

ALECENSA® Capsules 150 mg**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product name ALECENSA® Capsules 150 mg

Product code SAP-10156875

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

Use - pharmaceutical active substance (antineoplastic) *1

1.3. Details of the supplier of the safety data sheet

Company information

Enquiries:

Roche Products Pty Limited

P.O. Box 255

Dee Why, N.S.W. 2099

AUS-Australia

Australia

Local representation:

Phone 0061-2-9454-9624

Fax 0061-2-9971-7401

E-Mail info.sds@roche.com

1.4. Emergency telephone number

Emergency telephone number Phone 0061-2-9454-9624

*1 referring to: Alectinib

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SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

- 3.5 Germ cell mutagenicity (Category 2)
H341 Suspected of causing genetic defects.
- 3.7__ Reproductive toxicity (Category 2)
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
- 3.9 Specific target organ toxicity - Repeated exposure (Category 2)
H373 May cause damage to organs through prolonged or repeated exposure.

Signalword: Warning

Label:



Precautionary statements:

- P273 Avoid release to the environment.
- P201 Obtain special instructions before use.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

Australian Remark

- HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. *2
- Poisons Schedule - Schedule 4
- Not listed on the Australian Inventory of Chemical Substances (AICS) *2

2.3. Other hazards

Note

- no information available

*2 referring to:

Alectinib hydrochloride

SECTION 3: Composition/information on ingredients

Characterization

Alectinib with other inactive ingredients

Synonyms

- ALECTINIB Capsules (hard) 150 mg
- ALECTINIB Capsules 150 mg

Ingredient

**Concentration GHS-Classification
(pure ingredient)**

Alectinib hydrochloride
1256589-74-8

40.3 %

- Germ cell mutagenicity (Category 2), H341
- Reproductive toxicity (Category 2), H361fd
- Specific target organ toxicity - Repeated exposure (Category 2), H373

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Hydroxypropylmethyl cellulose 9004-65-3	19.2 %	
Sodium lauryl sulfate 151-21-3 01-2119489461-32	18.8 %	<ul style="list-style-type: none">- Flammable solids (Category 2), H228- Acute toxicity (Category 4), H332- Acute toxicity (Category 4), H302- Skin corrosion/irritation (Category 2), H315- Serious eye damage/eye irritation (Category 1), H318- Specific target organ toxicity - Single exposure (Category 3), H335
Calcium carboxymethyl cellulose 9050-04-8	10.8 %	
Lactose monohydrate 10039-26-6	8.4 %	
Magnesium stearate 557-04-0	0.4 %	

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse with tap water for 20 minutes - open eyelids forcibly
Skin contact	- when in contact with the skin, clean with soap and water
Inhalation	- in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note	- no information available
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	<ul style="list-style-type: none">- adapt extinguishing media to surrounding fire conditions- water spray jet, dry powder, foam, carbon dioxide
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5.2. Special hazards arising from the substance or mixture

Specific hazards	- formation of toxic and corrosive combustion gases (nitrous oxide, hydrogen chloride) possible
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5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - avoid exposure

6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - provide suitable exhaust ventilation at the processing machines

Suitable materials - stainless steel, aluminium, enamel, glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below 30 °C
- protected from light and humidity

Validity - see expiry date on the label

Packaging materials - polyethylene bag in metal drum
- tightly closing
- blister packages

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.001 mg/m³ *1

8.2. Exposure controls

General protective and hygiene measures - instruction of employees recommended

Respiratory protection - respiratory protection not necessary during normal operations

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Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Alectinib

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour white to yellow-white

Form capsules

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - temperatures above 100 °C
- humidity
- light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₀ 2'000 mg/kg (oral, rat)	*1
	- LD ₅₀ 1'427 mg/kg (oral, rat) (OECD No. 401)	*3
	- LD ₅₀ > 2'000 mg/kg (dermal, rabbit)	*3
Local effects	- eye: causes serious eye damage (rabbit; OECD No. 405)	*3
	- skin: irritant (rabbit; OECD No. 404)	*3
	- mucous membranes: irritant	*3
Sensitization	- possibly photosensitising (OECD No. 432)	*1
Mutagenicity	- negative, both with and without metabolic activation (Ames test)	*1
	- test system in vivo; OECD No. 474 (Micronucleus Test), oral; NOEL = 200 mg/kg/d; an increased number of micronucleated immature erythrocytes was seen at doses higher than 500 mg/kg/d*1	
	- does not induce chromosomal aberrations in vitro (in vitro test system; OECD No. 473 (Mammalian Cytogenic Test)); a slight increase in polyploid cells was seen at the dose of 10 mcg/ml	*1
	- positive (OECD No. 487 (In vitro Mammalian Cell Micronucleus Test))	*1
Carcinogenicity	- no information available	
Reproductive toxicity	- NOAEL = 3 mg/kg/d (oral, rat, female, 11 d)	*1
	- decrease in fetal weight	*1
	- visceral anomaly ratio increased	*1
	- retarded ossification	*1
	- increased frequency in skeletal variations	*1
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
Note	- possible side effects: leukopenia, neutropenia, thrombocytopenia, anemia, rash, nausea, increase of weight, headache	*1
*1	referring to:	Alectinib
*3	referring to:	Sodium lauryl sulfate

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- moderately toxic for algae (<i>Pseudokirchneriella subcapitata</i>) EC ₅₀ (72 h) > 10 mg/l (nominal concentration) NOE _y C (72 h) 10 mg/l (nominal concentration) NOE _r C (72 h) 10 mg/l (nominal concentration) (OECD No. 201)	*2
	- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC ₅₀ (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 100 mg/l (nominal concentration) (OECD No. 202)	*2
	- moderately toxic for fish (zebrafish) LC ₅₀ (96 h) > 10 mg/l (nominal concentration) (OECD No. 203)	*2
	- barely inhibitory on aerobic bacterial respiration (activated sludge) NOEC (3 h) 1000 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*2

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable 0 % BOD/ThOD, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*2
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12.3. Bioaccumulative potential

Note	- no information available
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12.4. Mobility in soil

Note	- no information available
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12.5. Results of PBT and vPvB assessment

PBT/vPvB	- not PBT, not vPvB	*2
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12.6. Other adverse effects

Note	- no information available
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*2 referring to: Alectinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues
- return to supplier or hand over to authorised disposal company
 - observe local/national regulations regarding waste disposal
 - incinerate in qualified installation with flue gas scrubbing
 - medicines should not be disposed of via wastewater

SECTION 14: Transport information

- Australian Remark
- ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other regulations.

SECTION 15: Regulatory information

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

- Water hazard class (Germany)
- 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005)

SECTION 16: Other information

- Safety-lab number
- BS10767
 - BS10498

*2

Full text of H-Statements referred to under section 3

- H228 Flammable solid.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H341 Suspected of causing genetic defects.
- H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.

- Note
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

- Edition documentation
- changes from previous version in sections 7, 9

- *2 referring to:
- Alectinib hydrochloride

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.