Version	Revision Date:	SDS Number:	Date of last issue: -
3.0	19.12.2017	13276	Date of first issue: 19.12.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

CRESTOR 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

CAS No. : Not applicable

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

Use of the Substance/Mixture : Cholesterol lowering agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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 produce headache, dizziness, gastrointestinal disorders, muscular pain (myalgia) and weakness (asthenia).
May form explosible dust-air mixture if dispersed.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Rosuvastatin Calcium	147098-20-2	3 -14

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
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.
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

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 : Ensure suitable personal protection during removal of spillages.
Avoid dispersal of dust in the air.
See Section 8.

Environmental precautions : Do not empty into drains.
Collect spillage.

Methods and materials for : Transfer spilled tablets to a suitable container for disposal.

containment and cleaning up

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.
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
Rosuvastatin Calcium	147098-20-2	TWA	0.005 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.
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	:	film-coated tablets
Colour	:	2.5, 5mg - yellow. 10, 20, 40, 80mg - pink.
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:

Rosuvastatin Calcium:

Acute oral toxicity	:	Lethal single dose (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 data available

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Rosuvastatin Calcium:

Remarks: Unlikely to be corrosive to the skin.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Rosuvastatin Calcium:

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:

Rosuvastatin Calcium:

Remarks: Unlikely to be a moderate or strong skin sensitiser.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Rosuvastatin Calcium:

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:

Rosuvastatin Calcium:

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

11.7 Reproductive toxicity

Not classified based on available information.

Components:

Rosuvastatin Calcium:

Reproductive toxicity - Assessment : By analogy with similar materials:, Potential for harm to the unborn child and breastfed babies., There is no evidence of reprotoxicity in animal tests.

11.8 STOT - single exposure

Not classified based on available information.

Components:

Rosuvastatin Calcium:

Exposure routes: Oral
Remarks: May produce headache, dizziness, gastrointestinal disorders, muscular pain (myalgia) and weakness (asthenia).
Symptoms may include nausea and abdominal pain.

11.9 STOT - repeated exposure

Not classified based on available information.

Components:

Rosuvastatin Calcium:

Exposure routes: Oral
Remarks: Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the liver and lens of the eye.
May cause increased serum glucose levels, thus increasing the risk for diabetes in patients with high risk of developing diabetes.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Rosuvastatin Calcium:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.
Remarks: No information on this formulation.
The following information refers to Rosuvastatin calcium

Components:

Rosuvastatin Calcium:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,000 mg/l Exposure time: 96 H Test Type: static test LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l Exposure time: 96 H Test Type: static test
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 63 mg/l Exposure time: 48 H Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae	:	NOEC (green algae): 350 mg/l Exposure time: 10 d NOEC (blue-green algae): 330 mg/l Exposure time: 16 d
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.018 mg/l Exposure time: 21 d LC50 (Daphnia magna (Water flea)): 0.17 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	(Sewage sludge organisms): 100 mg/l Method: OECD Test Guideline 209

Ecotoxicology Assessment

Acute aquatic toxicity	:	Harmful to aquatic life.
Chronic aquatic toxicity	:	Very toxic to aquatic life with long lasting effects.

Persistence and degradability

Components:

Rosuvastatin Calcium:

Biodegradability	:	Result: Not rapidly biodegradable Remarks: There is no evidence of hydrolysis in water. Readily photolysed in water. (T1/2 <13 minutes)

Bioaccumulative potential

Components:

Rosuvastatin Calcium:

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

Mobility in soil

Components:

Rosuvastatin Calcium:

Mobility : Remarks: Water solubility >= 1 mg/l.
The substance has high mobility in soil.

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.
Normal waste disposal is via incineration operated by an accredited disposal contractor.

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. (ROSUVASTATIN CALCIUM)
Class	:	9
Packing Group	:	III
Environmental hazards	:	Environmentally hazardous

IMO/IMDG

UN No.		3077
Proper Shipping Name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ROSUVASTATIN CALCIUM)

Class	:	9
Packing Group	:	III
Marine pollutant	:	Marine pollutant

ADR

UN No.		3077
Proper Shipping Name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ROSUVASTATIN CALCIUM)
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.
Rosuvastatin Calcium		147098-20-2
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	:	19.12.2017
Other information	:	The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., Full Review - minor changes, 6, 11, 12, 15
Date format	:	dd.mm.yyyy

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