SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

NEXIUM 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:
Esomeprazole gastro-resistant tablets
CAS No.: Not applicable.

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

Use of the Substance/Mixture: Symptomatic treatment of gastro-oesophageal reflux disease (GERD)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitisation: Category 1
Long-term (chronic) aquatic hazard: Category 3

GHS label elements
Hazard pictograms:

Signal word: Warning
Hazard statements:
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celluloses</td>
<td>9004-34-6</td>
<td>70 -71</td>
</tr>
<tr>
<td>Esomeprazole Magnesium Trihydrate</td>
<td>217087-09-7</td>
<td>5 -8</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>3.3</td>
</tr>
</tbody>
</table>

**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.

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

**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 burn and emit noxious and toxic fumes.

**Special protective equipment:** A self contained breathing apparatus and suitable protective
for firefighters 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.

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.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling:
Avoid contact with skin and eyes. Wear protective gloves. See Section 8. Minimize dust generation and accumulation. 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. Protect from light.

Recommended storage temperature:
< 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celluloses</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Esomeprazole Magnesium Trihydrate</td>
<td>217087-09-7</td>
<td>TWA</td>
<td>0.1 mg/m³</td>
<td>COM; HYG</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>TWA</td>
<td>2.5 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.1 fibres per cubic centimeter</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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**: Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. 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** : coated tablets

**Colour** : 20 mg-light pink, 40 mg-pink

**Odour** : No data available

**Odour Threshold** : No data available
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pH : No data available
Melting point/range : No data available
Initial boiling point and boiling range : Not applicable
Flash point : Not applicable
Evaporation rate : Not applicable
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 : Not applicable
Relative vapour density : Not applicable
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 : Not applicable
  Viscosity, kinematic : Not applicable
Explosive properties : No data available
Oxidizing properties : Not applicable

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: Acids (decomposes)

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:**
Esomeprazole Magnesium Trihydrate:
Acute oral toxicity: Evident toxicity with mortality in rats at a dose of: 480 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.
Remarks: Information refers to Esomeprazole

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:**
Esomeprazole Magnesium Trihydrate:
Result: Mild skin irritation

11.3 Serious eye damage/eye irritation
Not classified based on available information.

**Components:**
Esomeprazole Magnesium Trihydrate:
Remarks: May cause eye irritation.
May cause conjunctivitis.

11.4 Respiratory or skin sensitisation

**Skin sensitisation**
May cause an allergic skin reaction.

**Respiratory sensitisation**
Not classified based on available information.
Components:

Esomeprazole Magnesium Trihydrate:
Result: May cause sensitisation by skin contact.
Remarks: Omeprazole:
   - It is an extreme skin sensitiser in animal tests.
   - Many cases of occupational skin sensitisation have been reported.

Chronic toxicity

11.5 Germ cell mutagenicity
Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:
Germ cell mutagenicity - Assessment: The substance is not considered to be genotoxic.

11.6 Carcinogenicity
Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:
Carcinogenicity - Assessment: The substance is not considered to be carcinogenic.

11.7 Reproductive toxicity
Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:
Reproductive toxicity - Assessment: There is no evidence of reprotoxicity in animal tests.

11.8 STOT - single exposure
Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:
Exposure routes: Oral, Inhalation
Remarks: May cause nausea and vomiting.
   - Rare cases of hypersensitivity (including allergic reactions) and CNS-effects (including dizziness and muscle jerks) have been reported in patients.

Exposure routes: Inhalation
Remarks: Dust may be irritant to the respiratory tract.

11.9 STOT - repeated exposure
Not classified based on available information.
Components:

Esomeprazole Magnesium Trihydrate:

Exposure routes: Oral
Target Organs: Stomach
Remarks: Repeated exposure may produce adverse effects. These effects are derived from studies in animals.
Remarks: Common side effects reported from patients include headache, gastrointestinal disorders, sinusitis and respiratory infection. May cause effects as described under single exposure (STOT).

11.10 Aspiration toxicity
Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Esomeprazole Magnesium Trihydrate:

Toxicity to fish: LC50 (Danio rerio (zebra fish)): 42 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: (Omeprazole sodium)

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: (Omeprazole sodium)

Toxicity to algae: EbC50 (green algae): 19 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: (Esomeprazole sodium)

NOEC (green algae): 8.4 mg/l
Exposure time: 72 h
Test Type: growth rate
Method: OECD Test Guideline 201
Remarks: (Esomeprazole sodium)

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 1 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
Remarks: Information refers to Esomeprazole sodium
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Information refers to Esomeprazole sodium

Toxicity to microorganisms:

NOEC (activated sludge): 100 mg/l
Exposure time: 3 h
Remarks: There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l.

Persistence and degradability

Components:

Esomeprazole Magnesium Trihydrate:

Biodegradability: Result: Not rapidly biodegradable
               Biodegradation: < 0.6 %
               Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Esomeprazole Magnesium Trihydrate:

Bioaccumulation: Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Esomeprazole Magnesium Trihydrate:

Mobility: Remarks: Water solubility >= 1 mg/l.
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. 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

Not classified as dangerous in the meaning of transport regulations.

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 in compliance with the inventory
DSL: This product contains the following components that are not on the Canadian DSL nor NDSL.

Esomeprazole Magnesium Trihydrate

AICS: Not in compliance with the inventory
ENCS: Not in compliance with the inventory
ISHL: Not in compliance with the inventory
IECSC: Not in compliance with the inventory
TCSI: Not in compliance with the inventory
TSCA: Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information
Revision Date: 03.05.2019
SAFETY DATA SHEET

Version 4.0  Revision Date: 03.05.2019  SDS Number: 12359  Date of last issue: 15.01.2018

Other information:
- New significant SHE information:
  3. Composition/information on ingredients
  8. New Occupational Exposure Limit Value
- Minor changes:
  2
  10
  11
  12
  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; 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; ICSC - 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); 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

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.

AU / EN