Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Montelukast Sodium for Identification 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 1
Environmental hazards		
	Hazardous to the aquatic environment - Short-term (Acute) hazard	Category 2

Label elements

Pictograms

Signal word: Danger

Hazard statement:
Causes serious eye damage
Toxic to aquatic life

Precautionary statement:
【Prevention】
Wear protective eye protection/face protection.
Avoid release to the environment.
【Response】
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a doctor/physician.
【Disposal】
Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Montelukast sodium.
Synonym / common name	－
CAS No.	151767-02-1
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : 8-(1)-2723
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.
	Immediately call a doctor/physician.
Ingestion	Rinse mouth.
	If ingestion of a large amount dose occur, call a doctor/physician immediately.
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 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.
		Avoid release to the environment.
	Contact avoidance	See section 10 of the SDS.
Storage	Safe storage conditions	Keep container tightly closed.
	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.
Occupational Exposure Limits	TWA: 0.1 mg/m^3
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: Powder.
Colour	White to pale yellow-white.
Odor	Odorless.
Melting point/Freezing point	135.5℃
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	Freely soluble in ethanol, methanol. Practically insoluble in acetonitrile.
Partition coefficient n-octanol/water (log value)	2.3
Vapor pressure	No data available.
Density and/or relative density	0.15
Relative vapor density	No data available.
Particle characteristics	No data available.
Other information	No data available.
Minimum ignition energy (MIE)	10 ~ 30 mJ
Potential for dust explosion	Highly sensitive to ignition.

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	No data available.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. NaOx. Cl^-

１１．Toxicological Information

Acute toxicity

Tests	Species	Results
Oral LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg

Skin corrosion / irritation

Tests	Species	Results
Draize test	Rabbit	Mild irritation.

Serious eye damage / eye irritation

Tests	Species	Results
Draize test	Rabbit	Corrosive. Conjunctival redness. Corneal opacity. Iritis.

Respiratory sensitization No data available.

Skin sensitization

Tests	Species	Results
Sensitization assay	Guinea pig	No induction of active systemic or passive cutaneous anaphylaxis.

Germ cell mutagenicity

Tests	Results

Alkaline elution assay in rat hepatocytes	Negative.
Chromosome aberration assay in Chinese hamster ovary cells	Negative.
In vivo mouse bone marrow chromosome aberration assay	Negative.
Microbial mutagenesis assay	Negative.
V-79 mammalian cell mutagenesis assay	Negative.

Carcinogenicity

Tests	Species	Results
100 mg/kg/day Long-term carcinogenicity study, oral doses (92 weeks)	Mouse	No tumorigenicity.
200 mg/kg/day Long-term carcinogenicity study, oral doses (2 years)	Rat	No tumorigenicity.

Reproductive toxicity

Tests	Results
100 - 200 mg/kg Fertility assay in female rats, administered orally	Reductions in fertility and fecundity indices at the high dose but not at the low dose.
300 mg/kg/day Reproductivity and development test in rabbits, administered orally during gestation	Not fetotoxic or teratogenic.
400 mg/kg/day Reproductivity and development test in rats, administered orally during gestation	Not fetotoxic or teratogenic.
800 mg/kg Fertility assay in male rats, administered orally	No adverse effect on fertility.

Specific target organ toxicity - Single exposure	No data available.
Specific target organ toxicity - Repeated exposure	No data available.
Aspiration hazard	No data available.
Other information	No data available.

１２．Ecological Information

Ecotoxicity

Tests	Species	Results
Crustacea LC50	Water flea (*Daphnia magna*)	> 1.5 mg/L, 48 hours
Fish LC50	Fathead minnow (*Pimephales promelas*)	> 1.5 mg/L, 96 hours
	Rainbow Trout	4.47 mg/L

Persistence and degradability	Expected to degrade rapidly in water when exposed to sunlight.
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	MONs-01： Jun. 07, 2019
Revision date	MONs-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.