

Scientific Documentation

Bromfenac Sodium Sesquihydrate, bioCERTIFIED (TM)

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
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Specification for Bromfenac Sodium Sesquihydrate, bioCERTIFIED (TM) (BR901)

Item Number	BR901
Item	Bromfenac Sodium Sesquihydrate, bioCERTIFIED (TM)
CAS Number	120638-55-3
Molecular Formula	C ₁₅ H ₁₁ BrNNaO ₃ •1.5H ₂ O
Molecular Weight	383.17
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (HPLC)	99.0	101.0 %
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (HPLC)	TO PASS TEST	
IDENTIFICATION (SODIUM)	TO PASS TEST	
COLOR OF SOLUTION	TO PASS TEST	
SOLUBILITY	TO PASS TEST	
CLARITY OF SOLUTION AND DEGREE OF OPALESCENCE	TO PASS TEST	
pH	8.4	9.3
SODIUM (IC)	5.5	6.5%
WATER (KF)	6.5	7.5%
CHLORIDES		0.05 %
ELEMENTAL IMPURITIES	AS REPORTED	
RELATED SUBSTANCES:		
IMPURITY A (7-(4-BROMOBENZOYL)INDOLIN-2-ONE)		0.15 %
IMPURITY B (2-AMINO-3-(4-BROMOBENZOYL)BENZOIC ACID)		0.15 %
IMPURITY C (2-(2-AMINO-3-(4-BROMOBENZOYL)PHENYL)-2-OXOACETIC ACID)		0.15 %

Test	Specification	
	Min	Max
IMPURITY D (7-(4-BROMOBENZOYL)INDOLINE-2,3-DONE)		0.15 %
ANY UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT		10 ³ cfu/g
TOTAL YEAST AND MOLD COUNT		10 ² cfu/g
BACTERIAL ENDOTOXINS		10 EU/mg
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	BR901	Lot Number	4LB0003
Item	Bromfenac Sodium Sesquihydrate, bioCERTIFIED (TM)	Manufacturer Lot	BFS4O21002
CAS Number	120638-55-3	Manufacturer Code	15057
Molecular Formula	C ₁₅ H ₁₁ BrNNaO ₃ •1.5H ₂ O	Molecular Weight	383.17

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (HPLC)	99.0	101.0 %	99.4%
IDENTIFICATION (IR)	TO PASS TEST		PASSES TEST
IDENTIFICATION (HPLC)	TO PASS TEST		PASSES TEST
IDENTIFICATION (SODIUM)	TO PASS TEST		PASSES TEST
COLOR OF SOLUTION	TO PASS TEST		PASSES TEST
SOLUBILITY	TO PASS TEST		PASSES TEST
CLARITY OF SOLUTION AND DEGREE OF OPALESCENCE	TO PASS TEST		PASSES TEST
pH	8.4	9.3	8.9
SODIUM (IC)	5.5	6.5%	5.5% ADOPTED FROM MANUFACTURE COFA
WATER (KF)	6.5	7.5%	7.0%
CHLORIDES		0.05 %	<0.05%
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
RELATED SUBSTANCES:			.
IMPURITY A (7-(4-BROMOBENZOYL)INDOLIN-2-ONE)		0.15 %	0.0%
IMPURITY B (2-AMINO-3-(4-BROMOBENZOYL)BENZOIC ACID)		0.15 %	0.0%
IMPURITY C (2-(2-AMINO-3-(4-BROMOBENZOYL)PHENYL)-2-OXOACETIC ACID)		0.15 %	0.0%
IMPURITY D (7-(4-BROMOBENZOYL)INDOLINE-2,3-DONE)		0.15 %	0.0%

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ANY UNSPECIFIED IMPURITY		0.10 %	0.0%
TOTAL IMPURITIES		0.5 %	0.0%
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT		10 ³ cfu/g	< 10 ³ cfu/g
TOTAL YEAST AND MOLD COUNT		10 ² cfu/g	<10 ² cfu/g
BACTERIAL ENDOTOXINS		10 EU/mg	<10 EU/mg
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / 2-METHOXYETHANOL			<50 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
CLASS 3 (solvent) / ETHYL ACETATE			<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm
MANUFACTURE DATE			01-SEP-2021
EXPIRATION DATE			31-AUG-2026

Certificate of Analysis Results Entered By:

BPATEL
Bhargavi Patel
22-MAR-22 06:59:03

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BPATEL
Bhargavi Patel
22-MAR-22 06:59:43

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.

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 Micro Labs Limited at Plot No. 43-45, KIADB, Jigani - Bommasandra Link Road, Anekal Taluk, Bangalore, Karnataka 560105, 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

spectrum®



Revision date 21-October-2020

Revision Number 1

1. Identification

Product identifier

Product Name BROMFENAC SODIUM SESQUIHYDRATE

Other means of identification

Product Code(s) BR901

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 4
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Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed



Appearance Powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Unknown acute toxicity

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Bromfenac Sodium Sesquihydrate	120638-55-3	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Color	Yellow; Orange
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	285 - 292 °C / 545 - 557.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	No data available	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.

Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Acute toxicity

Numerical measures of toxicity
No information available

Unknown acute toxicity

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA	Not listed
Note	*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements
DSL/NDSL	Does not Comply
EINECS/ELINCS	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Does not Comply
PICCS	Does not Comply
AICS	This product does not comply with AICS

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 21-October-2020
Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

BR901, Bromfenac Sodium Sesquihydrate

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

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.

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