

Safety Data Sheet

1. Identification

Product name	Japanese Pharmacopoeia Bromfenac Sodium Reference Standard
Supplier Name	Pharmaceutical and Medical Device Regulatory Science Society of Japan
Address	2-12-15, Shibuya, Shibuya-ku, Tokyo 150-0002, Japan
Tel	+81-3-3400-5634
Emergency contact	Pharmaceutical and Medical Device Regulatory Science Society of Japan, Pharmaceutical Reference Standards Center
Tel	+81-6-6221-3444
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Recommended use	This product is analytical reagent.
Restrictions on use	It is not a medicine or clinical diagnostic agent, so it can not be used for human or animals.

2. Hazard Identification

GHS Classification of chemicals

Physicochemical hazards Not classified.

Health hazards

Acute toxicity (Oral)	Category 2
Reproductive toxicity	Category 2
Specific target organ toxicity - Single exposure	Category 2 (gastrointestinal tract)
Specific target organ toxicity - Repeated exposure	Category 1 (liver)

Environmental hazards Not classified.

Label elements Pictograms



Signal word Danger

Hazard statement
 Fatal if swallowed
 Suspected of damaging fertility or the unborn child
 May cause damage to organs (gastrointestinal tract)
 Causes damage to organs (liver) through prolonged or repeated exposure

Precautionary statement

【Prevention】
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wear protective gloves/protective clothing/eye protection/face protection.
 Do not breathe dust/fume/gas/mist/vapours/spray.

【Response】
 If swallowed: Immediately call a doctor/physician.
 Rinse mouth.
 If exposed or concerned: Call a doctor/physician.
 Get medical advice/attention if you feel unwell.

【Storage】
 Store locked up.

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

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Bromfenac sodium 1.5 hydrate.
Synonym / common name	—
CAS No.	120638-55-3
Component and concentration or concentration range	100%
Reference Number in Gazetted List in	ENCS : —

Japan	ISHL : —
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victim to fresh air and keep comfortable for breathing. Get medical attention if irritation develops and persists.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Immediately call a doctor/physician. Rinse mouth.
Most important symptoms/effects, acute and delayed	No data available.
Protection of first-aiders	Wear personal protective equipment as required.
Indication of immediate medical attention and special treatment needed	Provide the symptomatic treatment.

5. Fire-Fighting Measures

Suitable extinguishing media	Water spray, foam, dry chemical, carbon dioxide.
Unsuitable extinguishing media	No data available.
Specific hazards arising from the chemical product	Irritating, toxic or corrosive gases may be generated by a fire.
Special extinguishing method	Use standard firefighting procedures and consider the hazards of other involved materials. As with all fires, evacuate personnel to a safe area. Use water spray to cool unopened containers.
Protection of fire-fighters	Wear suitable protective equipment.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Avoid inhalation of dust or vapor etc from the spilled material. See section 8 of the SDS, wear suitable protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Avoid release to the environment.
Methods and materials for containment and cleaning up	Collect spillage in an appropriate way. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

7. Handling and Storage

Handling	Technical measures	See section 8 of the SDS, perform engineering controls and wear protective equipment. See section 8 of the SDS, perform local ventilation or general ventilation.
	Safety handling precautions	When handling Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wear personal protective equipment. After removing gloves, wash hands and other exposed skin thoroughly. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.
Storage	Contact avoidance	See section 10 of the SDS.
	Safe storage conditions	Keep container tightly closed. Store locked up.
	Safe packaging material	Store in an appropriate container according to applicable laws and regulations.

8. Exposure Controls/Personal Protection

Administrative Control Levels	Not set up.
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Occupational Exposure Limits	No data available.
Engineering controls	Install an eyewash facilities and a safety shower in the workplace where this material is stored or handled. Install general ventilation system and local exhaust ventilation. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Personal protective equipment	
Respiratory protection	Wear appropriate respiratory protection (e.g., dust mask, gas mask).
Hand protection	Wear appropriate protective gloves (e.g., chemically compatible gloves).
Eye protection	Wear appropriate eye protection/face protection (e.g., safety glasses with side shields, goggle-type protective glasses).
Skin and body protection	Wear appropriate protective clothing (e.g., lab coat, long sleeve work clothes).

