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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### BRILINTA TABLETS

Details of the supplier of the safety data sheet

: ASTRAZENECA PTY LTD  
PO Box 131  
66 Talavera Rd, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500

Emergency Telephone  
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

#### Alternative Names

Ticagrelor Tablets  
Brilinta Tablets 5 mg, 10 mg, 15 mg, 30 mg, 45 mg, 60 mg, 90 mg  
CAS No. : Not applicable

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

Use of the Substance/Mixture : Platelet aggregation inhibitor

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## SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : None

Hazard statements : H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

#### Prevention:

P273 Avoid release to the environment.

#### Response:

P391 Collect spillage.

#### Disposal:

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

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**Other hazards which do not result in classification**

May cause dizziness, headache, abdominal pain, dyspepsia, constipation and anxiety.  
Risk of hypersensitivity reactions in susceptible individuals.  
See Section 11.  
May form explosible dust-air mixture if dispersed.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture            :    Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ticagrelor	274693-27-5	15 -30
Celluloses	9004-34-6	8 -15
Titanium dioxide	13463-67-7	2
Magnesium stearate	557-04-0	1.5
Talc	14807-96-6	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.  
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

Notes to physician                 :    Symptomatic treatment and supportive therapy as indicated.  
For further detail consult the prescribing information.

**SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media    :    water spray, foam, dry powder or CO<sub>2</sub>.  
Water spray should be used to cool containers.

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 burn and 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.

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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.  
Avoid dispersal of dust in the air.  
See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.  
Collect spillage.
- Methods and materials for containment and cleaning up : Avoid dust generation.  
Transfer spilled tablets to a suitable container for disposal.  
Wash the spillage area with water.  
Avoid release to the environment.  
  
See section 13.

## SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.  
Wash hands after use.  
Minimize dust generation and accumulation.  
In case of accident, avoid breathing dust from crushed tablets.  
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage : Keep container tightly closed.  
Below 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
Ticagrelor	274693-27-5	TWA	0.5 mg/m <sup>3</sup>	COM; HYG
Celluloses	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			

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		TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH
Talc	14807-96-6	TWA	2.5 mg/m <sup>3</sup>	AU OEL
		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	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.

## Personal protective equipment

**Respiratory protection** : Use a negative pressure air purifying respirator (half face mask) with filter class P3 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** : Avoid contact with skin. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : tablets

Colour : 10mg: white 60mg: pink 45mg,90mg: yellow

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

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Explosive properties : No data available

Oxidizing properties : No data available

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## 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 : No conditions producing hazardous situations known.

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.

#### Components:

##### **Ticagrelor:**

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

### 11.2 Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Ticagrelor:**

Remarks : Unlikely to be corrosive to the skin.

### 11.3 Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **Ticagrelor:**

Remarks : Unlikely to be a severe irritant to the eye.

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#### 11.4 Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

Not classified based on available information.

##### Components:

##### Ticagrelor:

Remarks : Unlikely to cause skin sensitisation.

##### Chronic toxicity

#### 11.5 Germ cell mutagenicity

Not classified based on available information.

##### Components:

##### Ticagrelor:

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:

##### Ticagrelor:

Carcinogenicity - Assessment : The substance is unlikely to present a carcinogenic risk to humans.

#### 11.7 Reproductive toxicity

Not classified based on available information.

##### Components:

##### Ticagrelor:

Reproductive toxicity - Assessment : The results from reproductive toxicity studies in animals do not indicate a reproductive risk to humans.

#### 11.8 STOT - single exposure

Not classified based on available information.

##### Components:

##### Ticagrelor:

Exposure routes : Inhalation  
Target Organs : respiratory system  
Remarks : High concentrations of dust may be slightly irritant to the upper respiratory tract.

Exposure routes : Oral  
Remarks : May cause dizziness, headache, abdominal pain, dyspepsia, constipation and anxiety.

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Risk of hypersensitivity reactions in susceptible individuals.  
May cause effects as described under repeated exposure.(STOT)

### 11.9 STOT - repeated exposure

Not classified based on available information.

#### Components:

##### **Ticagrelor:**

Exposure routes : Oral, Inhalation  
Target Organs : Adrenals, Gastrointestinal tract, Lungs, Liver, Blood  
Remarks : Repeated ingestion or inhalation increases the risk of bleeding, which may cause hemorrhage in any tissue or organ.  
Exposure increases the risk of bleeding into the skin, bleeding gums and nose bleeds.  
Studies in animals have shown that repeated oral doses cause effects on the gastrointestinal tract and the ovaries.  
Studies in animals have shown that repeated doses may cause effects on blood components.

### 11.10 Aspiration toxicity

Not classified based on available information.

#### Components:

##### **Ticagrelor:**

No information available.

#### **Further information**

##### Product:

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

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Product:

##### **Ecotoxicology Assessment**

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.  
Remarks: The following information refers to active ingredient:

#### Components:

##### **Ticagrelor:**

Toxicity to fish : EC50 (Oncorhynchus mykiss (rainbow trout)): > 2.7 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1.4 mg/l



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- aquatic invertebrates      Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants      :    NOEC (green algae): 0.82 mg/l  
Exposure time: 72 h  
Test Type: growth rate  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity)      :    NOEC (Pimephales promelas (fathead minnow)): 1.8 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)      :    NOEC (Daphnia magna (Water flea)): 0.53 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- NOEC (Chironomus sp. (midge)): 30 mg/l  
Exposure time: 28 d  
Method: (OECD 218)
- Toxicity to microorganisms      :    Respiration inhibition (Sewage sludge organisms): 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

#### Ecotoxicology Assessment

- Acute aquatic toxicity      :    Toxic to aquatic life.
- Chronic aquatic toxicity      :    Toxic to aquatic life with long lasting effects.

#### Persistence and degradability

##### Components:

##### **Ticagrelor:**

- Biodegradability      :    Result: not rapidly degradable  
Biodegradation: < 5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

#### Bioaccumulative potential

##### Components:

##### **Ticagrelor:**

- Bioaccumulation      :    Bioconcentration factor (BCF): 6.4  
Exposure time: 28 d  
Method: OECD Test Guideline 305  
Remarks: The substance has low potential for bioaccumulation.  
Log Pow: See Section 9.

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## Mobility in soil

### Components:

#### **Ticagrelor:**

Mobility : Medium: Soil  
Method: OECD Test Guideline 105  
Remarks: The substance has high mobility in soil.  
Water solubility  $\geq 1$  mg/l.

Distribution among environmental compartments : Koc: 1.571 ml/g

#### **Other adverse effects**

No data available

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## 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.  
Dispose of contents/ container to an approved incineration plant.

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

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## SECTION 14. TRANSPORT INFORMATION

### **ICAO/IATA**

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

### **IMO/IMDG**

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

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## ADR

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

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## 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:**

TCSI : Not listed  
TSCA : Substance(s) not listed on TSCA inventory  
AICS : Not listed  
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
Ticagrelor  
ENCS : Not listed  
ISHL : Not listed  
KECI : Not listed  
IECSC : Not listed  
CHINV : Not in compliance with the inventory  
REACH : Not in compliance with the inventory

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TRINV : Not in compliance with the inventory

## SECTION 16. OTHER INFORMATION

### Further information

Revision Date : 15.01.2020

Other information : Minor changes:  
15

Date format : dd.mm.yyyy

### Full text of other abbreviations

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

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; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; 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; 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 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); 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; 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; 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; 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); TRINV - Turkey Inventory; 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; WHMIS - Workplace Hazardous Materials Information System

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The information provided in this 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.

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