Version	Revision Date:	SDS Number:	Date of last issue: 12.03.2018
2.0	21.08.2019	21650	Date of first issue: 12.03.2018

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

QTERN TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Saxagliptin/Dapagliflozin Film Coated Tablets
Saxagliptin/Dapagliflozin Film Coated Tablets 2.5/10mg, 5/10mg, 2.5/5mg, 5/5mg
Saxagliptin/Dapagliflozin Tablets
CAS No. : Not applicable

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

Use of the Substance/Mixture : Treatment of diabetes

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitisation	:	Category 1
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 1B
Effects on or via lactation		
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Endocrine system, Immune system, Skin, Kidney, Bone)

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs (Endocrine system, Immune system, Skin, Kidney, Bone) 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.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P281 Use personal protective equipment as required.
P285 In case of inadequate ventilation wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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 hypoglycemia.
May cause eye irritation.
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	> 55 -< 65
Dapagliflozin	960404-48-2	2.5 -5.5
Titanium dioxide	13463-67-7	< 5
Talc	14807-96-6	< 5
Saxagliptin	945667-22-1	1.1 -2.2

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.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
May cause harm to breast-fed children.
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 : Do not use water jet.
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 full 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 materials for containment and cleaning up : Avoid dust generation.
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.
Avoid breathing dust.
Wear protective gloves.
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 : Store in a well-ventilated place. Keep container tightly closed.
Protect from light.

Recommended storage temperature : 20 - 25 °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/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Dapagliflozin	960404-48-2	TWA	0.01 mg/m3	COM
Titanium dioxide	13463-67-7	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 (Titanium dioxide)	ACGIH
Talc	14807-96-6	TWA	2.5 mg/m3	AU OEL
		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable fraction)	2 mg/m3	ACGIH
Saxagliptin	945667-22-1	TWA	10 µg/m3	COM

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 self-contained breathing apparatus 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.

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	:	yellow, brown, red, or, purple
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	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method

Components:

Dapagliflozin:

Acute oral toxicity	:	Evident toxicity with mortality in rats at a dose of: 750 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	:	Remarks: No information available on acute toxicity. May cause effects as described under repeated exposure.(STOT)
Acute dermal toxicity	:	Remarks: No data available

Saxagliptin:

Acute oral toxicity	:	LD50 Oral (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 sensitisation.

Acute dermal toxicity : Remarks: No data available

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Dapagliflozin:

Remarks : Non-irritant.

Saxagliptin:

Remarks : Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Dapagliflozin:

Result : Eye irritation

Saxagliptin:

Remarks : Unlikely to cause eye irritation.

11.4 Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Dapagliflozin:

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

Saxagliptin:

Result : The product is a skin sensitiser, sub-category 1A.

: The product is a respiratory sensitiser, sub-category 1A.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Dapagliflozin:

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

Saxagliptin:

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:

Dapagliflozin:

Carcinogenicity - Assessment	:	Studies in animals have shown that chronic exposures produce no carcinogenic effects.

Saxagliptin:

Carcinogenicity - Assessment	:	Studies in animals have shown that repeated doses produce no carcinogenic effects.

11.7 Reproductive toxicity

May damage fertility or the unborn child.
May cause harm to breast-fed children.

Components:

Dapagliflozin:

Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments. Effects on or via lactation

Saxagliptin:

Reproductive toxicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments., Studies in animals have shown that high doses produce adverse reproductive effects in the presence of maternal toxicity.

11.8 STOT - single exposure

Not classified based on available information.

Components:

Dapagliflozin:

Remarks	:	May cause effects as described under repeated exposure.(STOT)

Saxagliptin:

Exposure routes	:	Oral
Remarks	:	High exposure effects include hyperactivity and increased respiration. May cause effects as described under sensitisation.

11.9 STOT - repeated exposure

May cause damage to organs (Endocrine system, Immune system, Skin, Kidney, Bone) through prolonged or repeated exposure if swallowed.

Components:

Dapagliflozin:

Exposure routes	:	Oral
Target Organs	:	Kidney, Bone
Assessment	:	Causes damage to organs through prolonged or repeated exposure.
Remarks	:	These effects are derived from studies in animals.
Remarks	:	Repeated exposure may cause diarrhea, nausea, gastrointestinal discomfort, weakness, headache, dizziness, sweating, paleness, rash, dermatitis, swelling, blurred vision, abdominal pain, flank pain, changes in clinical chemistry parameters, and lowered blood pressure. Increased risk of urinary tract infection and fungal infection. May cause hypoglycemia. It may produce diuretic effects.

Saxagliptin:

Exposure routes	:	Oral
Target Organs	:	Endocrine system, Immune system, Skin
Assessment	:	Causes damage to organs through prolonged or repeated exposure.
Remarks	:	Studies in animals have shown that repeated doses produce adverse effects on the heart, kidneys and liver. Ingestion studies in animals have shown that repeated doses produce adverse effects on the gastrointestinal tract. Based on human experience. May cause headache, nausea, vomiting, diarrhoea and skin rash. May cause a decreased white blood cell count.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Dapagliflozin:

No data available

Saxagliptin:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Dapagliflozin:

Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 120 mg/l

aquatic invertebrates		Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	ErC50 (green algae): 120 mg/l Exposure time: 72 h NOEC (green algae): 37 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 Remarks: Highest concentration tested (no effects).
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 microorganisms	:	(NOEC) Respiration inhibition (Sewage sludge organisms): 200 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Saxagliptin:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): > 91 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae	:	ErC50 (green algae): > 140 mg/l Test Type: growth rate Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 9.5 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)): 35 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	NOEC (Sewage sludge organisms): 821 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Persistence and degradability

Components:

Dapagliflozin:

Biodegradability	:	Biodegradation: 11 % Method: OECD Test Guideline 301F Remarks: Not rapidly degradable. The substance is not significantly hydrolyzed in water.

Saxagliptin:

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 5.9 %
Exposure time: 28 d
Method: OECD Test Guideline 310
Remarks: Carbon dioxide evolution

Bioaccumulative potential

Components:

Dapagliflozin:

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

Saxagliptin:

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

Mobility in soil

Components:

Dapagliflozin:

Mobility : Remarks: Water solubility >= 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Saxagliptin:

Mobility : Remarks: The substance has high mobility in soil.
Hydrolysed by water.

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 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:

REACH	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Saxagliptin Dapagliflozin
AICS	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	21.08.2019
Other information	:	Full Review - minor changes 2 11 12 13
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; 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

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.

AU / EN