9. Physical and Chemical Properties and Safety Characteristics

Physical state	Solid: Crystalline powder.
Colour	Yellow to orange.
Odor	No data available.
Melting point/Freezing point	260 - 275°C
Flammability	No data available.
Boiling point or initial boiling point and boiling range	No data available.
Lower and upper explosion limit/ flammability limit	
Lower limit(%)	No data available.
Upper limit (%)	No data available.
Flash point	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
pH	8.4 - 10.2 (1 g/20 mL, 25°C)
Kinematic viscosity	No data available.
Solubility Water	0.05 g/mL (25°C)
Other	No data available.
Partition coefficient n-octanol/water (log value)	No data available.
Vapor pressure	No data available.
Density and/or relative density	1.558 g/cm ³
Relative vapor density	No data available.
Particle characteristics	No data available.
Other information	No data available.

10. Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction under conditions of normal use.
Conditions to avoid	No data available.
Incompatible materials	Strong oxidizer.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Acute toxicity			
	Tests	Species	Results
	Oral-LD50	Rat	39.6 mg/kg
Skin corrosion / irritation	No data available.		
Serious eye damage / eye irritation	This material is used in ophthalmic drugs. Contact with eyes other than under appropriate dosage situations should be avoided as a precaution.		
Respiratory sensitization	No data available.		
Skin sensitization	No data available.		
Germ cell mutagenicity	As a result of various tests, this material was not considered to be mutagenic.		

Carcinogenicity

Tests	Species	Results
Long-term carcinogenicity test	Mouse, rat	No carcinogenicity.

Reproductive toxicity

Tests	Species	Results
0.9 mg/kg/day Oral administration test	Rat	Embryo-fetal lethality, reduced and postnatal growth.
7.5 mg/kg/day Oral administration test	Rabbit	Increased post-implantation loss.
Large oral doses test	—	Bromfenac may cross the placenta and may be excreted in breast milk.

Specific target organ toxicity - Single exposure

Tests	Species	Results
Oral administration test	Rat	Gastrointestinal tract damage (hemorrhagic spots) and kidney toxicity (blood in urine) were observed.

Specific target organ toxicity - Repeated exposure

Tests	Species	Results
Long-term toxicity test	Mouse, rat	Intestinal ulcers and dose-dependent adverse liver effects were observed.

Aspiration hazard	No data available.
Other information	No data available.

1 2 . Ecological Information

Ecotoxicity	No data available.
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Hazard to the ozone layer	This substance is not listed in the Annex to the Montreal Protocol.

1 3 . Disposal Considerations

Information on safe and environmentally desirable disposal or recycling of chemicals, contaminated containers and packaging.

Dispose in a safe manner in accordance with national and local regulations.

When empty containers are discarded, contents should be completely removed.

1 4 . Transport Information

UN Number	UN2811
Proper shipping name	Toxic solids, organic, N.O.S. (Bromfenac Sodium)
Hazard class	6.1
Subsidiary hazard class	—
Packing group	II
Domestic restriction	Rail and road Not regulated.
Marine	Comply with Ship Safety Act.
Aviation	Comply with Civil Aeronautics Act.

1 5 . Regulatory Information

Japanese regulations	
Pollutant Release and Transfer Register	Not regulated.
Poisonous and Deleterious Substances Control Act	Not regulated.
Industrial Safety and Health Act	Not regulated.
Fire Service Act	Not regulated.

1 6 . Other Information

Issued date	BRO-01 :	Mar. 12, 2019
Revision date	BRO-02 :	Apr. 01, 2021
References	Ministry of Health, Labour and Welfare : GHS model SDS information Japan Science and Technology Agency. : J-GLOBAL National Institute of Technology and Evaluation: NITE Chemical Risk Information Platform (NITE-CHRIP) etc.	

The information in this Safety Data Sheet is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification of this product. The information provided is correct to the best of our knowledge, information and belief at the date of its publication and so on. However, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity.