RSLAB
Precise is Safe

SAFETY DATA SHEET

1. Identification

Product name	Loteprednol Etabonate
Product code	RSL02343
CAS number	82034-46-6
Chemical name	(11β,17α)-17-[(Ethoxycarbonyl)oxy]-11-hydroxy-3-oxo-androsta-1,4-diene-17-carboxylic acid chloromethyl ester.
Suggested use	Specified quality tests and assay use only.
Advised limitations	Not for use as a drug. Not for administration to humans or animals.
Manufacturer	Reflabpharm LLC
Address	Armenia, Yerevan, 0019, Silikyan 2nd str. 25/1
Telephone	+37411554055
Website	www.reflab.am
E-mail	info@reflab.am

2. Hazard(s) Identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Signal word	Warning.
Hazard statement	Suspected of causing genetic defects.
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.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Loteprednol Etabonate	(11β,17α)-17-[(Ethoxycarbonyl)oxy]-11-hydroxy-3-oxo-androsta-1,4-diene-17-carboxylic acid chloromethyl ester.	82034-46-6	100

4. First-aid Measures

Inhalation	Remove to fresh air.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.
Ingestion	Clean mouth with water and drink afterwards plenty of water.
Most important symptoms/effects, acute and delayed	No information available.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO_2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers.
Equipment	Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section "Personal Protection" of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section "Disposal considerations" of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling	As a general rule, when handling CRMs, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	This material should be handled and stored per label instructions to ensure product integrity.

8. Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Biological limit values	No biological exposure limits noted for the ingredient(s).

Individual protection measures

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity

	and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point	213 - 219 °C (415.4-426.2°F)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	

Solubility (water)	Very soluble.
Solubility (other)	Chloroform: Soluble. Methanol: Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

9.3 Other information

Molecular formula	$C_{24}H_{31}ClO_7$
Molecular weight	466.96

10.Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
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

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Not available.

Information on toxicological effects

Acute toxicity	Not Known
Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization	Knowledge about health hazard is incomplete.
Skin sensitization	Knowledge about sensitization hazard is incomplete.
Germ cell mutagenicity	Contains a known or suspected mutagen. Classification based on data available for ingredients. Suspected of causing genetic defects.
Carcinogenicity	Knowledge about health hazard is incomplete.
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.
Aspiration hazard	Knowledge about health hazard is incomplete.
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.

12.Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this substance.
Bioaccumulative potential	
Octanol/water partition coefficient log Kow	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13.Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14.Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15.Regulatory information

Safety, health and environmental regulations/legislation specific for the substance

This Safety Data Sheet has been prepared in accordance with applicable GHS principles for hazard communication.

Chemical safety assessment

A chemical safety assessment has not been carried out for this substance.

16.Other information, including date of preparation or last revision

Disclaimer

Reflabpharm CRMs are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein applies solely to the chemical substance when used as a Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). CRMs are intended for use by persons having technical skills and at their discretion and risk. This information has been developed by Reflabpharm staff from sources considered reliable but has not been independently verified by Reflabpharm. Therefore, the Reflabpharm cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made concerning the information contained herein.