

Australian statement of hazardous nature : Classified as hazardous according to criteria of Safe Work Australia

## Section 1 - Identification

**Product Name** Darunavir ethanolate

**CAS No** 635728-49-3

**Product Code** 467040000; 467040010

**Address** ThermoFisher Scientific Australia Pty Ltd  
 5 Caribbean Drive, Scoresby  
 VICTORIA 3179, Australia

**Emergency Tel.** **CHEMTREC®**  
**03 9757 4559 or +613 9757 4559**

**Telephone / Fax Numbers** Tel: 1300 735 292  
 Fax: 1800 067 639

**E-mail address** ANZinfo@thermofisher.com

**Recommended Use** Laboratory chemicals.

**Uses advised against** This product does not contain any substance(s) on the Illicit Drug Precursors/Reagents list.  
 This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction. This product does not contain any substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern.

## Section 2 - Hazard(s) Identification

### Classification under Safe Work Australia

Classified as hazardous according to criteria of Safe Work Australia

**Physical hazards**  
 No hazards identified

### **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**  
 No hazards identified

### Label Elements



Exclamation Mark

**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**

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

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

P363 - Wash contaminated clothing before reuse

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

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

**Other information**

No information available

## Section 3 - Composition and Information on Ingredients

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

## Section 4 - First Aid Measures

|                       |   |
|-----------------------|---|
| <b>Inhalation</b>     | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.      |
| <b>Ingestion</b>      | Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.             |
| <b>Skin Contact</b>   | Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician. |
| <b>Eye Contact</b>    | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.   |
| <b>General Advice</b> | If symptoms persist, call a physician.  |

|  |                                      |
|--|--------------------------------------|
| <b>Self-Protection of the First Aider</b>  | No special precautions required.     |
| <b>First Aid Facilities</b>                | Eyewash, safety shower and washroom. |
| <b>Most important symptoms and effects</b> | None reasonably foreseeable.         |
| <b>Notes to Physician</b>                  | 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.

### Hazardous Decomposition Products

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>), Sulfur oxides.

### Specific Hazards Arising from the Chemical

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

### 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

### 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

#### Clean-up methods - small spillage

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

#### Clean-up methods - large spillage

Typically only supplied in small quantities as packaged goods.

If extremely toxic or used in larger quantities ensure a spillage action plan is in place. Evacuate area. Control the source and/or contain the spill if safe and able to do so. Use temporary diking, sand bags, dry sand, earth or proprietary booms/absorbent pads if available. Obtain advice on containment, neutralisation and clean-up from local emergency responders.

### Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

## Section 7 - Handling and Storage

### Precautions for 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.

### Conditions for Safe Storage, Including any Incompatibilities

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

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

## Section 8 - Exposure Controls and Personal Protection

### 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

### **Exposure Controls**

#### **Engineering Measures**

None under normal use conditions. Ensure that eyewash stations and safety showers are close to the workstation location.

### **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 | See manufacturers | -               | AS/NZS 2161     | (minimum requirement) |
| Neoprene       | recommendations   |                 |                 |                       |
| Natural rubber |                   |                 |                 |                       |
| PVC            |                   |                 |                 |                       |

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

#### **Appearance Physical State**

White  
Solid

#### **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 |  |
| Flash Point                             | No information available | <b>Method -</b> No information available |
| Evaporation Rate                        | Not applicable           | Solid                                    |
| Flammability (solid,gas)                | No information available |  |
| Explosion Limits                        | No data available        |  |
| Vapor Pressure                          | No data available        |  |
| Vapor Density                           | Not applicable           | Solid                                    |
| Specific Gravity / Density              | No data available        |  |
| Bulk Density                            | No data available        |  |
| Water Solubility                        | No information available |  |
| Solubility in other solvents            | No information available |  |
| Partition Coefficient (n-octanol/water) |                          |  |
| Autoignition Temperature                | No data available        |  |
| Decomposition Temperature               | No data available        |  |
| Viscosity                               | Not applicable           | Solid                                    |
| Explosive Properties                    | No information available |  |
| Oxidizing Properties                    | No information available |  |
| <b>Other information</b>                |                          |  |
| Molecular Formula                       | C29 H43 N3 O8 S          |  |
| Molecular Weight                        | 593.73                   |  |

## Section 10 - Stability and Reactivity

|                                  |  |
|----------------------------------|--|
| Reactivity                       | None known, based on information available                       |
| Stability                        | Stable under normal conditions.                                  |
| Conditions to Avoid              | Heat, flames and sparks.   |
| Incompatible Materials           | Strong oxidizing agents, Acids, Acid anhydrides, Acid chlorides. |
| Hazardous Decomposition Products | Carbon oxides. Nitrogen oxides (NOx). Sulfur oxides.             |
| Hazardous Polymerization         | Hazardous polymerization does not occur.                         |

