Version	Revision Date:	SDS Number:	Date of last issue: 13.11.2019
4.0	17.04.2020	13231	Date of first issue: 19.01.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

ATACAND PLUS TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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AUSTRALIA
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SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names

Atacand HCT 8/12.5mg, 16/12.5mg, 32/12.5mg and 32/25mg
Candesartan Cilexetil and Hydrochlorothiazide tablets

CAS No. : Not applicable

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

Use of the Substance/Mixture : antihypertensive agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, Blood)

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.
H373 May cause damage to organs (Kidney, Blood) through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: 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 lowering of blood pressure.
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)
Starch	9005-25-8	15.4
Candesartan Cilexetil	145040-37-5	6.1 -12.3
Hydrochlorothiazide	58-93-5	4.8 -9.6
Celluloses	9004-34-6	7.4
Magnesium stearate	557-04-0	0.3 -1

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 damage fertility or the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.

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	:	Prevent entry into drains, sewers or watercourses.
Methods and materials for containment and cleaning up	:	Transfer spilled tablets 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 crushed tablets is allowed to accumulate.
Conditions for safe storage	:	Keep container tightly closed and dry.
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
Starch	9005-25-8	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Candesartan Cilexetil	145040-37-5	TWA	0.001 mg/m3	COM; HYG
Hydrochlorothiazide	58-93-5	TWA	0.5 mg/m3	COM; HYG
Celluloses	9004-34-6	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m3	AU OEL

	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH

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 an air fed hood 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 or for repeated, excessive handling use full chemical protective suit 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	:	uncoated tablets
Colour	:	8/12.5mg : white 16/12.5mg : peach 32/12.5mg :yellow 32/25 mg: light 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	:	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	:	Not explosive

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	:	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.

Components:

Candesartan Cilexetil:

Acute oral toxicity	:	LD50 Oral (Rat): > 2,000 mg/kg Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	Remarks: No information available on acute toxicity. May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

Hydrochlorothiazide:

Acute oral toxicity	:	Remarks: Low acute oral toxicity.
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:

Candesartan Cilexetil:

Remarks	:	No evidence of irritant effects from normal handling and use.

Hydrochlorothiazide:

Remarks : Non-irritant in vivo.
Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Candesartan Cilexetil:

Remarks : No evidence of irritant effects from normal handling and use.

Hydrochlorothiazide:

Remarks : Non-irritant in vivo.
No evidence of irritant effects from normal handling and use.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Candesartan Cilexetil:

Remarks : It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

Hydrochlorothiazide:

Remarks : It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Candesartan Cilexetil:

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

Hydrochlorothiazide:

Germ cell mutagenicity - Assessment : Some evidence of genotoxcity in vitro but not considered to present a mutagenic hazard to man.

11.6 Carcinogenicity

Not classified based on available information.

Components:

Candesartan Cilexetil:

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

Hydrochlorothiazide:

Carcinogenicity - Assessment	:	The substance is unlikely to present a carcinogenic risk to humans.

11.7 Reproductive toxicity

May damage fertility or the unborn child.

Components:

Candesartan Cilexetil:

Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on development from human epidemiological studies., Studies in animals have shown that high doses produce embryo/foetotoxic effects.

Hydrochlorothiazide:

Reproductive toxicity - Assessment	:	There is no evidence of reprotoxicity in animal tests., The substance crosses the placenta and may affect the foetus., The substance passes into breast milk

11.8 STOT - single exposure

Not classified based on available information.

Components:

Candesartan Cilexetil:

Exposure routes	:	Oral
Remarks	:	May cause lowering of blood pressure.

Hydrochlorothiazide:

Exposure routes	:	Inhalation
Target Organs	:	Respiratory Tract
Remarks	:	May cause irritation to the upper respiratory tract.
Exposure routes	:	Oral, Inhalation
Remarks	:	May cause decreased blood pressure.

11.9 STOT - repeated exposure

May cause damage to organs (Kidney, Blood) through prolonged or repeated exposure if swallowed.

Components:

Candesartan Cilexetil:

Exposure routes	:	Oral
Target Organs	:	Kidney, Blood
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Remarks : These effects are derived from studies in animals.

Hydrochlorothiazide:

Exposure routes : Oral
Remarks : Side effects from patients include tachycardia, gastrointestinal disturbances, paresthesia and photosensitivity reactions.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Candesartan Cilexetil:

No data available

Hydrochlorothiazide:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Candesartan Cilexetil:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.017 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.016 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): > 0.012 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : IC50 (activated sludge): 1,000 mg/l
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Ecotoxicology Assessment

Chronic aquatic toxicity : May cause long lasting harmful effects to aquatic life.

Hydrochlorothiazide:

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100

mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 10 mg/l
Exposure time: 30 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 100 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (activated sludge): > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Candesartan Cilexetil:

Biodegradability : Result: not rapidly degradable
Biodegradation: < 9 %
Exposure time: 28 d

Hydrochlorothiazide:

Biodegradability : Biodegradation: 36 %
Exposure time: 28 d
Remarks: Not readily biodegradable.

Bioaccumulative potential

Components:

Candesartan Cilexetil:

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

Hydrochlorothiazide:

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

Mobility in soil

Components:

Candesartan Cilexetil:

Mobility : Remarks: Water solubility < 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Hydrochlorothiazide:

Mobility : Remarks: The substance has high mobility in soil.

Distribution among environmental compartments : Koc: 29 - 33
Method: OECD Test Guideline 106

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:

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. Candesartan Cilexetil
ENCS	:	Not listed
ISHL	:	Not listed
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	:	17.04.2020
Other information	:	Full Review - minor changes Minor changes: 11 12
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 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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