

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
Product Identifier

Perihal Produk: **Entrectinib**
 Product Description: **Entrectinib**
 Cat No. : 474610000; 474611000
 CAS No 1108743-60-7
 Molecular Formula C31 H34 F2 N6 O2

Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals.
 Uses advised against No Information available

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 CHEMTREC Malaysia **1-800-815-308** (Malay)
 CHEMTREC Malaysia (Kuala Lumpur) **+(60)-327884561** (Malay)

SECTION 2: HAZARDS IDENTIFICATION
Classification of the substance or mixture

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Acute oral toxicity	Category 4 (H302)
Skin Corrosion/Irritation	Category 2 (H315)
Serious Eye Damage/Eye Irritation	Category 2 (H319)
Specific target organ toxicity - (single exposure)	Category 3 (H335)

Label Elements


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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

Toxic to terrestrial vertebrates
This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Entrectinib	1108743-60-7	<=100

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General Advice

If symptoms persist, call a physician.

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.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

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Self-Protection of the First Aider No special precautions required.

Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

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.

Special hazards arising from the substance or mixture

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

Hazardous Combustion Products

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen fluoride.

Advice 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

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

Environmental precautions

Should not be released into the environment.

Methods and Material for Containment and Cleaning Up

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

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

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

Specific End Uses

Use in laboratories.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

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

Hand Protection

Protective gloves

Skin and body protection

Long sleeved clothing

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.

Respiratory Protection

No protective equipment is needed under normal use conditions

Recommended Filter type:

Particle filter

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

Powder Solid

Odor

No information available

Odor Threshold

No data available

pH

Not applicable

Melting Point/Range

No data available

Softening Point

No data available

Boiling Point/Range

No information available

Flash Point

No information available

Method - No information available

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Evaporation Rate	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	

Vapor Pressure	No data available	Solid
Vapor Density	Not applicable	
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	Solid
Decomposition Temperature	No data available	
Viscosity	Not applicable	
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Molecular Formula	C31 H34 F2 N6 O2
Molecular Weight	560.65

SECTION 10: STABILITY AND REACTIVITY

Reactivity

None known, based on information available.

Chemical Stability

Stable under normal conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.

Conditions to Avoid

None known.

Incompatible Materials

None known.

Hazardous Decomposition Products

Carbon oxides. Nitrogen oxides (NOx). Hydrogen fluoride.

SECTION 11: TOXICOLOGICAL INFORMATION

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Information on Toxicological Effects

Product Information

(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.

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity effects

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

Persistence and degradability

No information available

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<u>Bioaccumulative potential</u>	No information available
<u>Mobility in soil</u>	No information available.
<u>Endocrine Disruptor Information</u>	This product does not contain any known or suspected endocrine disruptors
<u>Other adverse effects</u>	No information available

SECTION 13: DISPOSAL CONSIDERATIONS

<u>Waste treatment methods</u>	
<u>Waste from Residues/Unused Products</u>	Waste is classified as hazardous Dispose of in accordance with the European Directives on waste and hazardous waste Dispose of in accordance with local regulations
<u>Contaminated Packaging</u>	Dispose of this container to hazardous or special waste collection point.
<u>Other Information</u>	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>IMDG/IMO</u>	Not regulated
<u>Road and Rail Transport</u>	Not regulated
<u>IATA</u>	Not regulated
<u>Special Precautions for User</u>	No special precautions required

SECTION 15: REGULATORY INFORMATION

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

<u>International Inventories</u>	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)
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National Regulations

<u>Persistent Organic Pollutant</u>	This product does not contain any known or suspected substance
<u>Ozone Depletion Potential</u>	This product does not contain any known or suspected substance

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SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

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

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

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

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

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

POW - Partition coefficient Octanol:Water

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

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

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

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

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

Key literature references and sources for data

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

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

Revision Date

23-Mar-2025

Revision Summary

SDS sections updated.

In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

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