SAFETY DATA SHEET

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

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 10 mg, 45 mg, 60 mg, 90 mg

CAS No. : Not applicable
Use : Platelet aggregation inhibitor

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Classification UN GHS</th>
<th>Hazard class</th>
<th>Category</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aquatic toxicity</td>
<td>2</td>
<td></td>
<td>H401</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>2</td>
<td></td>
<td>H411</td>
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<td></td>
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<td></td>
<td># Refer to Section 16 ‘Other Information’</td>
</tr>
</tbody>
</table>

Label elements

Hazard statements

H411 : Toxic to aquatic life with long lasting effects.

Precautionary statements

P273 : Avoid release to the environment.
P391 : Collect spillage.
P501 : Dispose of contents/container to an approved incineration plant.
Other hazards
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
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</thead>
<tbody>
<tr>
<td>Ticagrelor</td>
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<td>274693-27-5</td>
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<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celluloses</td>
<td>8 - 14</td>
<td>-</td>
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</table>

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<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium dioxide</td>
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<td>13463-67-7</td>
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</table>

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<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
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</thead>
<tbody>
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</table>

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# Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures
Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Wash skin with soap and water.
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.
Ingestion : 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

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.
5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable) : water spray, foam, dry powder or CO2. Water spray should be used to cool containers.
Extinguishing Media (unsuitable) : Avoid high pressure media which could cause the formation of a potentially explosive 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. Collect spillage.
Methods and material 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.

7. HANDLING AND STORAGE

Precautions for 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, including any incompatibilities : Keep container tightly closed. Below 30°C.
Specific end use(s) : Not applicable, refer to Section 1
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Control parameters</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Ticagrelor</td>
<td>0.5 mg/m³</td>
<td>LTEL 8hr TWA</td>
<td>COM, HYG</td>
</tr>
<tr>
<td>Celluloses (Total Inhalable Dust)</td>
<td>10 mg/m³</td>
<td>LTEL 8hr TWA</td>
<td>WEL</td>
</tr>
<tr>
<td>Cellulose (Respirable Dust)</td>
<td>4 mg/m³</td>
<td>LTEL 8hr TWA</td>
<td>WEL</td>
</tr>
<tr>
<td>Titanium Dioxide (Total Inhalable Dust)</td>
<td>10 mg/m³</td>
<td>LTEL 8hr TWA</td>
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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 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.

Skin 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

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

This 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 : Low acute oral toxicity.
Specific Target Organ Toxicity (STOT) : Single exposure
            Exposure routes: Inhalation
            Target Organs: Respiratory system
            High concentrations of dust may be slightly irritant to the upper respiratory tract.
            Exposure routes: Oral
            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)
Repeated exposure
            Exposure routes: Oral, Inhalation
            Repeated exposure increases the risk of bleeding, which may cause hemorrhage in any tissue or organ., 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.
Sensitisation : Unlikely to be a skin sensitiser.
Carcinogenicity : It is unlikely to present a carcinogenic hazard to man.
Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
Reproductive toxicity : The results from reproductive toxicity studies in animals do not indicate a reproductive risk to humans.

12. ECOLOGICAL INFORMATION

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

Toxicity : EC50 Daphnia magna 48 H (static) 1.4 mg/l
            NOEC Daphnia magna 21 d 0.53 mg/l
Effect on Effluent Treatment: There is no evidence of inhibition to the aerobic treatment process at a concentration of up to 100 mg/l.

Persistence and degradability: Biodegradability, 28 days, (OECD 301F) <5%. Not rapidly degradable.

Bioaccumulative potential: The substance has high potential for bioaccumulation.

Mobility in soil: Water solubility >= 1 mg/l. (OECD 105)

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 product 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. (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
15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard statements

H401 : Toxic to aquatic life.
H411 : Toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements:

Minor changes:; 1, 3, 8, 9, 16

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.