Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	13.07.2017	20378	Date of first issue: 13.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

NEXIUM FOR ORAL SUSPENSION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names
Pellets for Esomeprazole sachets for Delayed-Release Oral Suspension (2.5mg, 5mg,10mg, 20 and 40mg)
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

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
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.

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.
The product may form flammable dust clouds in air, if dust from pellets is allowed to accumulate and if it is dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Esomeprazole Magnesium Trihydrate	217087-09-7	>= 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	:	Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
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 swallowed	:	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.
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 detail 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 for firefighters	:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Avoid dispersal of dust in the air. Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses.
Methods and materials for containment and cleaning up	:	Transfer spilled pellets to a suitable container for disposal. Wash the spillage area with water.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from pellets is allowed to accumulate and if it is dispersed.
Conditions for safe storage	:	Keep container tightly closed.
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
Esomeprazole Magnesium Trihydrate	217087-09-7	TWA	0.1 mg/m3	COM; HYG

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.

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 substance 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 substance if the risk assessment does not support the

selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance 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	:	pellets, granules
Colour	:	No data available
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	:	No data available
Lower explosion 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	:	Acids , decomposes
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Remarks: Low 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: By analogy with Esomeprazole
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:

Result: Mild skin irritation

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:

Remarks: May cause eye irritation.
May cause conjunctivitis.

11.1.4 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.

11.1.5 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.

11.1.6 Carcinogenicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:

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

11.1.7 Reproductive toxicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:

Reproductive toxicity - Assessment : There is no evidence of a teratogenic potential or any other adverse effects on reproductive function.

11.1.8 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.

11.1.9 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)

11.1.10 Aspiration toxicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate:

No data 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	:	This product has no known ecotoxicological effects. Remarks: The following information refers to Omeprazole sodium

Components:

Esomeprazole Magnesium Trihydrate:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 42 mg/l Exposure time: 96 H Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 H Method: OECD Test Guideline 202
Toxicity to algae	:	ErC50 (green algae): > 76 mg/l Exposure time: 72 H Method: OECD Test Guideline 201 NOEC (green algae): 1.8 mg/l Exposure time: 72 H Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 1 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)): 10 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to bacteria	:	NOEC (Sewage sludge organisms): 100 mg/l Exposure time: 3 H Test Type: Respiration inhibition

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.
Remarks: Information refers to
Omeprazole sodium

Persistence and degradability

Components:

Esomeprazole Magnesium Trihydrate:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: < 60 %
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.

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.
Esomeprazole Magnesium Trihydrate		217087-09-7
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; 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); 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

Date format : dd.mm.yyyy

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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