Version	Revision Date:	SDS Number:	Date of last issue: 10.08.2017
3.0	18.01.2018	20993	Date of first issue: 10.08.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

TAGRISSO TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
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NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
AZD9291 Tablets
AZD9291 Mesylate tablets
CAS No. : Not applicable

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

Use of the Substance/Mixture : Potential anti-cancer agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Reproductive organs, Eyes, Gastrointestinal tract, Bone marrow, Skin, thymus, lymph node)
Acute aquatic toxicity	:	Category 2
Chronic aquatic toxicity	:	Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Reproductive organs, Eyes, Gastrointestinal tract, Bone marrow, Skin, thymus, lymph node) through prolonged or repeated exposure if swallowed.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P281 Use personal protective equipment as required.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Osimertinib

Other hazards which do not result in classification

Potentially irritant to the eye.
See Section 11.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	>= 10 -< 20
Osimertinib	1421373-66-1	>= 10 -< 20

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.
Obtain medical attention if ill effects remain.

If swallowed	:	Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.
Most important symptoms and effects, both acute and delayed	:	Refer to sections 2 and 11 May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.
Notes to physician	:	Symptomatic treatment and supportive therapy as indicated. Emergency medical treatment advice varies within different countries. For further information consult the Local National Poisons Information Services.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	water spray, foam, dry powder or CO2.
Unsuitable extinguishing media	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Specific hazards during firefighting	:	If involved in a fire, it may emit noxious and toxic fumes.
Special protective equipment for firefighters	:	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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. Avoid dispersal of dust in the air. See Section 8.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses. Use appropriate containment to avoid environmental contamination. Collect spillage.
Methods and materials for containment and cleaning up	:	Avoid release to the environment. Moisten spillages with water. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Minimize dust generation and accumulation.

Do not breathe dust.
Avoid contact with skin and eyes.
Avoid release to the environment.
Wash hands after use.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

Conditions for safe storage : Use appropriate containment to avoid environmental contamination.
Protect from light.

Recommended storage temperature : < 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Osimertinib	1421373-66-1	TWA	0.003 mg/m3	COM

Engineering measures : 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.

Personal protective equipment

Respiratory protection : Use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

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

Skin and body protection : Use full chemical protective suit to protect against direct contact with the product if the risk assessment does not support the selection of other protection. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures	:	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. All the information above 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	film-coated tablets
Colour	:	beige
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available

Solubility(ies)
Water solubility : No data available

Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 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 : Protect from light.
Stable at room temperature.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Osimertinib:

Acute oral toxicity : Evident toxicity in rats at a dose of: 1,000 mg/kg

Oral maximum tolerated dose: 300 mg/kg

Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Remarks: No information available on acute toxicity.
May cause effects as described under repeated exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Osimertinib:

Remarks: Unlikely to be corrosive to the skin.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Osimertinib:

Remarks: Potentially irritant to the eye.

11.4 Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Osimertinib:

Result: The product is a skin sensitiser, sub-category 1B.
Remarks: It is a moderate skin sensitiser in animal tests.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Osimertinib:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Not classified based on available information.

Components:

Osimertinib:

Carcinogenicity - Assessment : No information available.

11.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Osimertinib:

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Adverse effects on male and female reproduction in animals., (including embryolethality).

11.8 STOT - single exposure

Not classified based on available information.

Components:

Osimertinib:

Remarks: May cause effects as described under repeated exposure.(STOT)

11.9 STOT - repeated exposure

Causes damage to organs (Reproductive organs, Eyes, Gastrointestinal tract, Bone marrow, Skin, thymus, lymph node) through prolonged or repeated exposure if swallowed.

Components:

Osimertinib:

Exposure routes: Oral
Target Organs: Reproductive organs, Eyes, Gastrointestinal tract, Bone marrow, Skin, thymus, lymph node
Assessment: Causes damage to organs through prolonged or repeated exposure.
Remarks: These effects are derived from studies in animals.

Remarks: May cause rash and diarrhea.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Osimertinib:

No information available.

Further information

Product:

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Osimertinib:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1.5 mg/l Exposure time: 48 H Test Type: Immobilization Method: OECD Test Guideline 202
Toxicity to algae	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.23 mg/l Exposure time: 72 H Test Type: growth rate Method: OECD Test Guideline 201 NOEC (Selenastrum capricornutum (green algae)): 0.014 mg/l Exposure time: 72 H Test Type: growth rate Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.00075 mg/l Exposure time: 32 d Test Type: Early-life Stage Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.026 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 NOEC (Chironomus riparius (harlequin fly)): 79 Exposure time: 28 d Method: OECD Test Guideline 218
M-Factor (Chronic aquatic toxicity)	:	100
Toxicity to microorganisms	:	EC50 (activated sludge): >= 320 mg/l Exposure time: 3 H Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Osimertinib:

Biodegradability	:	Result: Not readily biodegradable. Remarks: The substance is substantially removed in biological

treatment processes.

Bioaccumulative potential

Components:

Osimertinib:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.
The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Osimertinib:

Mobility : Remarks: The substance has low mobility in soil.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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 disposal is via incineration operated by an accredited disposal contractor.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

ICAO/IATA

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

IMO/IMDG

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

ADR

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

SECTION 15. REGULATORY INFORMATION

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

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

Standard for the Uniform Scheduling of Medicines and Poisons	:	No poison schedule number allocated
Prohibition/Licensing Requirements	:	There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH	:	Not listed
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
Osimertinib		1421373-66-1
AICS	:	Not listed

ENCS	:	Not listed
ISHL	:	Not listed
IECSC	:	Not listed
TCSI	:	Not listed
TSCA	:	Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Further information

Revision Date	:	18.01.2018
Other information	:	New significant SHE information:, 2. New classification, 3. New classification, 12. Ecological information, 14. New classification, Minor changes:, 5, 6, 7, 8
Date format	:	dd.mm.yyyy
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne

Contaminants.

ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - time weighted average

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AU / EN