

## Section 1 - Identification

### Product Identifier

<b>Product Name</b>	<b><u>Loteprednol etabonate</u></b>
<b>CAS No</b>	82034-46-6
<b>Molecular Formula</b>	C <sub>24</sub> H <sub>31</sub> Cl O <sub>7</sub>
<b>Molecular Weight</b>	466.96
<b>Recommended Use</b>	Laboratory chemicals.
<b>Uses advised against</b>	No Information available

<b>Product Code</b>	<b>467700000; 467700010; 467700050</b>
<b>Address</b>	Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand
<b>Emergency Tel.</b>	<b>CHEMTREC®</b> <b>09 980 6780 or +64 9 980 6780</b>
<b>Telephone / Fax Numbers</b>	Tel: 09 980 6700 Fax: 09 980 6788
<b>E-mail address</b>	<a href="mailto:ANZinfo@thermofisher.com">ANZinfo@thermofisher.com</a>

## Section 2 - Hazard(s) Identification

### Classification under Work Safe New Zealand

Not classified as hazardous according to criteria of EPA New Zealand

### GHS Classification

#### Physical hazards

Based on available data, the classification criteria are not met

#### Health hazards

Based on available data, the classification criteria are not met

#### Environmental hazards

Based on available data, the classification criteria are not met

### Label Elements

None required

Other hazards which do not result in classification

## Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
Loteprednol etabonate	82034-46-6	<=100

## Section 4 - First Aid Measures

### Description of first aid measures

New Zealand Emergency Tel.	CHEMTREC® 09 980 6780 or +64 9 980 6780
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Self-Protection of the First Aider	No special precautions required.
First Aid Facilities	Eyewash, safety shower and washroom.
Most important symptoms and effects	None reasonably foreseeable.
Notes to Physician	Treat symptomatically.

## Section 5 - Fire Fighting Measures

### Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO<sub>2</sub>, water spray or alcohol-resistant foam.

### Extinguishing media which must not be used for safety reasons

No information available.

### Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

### Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Hydrogen chloride.

### Special protective equipment and precautions for fire fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## Section 6 - Accidental Release Measures

### Personal Precautions, Protective Equipment and Emergency Procedures

**Emergency procedures**

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

**Environmental Precautions**

Should not be released into the environment.

**Methods for Containment and Clean Up**

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

**Precautions to prevent secondary hazards**

Clean contaminated objects and areas thoroughly observing environmental regulations

**Reference to Other Sections**

Refer to protective measures listed in Sections 8 and 13.

## **Section 7 - Handling and Storage**

**Precautions for Safe Handling****Advice on safe handling**

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

**Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

**Conditions for Safe Storage, Including any Incompatibilities****Storage Conditions**

Keep container tightly closed in a dry and well-ventilated place. Store in freezer.

**Incompatible Materials**

Strong acids. Oxidizing agent.

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

## **Section 8 - Exposure Controls and Personal Protection**

**Control parameters****Exposure limits**

The product does not contain any hazardous materials with occupational exposure limits established.

**Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

**Appropriate engineering controls****Engineering Measures**

None under normal use conditions.

**Individual protection measures, such as personal protective equipment****Eye Protection**

Wear safety glasses with side shields (or goggles) (Australian/New Zealand Standard AS/NZS 1337 - Eye protectors for Industrial applications)

**Hand Protection**

Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Nitrile rubber, Neoprene, Natural rubber, PVC.	See manufacturers recommendations	-	AS/NZS 2161	(minimum requirement)

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Skin and body protection** Long sleeved clothing

**Respiratory Protection** Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use and maintenance of respiratory protective devices

**Recommended Filter type:** Particle filter (or AUS/NZ equivalent)

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## Section 9 - Physical and Chemical Properties

### Information on basic physical and chemical properties

<b>Physical State</b>	Solid Powder	
<b>Appearance</b>	Off-white	
<b>Odor</b>	No information available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available	
<b>Melting Point/Range</b>	226 - 233 °C / 438.8 - 451.4 °F	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available	
<b>Flammability (liquid)</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available	
<b>Flash Point</b>	No information available	<b>Method -</b> No information available
<b>Autoignition Temperature</b>	No data available	
<b>Decomposition Temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Water Solubility</b>	Insoluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Component</b>	<b>log Pow</b>	
Loteprednol etabonate	4.539	
<b>Vapor Pressure</b>	No data available	
<b>Density / Specific Gravity</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Particle characteristics</b>	No data available	

### Other information

<b>Molecular Formula</b>	C24 H31 Cl O7
<b>Molecular Weight</b>	466.96
<b>Evaporation Rate</b>	Not applicable - Solid

## Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Stable under recommended storage conditions.
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available
Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.
Conditions to Avoid	Incompatible products.
Incompatible Materials	Strong acids, Oxidizing agent.
Hazardous Decomposition Products	Carbon monoxide (CO). Carbon dioxide (CO <sub>2</sub> ). Hydrogen chloride.

