 12/J2GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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West Coast Facility:

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