Safety Data Sheet

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-10192986
Synonyms	- Alectinib Hard Capsules (150 mg) - Alectinib Capsules (150 mg)

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:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

Local representation:

1.4. Emergency telephone number

Emergency telephone number: US Chemtrec phone: (800)-424-9300

1 referring to: Alectinib

SECTION 2: Hazards identification

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 + P310 IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician.

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization: Alectinib with other inactive ingredients

Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Alectinib hydrochloride 1256589-74-8	40.3 %	- Combustible dust (No category), USH003 - Germ cell mutagenicity (Category 2), H341 - Reproductive toxicity (Category 2), H361fd - Specific target organ toxicity - Repeated exposure (Category 2), H373
Hydroxypropylmethyl cellulose 9004-65-3	19.2 %	

Sodium lauryl sulfate 151-21-3	18.8 %	- 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 %	

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

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions - water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	- formation of toxic and corrosive combustion gases (nitrous oxide, hydrogen chloride) possible

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/m^3	*1

8.2. Exposure controls

General protective and hygiene measures	- instruction of employees recommended
Respiratory protection	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - respiratory protection not necessary during normal operations
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

Color	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)	*2
	- LD_{50} > 2'000 mg/kg (dermal, rabbit)	*2
Local effects	- eye: causes serious eye damage (rabbit; OECD No. 405)	*2
	- skin: irritant (rabbit; OECD No. 404)	*2
	- mucous membranes: irritant	*2
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**
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: not listed by NTP, IARC or OSHA	

1 referring to: Alectinib
2 referring to: Sodium lauryl sulfate

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

- moderately toxic for algae (Pseudokirchneriella subcapitata)
  EC_{50} (72 h) > 10 mg/l (nominal concentration)
  NOEyC (72 h) 10 mg/l (nominal concentration)
  NOErC (72 h) 10 mg/l (nominal concentration)
  (OECD No. 201) *3
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC_{50} (48 h) > 100 mg/l (nominal concentration)
  NOEC (48 h) 100 mg/l (nominal concentration)
  (OECD No. 202) *3
- moderately toxic for fish (zebrafish)
  LC_{50} (96 h) > 10 mg/l (nominal concentration)
  (OECD No. 203) *3
- barely inhibitory on aerobic bacterial respiration (activated sludge)
  NOEC (3 h) 1000 mg/l
  (Activated Sludge Respir. Inhib. Test, OECD No. 209) *3

12.2. Persistence and degradability

Ready biodegradability

- not readily biodegradable
  0 % BOD/ThOD, 28 d
  (Manometric Respirometry Test, OECD No. 301 F) *3

12.3. Bioaccumulative potential

Note

- no information available

12.4. Mobility in soil

Note

- no information available

12.5. Results of PBT and vPvB assessment

PBT/vPvB

- not PBT, not vPvB *3

12.6. Other adverse effects

Note

- no information available

3 referring to: Alectinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues	- return to supplier or hand over to authorized disposal company - observe local/national regulations regarding waste disposal - incinerate in qualified installation with flue gas scrubbing - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

Note	- not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status	- FDA Exemption - not on inventory
Reporting Requirements	- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases, which are likely to endanger the public health, harm the environment or cause a complaint, to the NJDEPE Hotline and to local officials. - State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Safety-lab number	- BS10767 - BS10498 *3

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.
USH003	May form combustible dust concentrations in the air

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 2

3 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.