Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Clobetasol Propionate 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 an 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		
	Reproductive toxicity	Category 1B
	Specific target organ toxicity - Repeated exposure	Category 1 (Adrenal, immune system)
Environmental hazards		
	Hazardous to the aquatic environment - Long-term (Chronic) hazard	Category 4

Label elements

Pictograms

Signal word: Danger

Hazard statement:
May damage fertility or the unborn child
Causes damage to organs (Adrenal, immune system) through prolonged or repeated exposure
May cause long lasting harmful effects to aquatic life

Precautionary statement:
【Prevention】
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.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.
【Response】
If exposed or concerned: Get medical advice/attention.
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	Clobetasol propionate.
Synonym / common name	－
CAS No.	25122-46-7
Component and concentration or concentration range	100%

Reference Number in Gazetted List in Japan	ENCS : － ISHL : 7-(1)-390
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 with water. Get medical attention if irritation develops and persists.
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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy and while nursing.

		Avoid release to the environment.
	Contact avoidance	See section 10 of the SDS.
Storage	Safe storage conditions	Keep container tightly closed.
		Store in a well-ventilated place. Keep it in a cool place.
	Safe packaging material	Store in an appropriate container according to applicable laws and regulations.

8. Exposure Controls/Personal Protection

Occupational Exposure Limits		TWA : 2 μg/m^3 (Skin)
		OHC : 4 (Skin)
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.
Odour		No data available.
Melting point/Freezing point		195℃
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	No data available.
	Other	No data available.
Partition coefficient n-octanol/water (log value)		3.49 (Measured).
Vapor pressure		< 1.00×10^{-7} kPa (25℃)
Density and/or relative density		No data available.
Relative vapor density		No data available.
Particle characteristics		No data available.
Other information		
	pH in aqueous solution	6.8 - 7 (10% suspension solution, 21 ℃)
	Dust explosivity	Group: A
		Pmax: 8 bar
		dP/d: 718 bar/s
		Kst: 195 bar.m/s
		St class: 1 (Tested at particle size: < 75 μm)
		Limiting oxygen concentration (LOC): 12% v/v
		Minimum ignition energy (MIE)-dust clouds: 3~4 mJ (Tested at particle size: < 75 μm).
		Minimum ignition temperature (MIT)-dust clouds：480℃.
		Minimum ignition temperature (MIT)-dust layer: No ignition or exotherm observed up to 400℃.
	Electrostatic risk	Charge relaxation time (ambient humidity): 40664 sec (45%, 24℃).

	Charge relaxation time (low humidity): 124521 sec (1%, 22℃).
	Resistivity (ambient humidity): 4.00×10^{14} Ωm (45%, 24℃)
	Resistivity (low humidity): 6.00×10^{14} Ωm (1%, 22℃)
Oxygen balance	-209 (This material is considered to be of low energy hazard potential).
Temperature rating	IEC:T2
	USA:T2
Burning rate test	Non-combustible. (Supports localised combustion).

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	Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimise dust generation and accumulation. Avoid dispersion as a dust cloud.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Fluorine and chlorine compounds.

１１．Toxicological Information

Acute toxicity

Tests	Species	Results
Oral LD50	Rat	> 2000 mg/kg

Skin corrosion / irritation	Skin corrosivity: Negative
Serious eye damage / eye irritation	Dust or powder may irritate eye tissue.
	Eye irritation: Negative
Respiratory sensitization	No data available.

Skin sensitization

Tests	Results
Buehler assay, DEREK, Lhasa, UK	Negative
SAR / QSAR, OECD QSAR Toolbox, Laboratory ofMathematical Chemistry, Bulgaria	Positive.

Germ cell mutagenicity

Tests	Results
Ames test	Negative.
Micronucleus test	Negative.
Mutation - *E. coli* fluctuation test	Negative.
Yeast mutation	Negative.

Carcinogenicity

Tests	Species	Results
2-year dermal study	Rat	Negative

Reproductive toxicity

Tests	Results
>= 0.03 mg/kg/day Embryofetal development test in mouse, sub-cutaneous administration	Developmental effects including cleft palate.
25-50 µg/kg/day Fertility test in rat, sub-cutaneous administration	Parental toxicity. Reduced fertility at high dose.
3-10 µg/kg/day Embryofetal development test in rabbit, sub-cutaneous administration	Developmental effects including cleft palate.

Specific target organ toxicity - Single exposure	No data available.
Specific target organ toxicity - Repeated exposure	Glucocorticoid. Adrenals. Immune system. Bone. Eyes.

Aspiration hazard — No data available.

12. Ecological Information

Ecotoxicity

Tests	Species	Results
Activated sludge respiration IC50	Residential sludge	> 100 mg/L, 3 hours (nominal)
Activated sludge respiration NOEC	Residential sludge	100 mg/L, 3 hours
Algae EC50	*Selenastrum capricornutum*	> 4.2 mg/L, 72 hours (measured)
Algae NOEC	*Selenastrum capricornutum*	1.3 mg/L, 72 hours
Crustacea EC50	*Daphina magna*	> 1.4 mg/L, 48 horus (measured)
Crustacea NOEC	*Daphina magna*	1.4 mg/L, 48 hours
Fish EC50	Rainbow trout	> 0.75 mg/L, 96 hours (measured)
Fish NOEC	Rainbow trout	0.75 mg/L, 96 hours

Persistence and degradability — < 5 %,14 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Bioaccumulative potential — Partition coefficient n-octanol/water (log value): 3.49 (Measured).

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	CLO-01 :	Feb. 13, 2020
Revision date	CLO-03 :	Jul. 06, 2022

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.