

SAFETY DATA SHEET

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

Section 1 - Identification

Product Identifier

Product Name <u>Avapritinib</u>

CAS No 1703793-34-3

Synonyms (S)-1-(4-Fluorophenyl)-1-(2-(4-(6-(1-methyl-1H-pyrazol-4-yl)pyrrolo[2,1-f][1,2,4]triazin-4-yl)pi

perazin-1-yl)pyrimidin-5-yl)ethan-1-amine

Molecular Formula C26 H27 F N10

Molecular Weight 498.57

Recommended Use Laboratory chemicals. Uses advised against No Information available

Product Code 474800000; 474801000

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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

Skin Corrosion/Irritation

Serious Eye Damage/Eye Irritation

Specific target organ toxicity - (single exposure)

Category 2

Category 2

Category 2

Category 3

Environmental hazards

Based on available data, the classification criteria are not met

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Label Elements



Signal Word

Warning

Hazard Statements

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

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

No information available Toxic to terrestrial vertebrates

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
Avapritinib	1703793-34-3	<=100

Section 4 - First Aid Measures

Description of first aid measures

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Inhalation Remove to fresh air.

Eye ContactRinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated

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clothes and shoes.

Ingestion Clean mouth with water and drink afterwards plenty of water.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

First Aid Facilities Eyewash, safety shower and washroom.

Most important symptoms and

effects

No information available.

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.

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 (NOx), Hydrogen fluoride.

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.

Environmental Precautions

See Section 12 for additional Ecological Information.

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

Ensure adequate ventilation.

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.

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Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

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

Incompatible Materials

None known.

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

Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

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,	See manufacturers	-	AS/NZS 2161	(minimum requirement)
	Natural rubber, PVC.	recommendations			

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

Repiratory ProtectionUse 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 repiratory protective devices

Recommended Filter type: Particulates filter conforming to EN 143 (or AUS/NZ equivalent)

Recommended half mask:- Particle filtering: EN149:2001 (or AUS/NZ equivalent)

When RPE is used a face piece Fit Test should be conducted

Hygiene MeasuresHandle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

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Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties

Physical State Powder Solid

Appearance

Odor No information available No data available **Odor Threshold** Not applicable pН **Melting Point/Range** No data available **Softening Point** No data available **Boiling Point/Range** No information available

Flammability (liquid) Not applicable

Flammability (solid, gas) No information available

Explosion Limits No data available

No information available **Flash Point** Method - No information available

Solid

Autoignition Temperature No data available

Decomposition Temperature No data available

Viscosity Not applicable Solid

No information available Water Solubility Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

No data available **Vapor Pressure Density / Specific Gravity** No data available **Bulk Density** No data available **Vapor Density** Not applicable

Solid

Particle characteristics No data available

Other information

C26 H27 F N10 Molecular Formula

Molecular Weight 498.57

Not applicable - Solid **Evaporation Rate**

Section 10 - Stability and Reactivity

Reactivity None known, based on information available

Stability Moisture sensitive.

Sensitivity to Mechanical Impact No information available

Sensitivity to Static Discharge No information available

Hazardous Polymerization No information available.

Hazardous Reactions No information available.

Conditions to Avoid Heat, flames and sparks.

Incompatible Materials None known.

Hazardous Decomposition Products Carbon oxides. Nitrogen oxides (NOx). Hydrogen fluoride.

Section 11 - Toxicological Information

Acute Effects

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Information on likely routes of exposure

Product Information

Inhalation Avoid breathing dust or spray mist. May be harmful if inhaled.

Eyes Avoid contact with eyes. Irritating to eyes. **Skin** Avoid contact with skin. May cause irritation.

Ingestion May be harmful if swallowed.

Numerical measures of toxicity

(a) acute toxicity;

Oral Category 4
Dermal No data available
Inhalation No data available

(b) skin corrosion/irritation; Category 2

(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

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.

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Terrestrial ecotoxicity There is no data for this product

Persistence and Degradability No information available

Bioaccumulative Potential No information available

Mobility No information available.

Other adverse effects

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

This product does not contain any known or suspected substance 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 conta

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

NZS 5433:2020 Not regulated

IATA Not regulated

IMDG/IMO 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

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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

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

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

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
Avapritinib	1703793-34-3	-	-	-	-	-	-	-	-
									•
Component	CAS No	TSCA	TSCA Ir	ventory	DSI	NDSI	PICCS	ISHL	FNCS

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
Avapritinib	1703793-34-3	-	ı	ı	ı	ı	ı	-

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/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

IECSC - Chinese Inventory of Existing Chemical Substances

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

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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)

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.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Revision Date 16-Mar-2023

Revision Summary SDS sections updated

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

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