## Section 11 - Toxicological Information

### Information on Toxicological Effects

|  |   |
|--|---|
| Product Information                    | The toxicological properties have not been fully investigated |
| (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; |   |

|   |  |
|---|--|
| <b>Respiratory</b>                                | No data available  |
| <b>Skin</b>                                       | No data available  |
| <b>(e) germ cell mutagenicity;</b>                | No data available  |
| <b>(f) carcinogenicity;</b>                       | No data available<br>There are no known carcinogenic chemicals in this product |
| <b>(g) reproductive toxicity;</b>                 | No data available  |
| <b>(h) STOT-single exposure;</b>                  | Category 3   |
| <b>Results / Target organs</b>                    | Respiratory system   |
| <b>(i) STOT-repeated exposure;</b>                | No data available  |
| <b>Target Organs</b>                              | None known.  |
| <b>(j) aspiration hazard;</b>                     | Not applicable<br>Solid  |
| <b>Other Adverse Effects</b>                      | No information available   |
| <b>Symptoms / effects, both acute and delayed</b> | No information available   |

## Section 12 - Ecological Information

|  |   |
|--|---|
| <b>Ecotoxicity effects</b>             | Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants. |
| <b>Persistence and Degradability</b>   | No information available  |
| <b>Bioaccumulative Potential</b>       | No information available  |
| <b>Mobility</b>                        | No information available.   |
| <b>Endocrine Disruptor Information</b> | This product does not contain any known or suspected endocrine disruptors   |
| <b>Persistent Organic Pollutant</b>    | This product does not contain any known or suspected substance  |
| <b>Ozone Depletion Potential</b>       | This product does not contain any known or suspected substance  |

## Section 13 - Disposal Considerations

|  |  |
|--|--|
| <b>Waste from Residues/Unused Products</b> | 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. |
| <b>Contaminated Packaging</b>              | Dispose of this container to hazardous or special waste collection point.  |
| <b>Other Information</b>                   | Chemical wastes should be disposed through a licensed commercial waste collection service. 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

|                 |               |
|-----------------|---------------|
| <b>IMDG/IMO</b> | Not regulated |
|-----------------|---------------|

|                               |                                 |
|-------------------------------|---------------------------------|
| <b>ADG</b>                    | Not regulated                   |
| <b>IATA</b>                   | Not regulated                   |
| <b>Environmental hazards</b>  | No hazards identified           |
| <b>Special Precautions</b>    | No special precautions required |
| <b>Additional information</b> | None known                      |

## Section 15 - Regulatory Information

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

#### National Regulations                      **Australia**

See section 8 for national exposure control parameters.

#### **Standard for the Uniform Scheduling of Medicines and Poisons**

No poison schedule number allocated.

#### **Australian - Illicit Drug Precursors/Reagents Substance List**

This product does not contain any substance(s) on the Illicit Drug Precursors/Reagents list.

#### **Chemicals of Security Concern**

This product does not contain any substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern

#### **National pollutant inventory**                      Not applicable

### Prohibition or notification/licensing requirements

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

This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction.

### International Inventories

**Legend:** X - Listed. '-' - Not Listed. **KECL** - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

### 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

**Basel convention on the control of transboundary movements of hazardous wastes and their disposal**  
Not applicable.

| Component            | CAS No      | OECD HPV       | Restriction of Hazardous Substances (RoHS) | Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification | Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements |
|----------------------|-------------|----------------|--|---|--|
| Darunavir ethanolate | 635728-49-3 | Not applicable | Not applicable                             | Not applicable  | Not applicable   |

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

## Section 16 - Other Information

### Legend

**AICS** - Australian Inventory of Chemical Substances  
**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  
**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association  
**MARPOL** - International Convention for the Prevention of Pollution from Ships  
**NZS 5433:2012** - Transport of Dangerous Goods on Land  
**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)

**NZIoC** - New Zealand Inventory of Chemicals  
**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  
**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code  
**ADG** Australian Code for the Transport of Dangerous Goods by Road and Rail  
**OECD** - Organisation for Economic Co-operation and Development  
**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

<https://echa.europa.eu/information-on-chemicals>  
 Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

### Training Advice

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

**Revision Date** 17-Nov-2022  
**Revision Summary** Not applicable.

**This Safety Data Sheet (SDS) is prepared in accordance to and complies with the requirements of Safe Work Australia - Work Health and Safety Regulations (WHS Regulations).**

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**