

Classified as hazardous in accordance with the criteria of EPA New Zealand

Section 1 - Identification

Product Identifier

| | |
|----------------------|---|
| Product Name | <u>Darunavir ethanolate</u> |
| CAS No | 635728-49-3 |
| Molecular Formula | C ₂₉ H ₄₃ N ₃ O ₈ S |
| Molecular Weight | 593.73 |
| Recommended Use | Laboratory chemicals. |
| Uses advised against | No Information available |

| | |
|-------------------------|---|
| Product Code | 467040000; 467040010 |
| Address | Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand |
| Emergency Tel. | CHEMTREC® 09 980 6780 or +64 9 980 6780 |
| Telephone / Fax Numbers | Tel: 09 980 6700 Fax: 09 980 6788 |
| E-mail address | <u>ANZinfo@thermofisher.com</u> |

Section 2 - Hazard(s) Identification

Classification under Work Safe New Zealand

Classified as hazardous in accordance with the criteria of EPA New Zealand

GHS Classification

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

| | |
|--|------------|
| Acute Oral Toxicity | Category 4 |
| Acute Dermal Toxicity | Category 4 |
| Serious Eye Damage/Eye Irritation | Category 2 |
| Specific target organ toxicity - (single exposure) | Category 3 |

Environmental hazards

Based on available data, the classification criteria are not met

Label Elements

**Signal Word****Warning****Hazard Statements**

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

H302 + H312 - Harmful if swallowed or in contact with skin

Precautionary Statements**Prevention**

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P271 - Use only outdoors or in a well-ventilated area

P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P312 - Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P362 + P364 - Take off contaminated clothing and wash it before reuse

Storage

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other hazards which do not result in classification

Section 3 - Composition and Information on Ingredients

| Component | CAS No | Weight % |
|----------------------|-------------|----------|
| Darunavir ethanolate | 635728-49-3 | <=100 |

Section 4 - First Aid Measures

Description of first aid measures**General Advice**

If symptoms persist, call a physician.

New Zealand Emergency Tel.CHEMTREC®
09 980 6780 or +64 9 980 6780**Inhalation**

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention 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. If skin irritation persists,

| | |
|--|---|
| | call a physician. |
| 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, CO₂, 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 oxides, Nitrogen oxides (NO_x), Sulfur oxides.

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. Keep in suitable, closed containers for disposal.

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 ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

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.

Incompatible Materials

Strong oxidizing agents. Acids. Acid anhydrides. Acid chlorides.

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. Ensure that eyewash stations and safety showers are close to the workstation location.

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

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 compatibility, 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

| | | |
|---|---|-----------------------------------|
| Physical State | Solid | |
| Appearance | White | |
| Odor | No information available | |
| Odor Threshold | No data available | |
| pH | No information available | |
| Melting Point/Range | No data available | |
| Softening Point | No data available | |
| Boiling Point/Range | No information available | |
| Flammability (liquid) | Not applicable | Solid |
| Flammability (solid,gas) | No information available | |
| Explosion Limits | No data available | |
| Flash Point | No information available | Method - No information available |
| Autoignition Temperature | No data available | |
| Decomposition Temperature | No data available | |
| Viscosity | Not applicable | Solid |
| Water Solubility | No information available | |
| Solubility in other solvents | No information available | |
| Partition Coefficient (n-octanol/water) | | |
| Vapor Pressure | No data available | |
| Density / Specific Gravity | No data available | |
| Bulk Density | No data available | |
| Vapor Density | Not applicable | Solid |
| Particle characteristics | No data available | |
| Other information | | |
| Molecular Formula | C ₂₉ H ₄₃ N ₃ O ₈ S | |
| Molecular Weight | 593.73 | |
| Evaporation Rate | Not applicable - Solid | |

Section 10 - Stability and Reactivity

| | |
|----------------------------------|---|
| Reactivity | None known, based on information available |
| Stability | Stable under normal conditions. |
| Sensitivity to Mechanical Impact | No information available |
| Sensitivity to Static Discharge | No information available |
| Hazardous Polymerization | Hazardous polymerization does not occur. |
| Hazardous Reactions | None under normal processing. |
| Conditions to Avoid | Heat, flames and sparks. |
| Incompatible Materials | Strong oxidizing agents, Acids, Acid anhydrides, Acid chlorides. |
| Hazardous Decomposition Products | Carbon oxides. Nitrogen oxides (NO _x). Sulfur oxides. |

Section 11 - Toxicological Information

Acute Effects**Information on likely routes of exposure**

| | |
|----------------------------|--|
| Product Information | The toxicological properties have not been fully investigated |
| Inhalation | Not an expected route of exposure. |
| Eyes | Avoid contact with eyes. Irritating to eyes. |
| Skin | Avoid contact with skin. May cause irritation. Harmful in contact with skin. |
| Ingestion | May be harmful if swallowed. |

Numerical measures of toxicity

| | |
|---|--|
| (a) acute toxicity; | |
| Oral | Category 4 |
| Dermal | Category 4 |
| Inhalation | No data available |
| (b) skin corrosion/irritation; | No data available |
| (c) serious eye damage/irritation; | Category 2 |
| (d) respiratory or skin sensitization; | |
| Respiratory | No data available |
| Skin | No data available |
| (e) germ cell mutagenicity; | No data available |
| (f) carcinogenicity; | No data available There are no known carcinogenic chemicals in this product |
| (g) reproductive toxicity; | No data available |
| (h) STOT-single exposure; | Category 3 |
| Results / Target organs | Respiratory system |
| (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 | No information available |
| Bioaccumulative Potential | No information available |
| Mobility | No information available. |
| <u>Other adverse effects</u> | |
| 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 conformity with all applicable regulations. |
| Contaminated Packaging | Dispose of this container to hazardous or special waste collection point. |
| Other Information | Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations . Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. |

Section 14 - Transport Information

| | |
|---|---|
| <u>NZS 5433:2020</u> | Not regulated |
| <u>IATA</u> | Not regulated |
| <u>IMDG/IMO</u> | Not regulated |
| Environmental hazards | No hazards identified |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable, packaged goods |
| Special Precautions | No special precautions required. Please refer to the applicable dangerous goods regulations for additional information. |
| Additional information | 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 licensing requirements when they apply.

International Regulations

Ozone Depletion Potential This product does not contain any known or suspected substance

Persistent Organic Pollutant This product does not contain any known or suspected substance

Rotterdam Convention (PIC) 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 |
|----------------------|-------------|-------|------|--------|--------|-----|------|-------|------|
| Darunavir ethanolate | 635728-49-3 | - | - | - | - | - | - | - | - |

| Component | CAS No | TSCA | TSCA Inventory notification - Active-Inactive | DSL | NDL | PICCS | ISHL | ENCS |
|----------------------|-------------|------|---|-----|-----|-------|------|------|
| Darunavir ethanolate | 635728-49-3 | - | - | - | - | - | - | - |

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

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

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)**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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet