SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

ATACAND PLUS TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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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
Use : antihypertensive agent

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS

Hazard class	Category	Hazard statements
Reproductive toxicity Specific target organ toxicity - repeated exposure	1A 2	H360 H373 # Refer to Section 16 'Other Information'

Label elements

Signal word
Danger

Hazard statements

H360 : May damage the unborn child.

H373 : May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

P201 Obtain special instructions before use.

P261 Avoid breathing dust.

P281 Use personal protective equipment as required.

P308 + P313	:	IF exposed or concerned: Get medical advice/ attention.
P501	:	Dispose of contents/ container to an approved incineration plant.

Other hazards
May cause lowering of blood pressure. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	**%**	**CAS No.**		
Candesartan Cilexetil	6 - 12	145040-37-5		
	Hazard class #		**Category**	**Hazard statements** #
	Reproductive toxicity		1A	H360
	Specific target organ toxicity - repeated exposure		2	H373
	Chronic aquatic toxicity		4	H413
Component	**%**	**CAS No.**		
Hydrochlorothiazide	5 - 10	58-93-5		
	Hazard class #		**Category**	**Hazard statements** #
	Acute aquatic toxicity		3	H402

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation	:	Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact	:	Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.
Eye Contact	:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Ingestion	:	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

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated.For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable)	:	water spray, foam, dry powder or CO2.
Extinguishing Media (unsuitable)	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Special hazards arising from the substance or mixture	:	If involved in a fire, it may burn and emit noxious and toxic fumes.
Special protective actions for fire-fighters	:	A self contained breathing apparatus and suitable protective

clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

Precautions for 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, including any incompatibilities	:	Keep container tightly closed and dry. Storage temperature : < 30 °C
Specific end use(s)	:	Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Candesartan Cilexetil	0,001 mg/m3	LTEL 8hr TWA	COM, HYG
Hydrochlorothiazide	0,5 mg/m3	LTEL 8hr TWA	COM, HYG

Exposure Controls
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.
Occupational exposure controls
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.
The information below 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.

Respiratory protection
Use an air fed hood if the risk assessment does not support the selection of other protection.

Skin 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form	:	tablets
Colour	:	8/12.5mg : white 16/12.5mg : peach 32/12.5mg :yellow 32/25 mg: light pink

Other information

No other data available

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.

11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation	:	May cause effects as described under single exposure.(STOT)
Skin Contact	:	No evidence of irritant effects from normal handling and use.
Eye Contact	:	No evidence of irritant effects from normal handling and use.
Ingestion	:	Low acute oral toxicity.
Specific Target Organ Toxicity (STOT)	:	**Single exposure** Exposure routes: Oral May cause gastrointestinal irritation, nausea, dizziness and weakness., May cause lowering of blood pressure. **Repeated exposure** Exposure routes: Oral Target Organs: See below. May cause damage to organs through prolonged or repeated exposure. Studies in animals have shown that repeated doses produce adverse effects, on, kidneys, heart, and, blood
Sensitisation	:	No information available.
Carcinogenicity	:	It is unlikely to present a carcinogenic hazard to man.
Mutagenicity	:	No information available.
Reproductive toxicity	:	May cause harm to the unborn child. Foetal and neonatal toxicity in babies born to women receiving treatment during pregnancy has been reported.

12. ECOLOGICAL INFORMATION

There is no data available for this product. This environmental hazard assessment is based on information available on the components of the formulation.

Toxicity	:	Candesartan Cilexetil : EC50 Algae 72 H > 0,012 mg/l Hydrochlorothiazide : EC50 Chlorella vulgaris (Fresh water algae) 72 H 34,35 mg/l NOEC Pseudokirchneriella subcapitata (green algae) 72 H 100 mg/l Candesartan Cilexetil : EC50 Daphnia magna 48 H > 0,016 mg/l Hydrochlorothiazide : NOEC Daphnia magna 21 d (reproduction) 100 mg/l Candesartan Cilexetil : LC50 Fish 96 H > 0,017 mg/l Hydrochlorothiazide : NOEC fathead minnow 30 d 10 mg/l
Effect on Effluent Treatment	:	No information available.
Persistence and degradability	:	Candesartan Cilexetil : Not readily biodegradable. Hydrochlorothiazide : The substance is partially biodegradable in water.
Bioaccumulative potential	:	Candesartan Cilexetil : The substance has high potential for bioaccumulation. May cause long lasting harmful effects to aquatic life.
Mobility in soil	:	Candesartan Cilexetil : The substance is essentially insoluble in water.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	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.

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.
In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements	H360 : May damage the unborn child. H373 : May cause damage to organs through prolonged or repeated exposure. H402 : Harmful to aquatic life. H413 : May cause long lasting harmful effects to aquatic life.

The following sections contain revisions or new statements :

Minor changes:, 1, 3, 4, 6, 8, 16

GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.