

Version 4.1 Revision Date: 14.01.2020 SDS Number: 12359 Date of last issue: 03.05.2019
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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

NEXIUM TABLETS

Details of the supplier of the safety data sheet

: ASTRAZENECA PTY LTD Emergency Telephone
PO Box 131 +44 (0) 1235 239 670
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

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.

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Disposal:

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

Other hazards which do not result in classification

May cause irritation to skin, eyes and respiratory system.

See Section 11.

The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	70 -71
Esomeprazole Magnesium Trihydrate	217087-09-7	5 -8
Talc	14807-96-6	3.3

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.
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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.
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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.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m ³	ACGIH
Esomeprazole Magnesium Trihydrate	217087-09-7	TWA	0.1 mg/m ³	COM; HYG
Talc	14807-96-6	TWA	2.5 mg/m ³	AU OEL
		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable fraction)	2 mg/m ³	ACGIH

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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

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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 : 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.

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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.

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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

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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: (Esomeprazole 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: (Esomeprazole sodium)

Toxicity to algae/aquatic plants : 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

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- 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 \geq 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

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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 : No poison schedule number allocated
Scheduling of Medicines and
Poisons

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.

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ENCS : Not listed

ISHL : Not listed

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KECI	:	Not listed
IECSC	:	Not listed
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

SECTION 16. OTHER INFORMATION**Further information**

Revision Date	:	14.01.2020
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

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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

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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