Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Ozagrel 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
	Fax	+81-6-6221-3445
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		
	Serious eye damage / eye irritation	Category 2B
	Specific target organ toxicity - Single exposure	Category 2 (cardiovascular, digestive system)
	Specific target organ toxicity - Repeated exposure	Category 1 (cardiovascular, digestive system, liver, kidney, blood system)
Environmental hazards		Not classified.

Label elements

Pictograms

Signal word: Danger

Hazard statement:
Causes eye irritation
May cause damage to organs (cardiovascular, digestive system)
Causes damage to organs (cardiovascular, digestive system, liver, kidney, blood system) through prolonged or repeated exposure

Precautionary statement:
【Prevention】
Wash hands thoroughly after handling.
Do not breathe dust/fume/gas/mist/vapours/spray.
Do not eat, drink or smoke when using this product.
【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 exposed or concerned: Call a doctor/physician.
Get medical advice/attention if wou 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	Ozagrel sodium.
Synonym / common name	－
CAS No.	189224-26-8
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : 8-(2)-1335
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victime 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 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.
Ingestion	Rinse mouth.
	If ingestion of a large amount dose occur, call a doctor/physician immediately.
Most important symptoms/effects, acute and delayed	Shock. Anaphylactoid symptoms.
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	Straight discharge of water.
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 ventiration 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.
	Contact avoidance	See section 10 of the SDS.
Storage	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	No set up.
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: Crystals or crystalline powder.
Colour		White.
Odour		Odorless.
Melting point/Freezing point		about 300℃
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		No data available.
Kinematic viscosity		No data available.
Solubility	Water	Freely soluble.
	Other	Soluble in methanol. Practically insoluble in anhydrous ethanol, acetone, ether.
Partition coefficient n-octanol/water (log value)		No data available.
Vapor pressure		No data available.
Density and/or relative density		No data available.
Relative vapor density		No data available.
Particle characteristics		No data available.
Other information		
	Aqueous solution pH	9.5 - 10.5 (0.5 g/water 10 mL)

10. Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Heat: Stable for 3 months at 40 ℃ (sealed, light resistant), 24 months at 25 ℃ (sealed, light resistant). Light: Stable for 4 weeks at 1800 lux (slightly unstable to light).
Possibility of hazardous reactions	No dangerous reaction under conditions of normal use.
Conditions to avoid	Avoid mixing with air in powder or granular form. Avoid the generation of dust.
Incompatible materials	Reducing agents. Oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological Information

Acute toxicity

Tests	Species	Results
Oral LD50	Mouse	Male: 3800 mg/kg, Female: 3600 mg/kg
	Rat	Male: 5900 mg/kg, Female: 5700 mg/kg

Skin corrosion / irritation: Listed in the below table.

Serious eye damage / eye irritation

Tests	Species	Results
Ocular-mucous membrance irritation test, skin primary irritation test and muscle irritation test	Rabbit	0.02-0.2%: Almost no irritation. 2%: Mild irritation.

Respiratory sensitization

Tests	Species	Results
Histamine release test	Rabbit	Non-antigenic.
Indirect hemagglutination reaction	Rabbit	Non-antigenic.
Passive skin anaphylactic reaction	Rabbit	Non-antigenic.
Systemic anaphylactic reaction	Guinea pig	Non-antigenic.

Skin sensitization The same as above.

Germ cell mutagenicity

Tests	Results
Reverse mutation test	Negative.
Mouse micronucleus test	Negative.

Carcinogenicity

Tests	Results
Mixed feeding administration test (ozagrel hydrochloride) for 80 weeks in mouse	Non-carcinogenic.
Mixed feeding administration test (ozagrel hydrochloride) for 104 weeks in rat	Non-carcinogenic.

Reproductive toxicity

Tests	Results
Administration test prior and in the early stages of pregnancy in rat, administration test during the period of organogenesis in rabbit and rat, administration test during the perinatal and lactation period in rat	Male and female fertility, teratogenic effects, influence on postnatal education was not observed.

Specific target organ toxicity - Single exposure

Tests	Results
Case of rat and mouse	Symptoms presumed to be caused by lowering blood pressure were observed. Cause of death is thought to be respiratory dysfunction associated with decreased blood pressure.
Single intravenous administration test in 8 healthy adult men (5, 25 mg administered slowly over 3 minutes), intravenous continuous administration test in 4 healthy adult men (0.2, 1, 5, 15 μg/kg/min for 3 hours)	No abnormalities were observed in subjective symptoms, objective findings, blood pressure, pulse rate, body temperature, electrocardiogram, general examination, blood biochemical examination, general urine examination, and urine chemical examination.
Continuous administration in humans	Hypersensitivity may include rash, hives, erythema, asthma (like) attack, pruritus. Cardiovascular symptoms may include supraventricular extrasystole and decreased blood pressure. Gastrointestinal symptoms may include nausea, vomiting, diarrhea, loss of appetite, and fullness feeling. Other symptoms may include fever, headache, pain in the chest, redness/tumor/pain in the injection area, hot flashes, chills / shivering, arthritis, increased CRP, and increased CK (CPK).

Specific target organ toxicity - Repeated exposure

Tests	Results
5, 25, 125, 625 mg/kg, Intravenous administration test for 30 days in rat	In 125 mg/kg or more, increased urinary electrolyte excretion and decreased ovarian weight were observed.
5, 25, 125, 500 mg/kg, Intravenous administration test for 6 months in rat	In 500 mg/kg or more, increased hair loss on dorsal neck, suppression of weight gain, changes in urinary electrolytes, mild anemia, decreased serum lipids, and increased adrenal weight were observed. NOEL is estimated to be 125 mg/kg.
12.5, 50, 200 mg/kg, Intravenous administration test for 3 months in dog	In 50 mg/kg or more, increased serum CK (CPK), transient nasal discharge, salivation, symptoms of collapse, loose stool, vomiting were observed. In 200 mg/kg, increased serum K^+ and decreased brain weight were observed.
10, 30, 100 mg/kg Intravenous administration test for 6 months in dog	In 30 mg/kg or more, nasal discharge, salivation, symptoms of collapse were observed during or immediately after medication. In 100 mg/kg or more, loose stools and vomiting were observed. NOEL is estimated to be 10 mg/kg. All of these symptoms have been recovered by withdrawal.

Continuous administration in humans	Hemorrhagic cerebral infarction/ epidural hematoma/intracerebral hemorrhage, gastrointestinal hemorrhage, subcutaneous hemorrhage, hematuria may occur (to suppress platelet aggregation ability). May cause shock or anaphylactoid symptoms. Hepatic function disorder, jaundice, severe hepatic function disorder accompanied by significant increase in AST (GOT) / ALT (GPT), jaundice, LDH, alkaline phosphatase, and increased bilirubin may occur. Leukopenia and granulocytopenia may occur, and fever, chills, etc. are often observed at the time of onset. If these symptoms appear, suspect this conditions and perform a blood test. Serious renal dysfunction (acute renal failure, etc.), increased BUN, and increased creatinine may occur (frequency unknown). Thrombocytopenia is often associated with renal dysfunction.
Aspiration hazard	No data available.
Other information	
Pharmacological activity	Thromboxane synthase inhibitory action.

12. 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.

13. 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.

14. Transport Information

UN Number		Not regulated.
Proper shipping name		
Hazard class		
Subsidiary hazard class		
Packing group		
Domestic restriction	Rail and road	Not regulated.
	Marine	Not regulated.
	Aviation	Not regulated.

15. 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.

16. Other Information

Issued date	OZA-01 :	Oct. 11, 2019
Revision date	OZA-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.