Version	Revision Date:	SDS Number:	Date of last issue: 18.09.2017
6.0	22.11.2017	8272	Date of first issue: 18.09.2017

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
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute aquatic toxicity : Category 2

Chronic aquatic toxicity : 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.

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

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Ticagrelor	274693-27-5	>= 30 -< 40
Celluloses	9004-34-6	>= 10 -< 20
Titanium dioxide	13463-67-7	>= 1 -< 10
Magnesium stearate	557-04-0	>= 1 -< 10
Talc	14807-96-6	>= 1 -< 10

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 CO2.
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.
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/m3	COM; HYG
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
Titanium dioxide	13463-67-7	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 (Titanium dioxide)	ACGIH
Magnesium stearate	557-04-0	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
Talc	14807-96-6	TWA	2.5 mg/m3	AU OEL

		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable fraction)	2 mg/m3	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.

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
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	:	No conditions producing hazardous situations known.
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	:	Remarks: Low acute oral toxicity.

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.

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.
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.

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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.4 mg/l
Exposure time: 48 H
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae : 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.

Mobility in soil

Components:

Ticagrelor:

Mobility	:	Medium: Soil Method: OECD Test Guideline 105 Remarks: The substance has high mobility in soil. Water solubility >= 1 mg/l.
Distribution among	:	Koc: 1.571 ml/g

environmental compartments

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

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

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.
Ticagrelor		274693-27-5
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	:	22.11.2017
Other information	:	New significant SHE information:, 8. New Occupational Exposure Limit Value, Minor changes:, 3, 8, 15, 16 New significant SHE information:, 8. New Occupational Exposure Limit Value, Minor changes:, 3, 8, 15, 16
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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