

Version 7.0 Revision Date: 18.01.2018 SDS Number: 20993 Date of last issue: 10.08.2017
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SECTION 1. IDENTIFICATION

1.1 Product identifier

TAGRISO TABLETS

Details of the supplier of the safety data sheet

: ASTRAZENECA
P.O. Box 15437
Wilmington, DE 19850-5437
USA

Phone (24 hr.) Medical :
(800) 236-9933
(24 hr.) Chemical / Spill Emergency:
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Osimertinib mesylate tablets
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 in accordance with 29 CFR 1910.1200

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ systemic 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.

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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/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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.

Other hazards

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 and if it is dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	>= 10 - < 20
Osimertinib	1421373-66-1	>= 10 - < 20
Titanium dioxide	13463-67-7	>= 0.1 - < 1

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.

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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. FIRE-FIGHTING MEASURES

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

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.

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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 and if it is dispersed.

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

Recommended storage temperature : < 86 °F

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Osimertinib	1421373-66-1	TWA	0.003 mg/m ³	COM
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA	10 mg/m ³ (Titanium dioxide)	ACGIH

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.

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Personal protective equipment

- Respiratory protection : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.
- 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
- Color : beige
- Odor : No data available
- Odor 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

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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

Vapor pressure : No data available

Relative vapor 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

Autoignition 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.

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SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,732 mg/kg
Method: Calculation method

Ingredients:

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.

Ingredients:

Osimertinib:

Remarks: Unlikely to be corrosive to the skin.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Osimertinib:

Remarks: Potentially irritant to the eye.

11.4 Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Osimertinib:

Result: The product is a skin sensitizer, sub-category 1B.

Remarks: It is a moderate skin sensitizer in animal tests.

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11.5 Germ cell mutagenicity

Not classified based on available information.

Ingredients:**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.

Ingredients:**Osimertinib:**

Carcinogenicity - Assessment : No information available.

IARC

Group 2B: Possibly carcinogenic to humans

Titanium dioxide 13463-67-7

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

11.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Ingredients:**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.

Ingredients:**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.

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Ingredients:**Osimertinib:**

Routes of exposure: 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.

Ingredients:**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****Ingredients:****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

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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

Ingredients:

Osimertinib:

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

Bioaccumulative potential

Ingredients:

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

Ingredients:

Osimertinib:

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

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I

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Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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

This material is not regulated for domestic transportation within the US when shipped in non-bulk packages by air, highway or rail.

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/MDG

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

DOT (Department of Transport)

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

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SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Ingredients	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Celluloses 9004-34-6

Pennsylvania Right To Know

Celluloses 9004-34-6
Osimertinib 1421373-66-1

New Jersey Right To Know

Celluloses 9004-34-6
Osimertinib 1421373-66-1

California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.

California Permissible Exposure Limits for Chemical Contaminants

Celluloses 9004-34-6

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

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REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Osimertinib

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

OSHA P0 / TWA : 8-hour time weighted average

OSHA Z-1 / TWA : 8-hour time weighted average

AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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

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Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

New significant SHE information:

- 2. New classification
- 3. New classification
- 8. New Occupational Exposure Limit Value
- 12. Ecological information
- 14. New classification

Minor changes:

- 5
- 6
- 7
- 8
- 15
- 16

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The information provided in this Material 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.

US / Z2