## Section 11 - Toxicological Information

### Acute Effects

### Information on likely routes of exposure

Product Information	The toxicological properties have not been fully investigated
Inhalation	Avoid breathing dust or spray mist.
Eyes	Not an expected route of exposure.
Skin	No known effect based on information supplied.
Ingestion	No known effect based on information supplied.

### Numerical measures of toxicity

(a) acute toxicity;	
Oral	No data available
Dermal	No data available
Inhalation	No data available

(b) skin corrosion/irritation;	No data available
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(c) serious eye damage/irritation;	No data available
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(d) respiratory or skin sensitization;	
Respiratory	No data available
Skin	No data available

(e) germ cell mutagenicity;	No data available
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(f) carcinogenicity;	No data available
	There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;	No data available
(h) STOT-single exposure;	No data available
(i) STOT-repeated exposure;	No data available
Target Organs	None known.
(j) aspiration hazard;	Not applicable Solid
Other Adverse Effects	No information available

**Symptoms / effects, both acute and delayed**

No information available.

## Section 12 - Ecological Information

### Ecotoxicity

**Aquatic ecotoxicity** Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

**Terrestrial ecotoxicity** There is no data for this product

**Persistence and Degradability** Readily biodegradable

**Persistence** May persist.

**Bioaccumulative Potential** Product has a high potential to bioconcentrate

Component	log Pow	Bioconcentration factor (BCF)
Loteprednol etabonate	4.539	No data available

**Mobility** Spillage unlikely to penetrate soil. Is not likely mobile in the environment due its low water solubility. Is not likely mobile in the environment due its low water solubility and propensity to bind to soil particles

### Other adverse effects

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors  
**Persistent Organic Pollutant** This product does not contain any known or suspected substance  
**Ozone Depletion Potential** This product does not contain any known or suspected substance

## Section 13 - Disposal Considerations

### Waste treatment methods

**Waste from Residues/Unused Products** Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure

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	conformity with all applicable regulations.
<b>Contaminated Packaging</b>	Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.
<b>Other Information</b>	Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations .

## Section 14 - Transport Information

<u>NZS 5433:2020</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated
<b>Environmental hazards</b>	No hazards identified
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable, packaged goods
<b>Special Precautions</b>	No special precautions required. Please refer to the applicable dangerous goods regulations for additional information.
<b>Additional information</b>	None known

## Section 15 - Regulatory Information

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

#### **National Regulations**

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

#### **Certified handlers, tracking and controlled substance license requirements**

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information. Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

#### **Prohibition or notification/licensing requirements**

Shown below are details of specific prohibition/notifications or licencing requirements when they apply.

#### International Regulations

<b>Ozone Depletion Potential</b>	This product does not contain any known or suspected substance
<b>Persistent Organic Pollutant</b>	This product does not contain any known or suspected substance
<b>Rotterdam Convention (PIC)</b>	Not applicable

**Authorisation/Restrictions according to EU REACH** Not applicable

### International Inventories

New Zealand (NZIoC), Australia (AICS), Europe (EINECS/ELINCS/NLP), Korea (KECL), China (IECSC), Taiwan (TCSI), Japan (ENCS), Japan (ISHL), Canada (DSL/NDL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
Loteprednol etabonate	82034-46-6	-	-	-	-	-	-	-	-

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDL	PICCS	ISHL	ENCS
Loteprednol etabonate	82034-46-6	-	-	-	-	-	-	-

**Legend:** X - Listed '-' - Not Listed

**KECL** - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

## Section 16 - Other Information

**This safety data sheet complies with the requirements of the EPA Hazardous Substances (Hazard Classification) Notice 2020 and WorkSafe New Zealand Regulations**

### Legend

**NZIoC** - New Zealand Inventory of Chemicals

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

**IECSC** - Chinese Inventory of Existing Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**NZS 5433:2020** - Transport of Dangerous Goods on Land

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**WEL** - Workplace Exposure Limit

**DNEL** - Derived No Effect Level

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**VOC** - (Volatile Organic Compound)

**AICS** - Australian Inventory of Chemical Substances

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**ENCS** - Japanese Existing and New Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**CAS** - Chemical Abstracts Service

**ACGIH** - American Conference of Governmental Industrial Hygienists

**PNEC** - Predicted No Effect Concentration

**OECD** - Organisation for Economic Co-operation and Development

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**ADG** - Australian Code for the Transport of Dangerous Goods by Road and Rail

**LC50** - Lethal Concentration 50%

**ATE** - Acute Toxicity Estimate

**RPE** - Respiratory Protective Equipment

**NOEC** - No Observed Effect Concentration

**BCF** - Bioconcentration factor

**PBT** - Persistent, Bioaccumulative, Toxic

### Key literature references and sources for data

HSNO classifications provided in the New Zealand Chemical Classification Information Database (CCID).

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

EPA Guide to classifying hazardous substances in New Zealand

EPA - Assigning a product to an existing HSNO approval guide

### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

**Revision Date** 10-Mar-2023

**Revision Summary** Not applicable

### Disclaimer



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**End of Safety Data Sheet**