

# SAFETY DATA SHEET



## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Product identifier

## CAPRELSA TABLETS

**Details of the supplier of the safety data sheet** : ASTRAZENECA PTY LTD  
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### Alternative Names

Zactima tablets  
 Zeneca ZD6474 Tablets  
 Vandetanib tablets

CAS No. : Not applicable  
 Use : Anti-tumour agent

## 2. HAZARDS IDENTIFICATION

### Classification of the substance or mixture

Classification UN GHS		
Hazard class	Category	Hazard statements
Acute toxicity	4	H302
Reproductive toxicant	1B	H360Df
Specific target organ toxicity - repeated exposure	2	H373
Acute aquatic toxicity	1	H400
Chronic aquatic toxicity	1	H410
		# Refer to Section 16 'Other Information'

Label elements	
<b>Signal word</b> Danger	

**Hazard statements**

- H302 : Harmful if swallowed.
- H360Df : May damage the unborn child. Suspected of damaging fertility.
- H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
- H410 : Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P281 Use personal protective equipment as required.
- P314 : Get medical advice/ attention if you feel unwell.
- P501 : Dispose of contents/ container to an approved incineration plant.

**Other hazards**

May cause diarrhea, acne, skin rashes and cardiovascular effects such as arrhythmia and hypertension. May form explosible dust-air mixture if dispersed.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Mixture:

Component	%	CAS No.		
Vandetanib	36 - 40	443913-73-3		
		Hazard class #	Category	Hazard statements #
		Reproductive toxicant	1B	H360Df
		Specific target organ toxicity - repeated exposure	2	H373
		Acute toxicity	4	H302
		Acute aquatic toxicity	1	H400
		Chronic aquatic toxicity	1	H410
Component	%	CAS No.		
Celluloses	9 - 10	-		
		Hazard class #	Category	Hazard statements #
		-	-	-

# Refer to Section 16 'Other Information'

### 4. FIRST-AID MEASURES

#### Description of first aid measures

- Inhalation : Remove patient from exposure, keep warm and at rest. Obtain medical attention.
- Skin Contact : Take off immediately all contaminated clothing. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
- Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
- Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

#### Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

#### Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

### 5. FIRE-FIGHTING MEASURES

- Extinguishing Media (suitable) : water spray, foam, dry powder or CO<sub>2</sub>.
- Extinguishing Media (unsuitable) : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.
- Methods and material for containment and cleaning up : Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

## 7. HANDLING AND STORAGE

- Precautions for safe handling : Do not breathe dust. Avoid contact with skin and eyes. See Section 8. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Protect from light.
- Specific end use(s) : Not applicable, refer to Section 1

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Vandetanib	0,001 mg/m <sup>3</sup>	LTEL 8hr TWA	COM, PROV, HYG

### Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.

### Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

### Respiratory protection

Use an air fed hood if the risk assessment does not support the selection of other protection.

### Skin protection

Use impervious clothing to protect against direct contact with the substance or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

### Eye protection

Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Form : solid  
Colour : white

### Other information

**No other data available**

## 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : None known.  
Conditions to avoid : No conditions producing hazardous situations known.  
Incompatible materials : None known.  
Hazardous decomposition products : No hazardous decomposition products are known.

## 11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation : No information available on acute toxicity.  
May cause effects as described under single exposure.(STOT)

Skin Contact : Unlikely to be corrosive to the skin.

Eye Contact : Unlikely to be a severe irritant to the eye.

Ingestion : Harmful if swallowed. Evident toxicity with mortality in rats at a dose of 2 000 mg/kg

Specific Target Organ Toxicity (STOT) : **Single exposure**  
Exposure routes: Oral  
May cause diarrhea, acne, skin rashes and cardiovascular effects such as arrhythmia and hypertension.

**Repeated exposure**  
Exposure routes: Oral  
May cause damage to organs through prolonged or repeated exposure. Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the kidneys, liver, gastro-intestinal tract and skin.

Sensitisation : Unlikely to cause skin sensitisation.

Carcinogenicity : No information available.

Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.

Reproductive toxicity : May damage the unborn child. Suspected of damaging fertility. Studies in animals have shown that low doses produce embryo/foetotoxic effects in the absence of maternal toxicity. (including embryoethality).  
A study in animals has shown that high doses produce adverse effects on

the uterus, vagina and ovaries.

## 12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to active ingredient:

Toxicity	:	ErC50 green algae 72 H 0,303 mg/l NOEC green algae 72 H 0,11 mg/l EC50 Daphnia magna 48 H 2,6 mg/l NOEC Daphnia magna 48 H 0,10 mg/l (OECD 202) NOEC Daphnia magna 21 d 0,3 mg/l (OECD 211) NOEC Earthworm 14 d 1 000 mg/l LC50 Rainbow trout 96 H 4,1 mg/l NOEC Rainbow trout 96 H 2,5 mg/l NOEC fathead minnow 32 d (flow through) 0,01 mg/l (OECD 210)
Effect on Effluent Treatment	:	Evidence of inhibition to aerobic process at 10-100mg/l (EC20).
Persistence and degradability	:	Not rapidly degradable. Biodegradability, 28 days, (OECD 301F) <5%. There is no evidence of hydrolysis in water.
Bioaccumulative potential	:	The substance has low potential for bioaccumulation.
Mobility in soil	:	Water solubility $\geq$ 1 mg/l. Solid with low volatility. The substance has high mobility in soil at pH1 (log Koc=2.1) The substance has low mobility in soil at pH11 (log Koc>3.88)
Other adverse effects	:	No information available.

## 13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.
Contaminated Packaging	:	Empty container will retain residue. Observe all hazard precautions.

## 14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

### ICAO/IATA

UN No.	:	3077
Proper Shipping Name	:	Environmentally hazardous substance, solid, n.o.s. (VANDETANIB)
Class	:	9
Packing Group	:	III
Environmental hazards	:	Environmentally hazardous

**IMO/IMDG**

UN No. : 3077  
 Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (VANDETANIB)  
 Class : 9  
 Packing Group : III  
 Marine Pollutant : Marine Pollutant

**ADR**

UN No. : 3077  
 Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (VANDETANIB)  
 Class : 9  
 Label(s) : 9  
 Packing Group : III  
 Environmental hazards : Environmentally hazardous

**15. REGULATORY INFORMATION**

In order to comply with legal duties it is necessary to consult local and national legislation.

**16. OTHER INFORMATION**

Hazard statements : H302 : Harmful if swallowed.  
 H360Df : May damage the unborn child. Suspected of damaging fertility.  
 H373 : May cause damage to organs through prolonged or repeated exposure.  
 H401 : Toxic to aquatic life.  
 H410 : Very toxic to aquatic life with long lasting effects.

**GLOSSARY**

COM : In-house occupational exposure limit  
 LTEL : Long-term exposure limit (8 hour TWA (time-weighted average))  
 STEL : Short-term exposure limit (15-minute TWA (time-weighted average))  
 TLV : Threshold Limit Value (ACGIH)  
 TLV-C : Threshold Limit Value - Ceiling limit (ACGIH)  
 HYG : An in-house analytical method for occupational exposure monitoring is available  
 Sk : Can be absorbed through skin, thus contributing to systemic effects  
 Sen : Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.