Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2017
2.0	07.03.2018	21115	Date of first issue: 06.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

ONGLYZA 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 2.5mg and 5mg tablets
BMS 477118-11
Saxagliptin 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
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Endocrine system, Immune system, Skin)

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.
H373 May cause damage to organs (Endocrine system, Immune system, Skin) through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.
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.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Saxagliptin

Other hazards which do not result in classification

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)
Talc	14807-96-6	< 60
Celluloses	9004-34-6	< 40
Titanium dioxide	13463-67-7	< 5
Saxagliptin	945667-22-1	>= 1 -<= 2

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
OBTAIN IMMEDIATE MEDICAL ATTENTION.

In case of skin contact : Take off all contaminated clothing immediately.
After contact with skin, wash immediately with plenty of water.
Obtain medical attention.

In case of eye contact : Immediately 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. May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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 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	:	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. Keep away from heat, sources of ignition and direct sunlight. 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
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
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
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
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.

Skin and body protection : Use impervious clothing to protect against direct contact with the product 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	:	coated tablets
Colour	:	light yellow, 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
Molecular weight	:	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.

Product:

Acute oral toxicity	:	Remarks: Low acute oral toxicity.

Components:

Saxagliptin:

Acute oral toxicity	:	LD50 Oral (Rat): > 300 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:

Saxagliptin:

Remarks: Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

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:

Saxagliptin:

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

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

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

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:

Saxagliptin:

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

11.7 Reproductive toxicity

Not classified based on available information.

Components:

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.

11.8 STOT - single exposure

Not classified based on available information.

Components:

Saxagliptin:

Exposure routes: Oral, Inhalation
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) through prolonged or repeated exposure if swallowed.

Components:

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.
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:

Saxagliptin:

No information 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

Components:

Saxagliptin:

Toxicity to fish	:	EC50 (Brachydanio rerio (zebrafish)): > 91 mg/l Exposure time: 96 H
Toxicity to algae	:	ErC50 (green algae): > 140 mg/l Test Type: growth rate
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
Toxicity to microorganisms	:	NOEC (Sewage sludge organisms): 821 mg/l Exposure time: 3 H Method: OECD Test Guideline 209

Persistence and degradability

Components:

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:

Saxagliptin:

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

Mobility in soil

Components:

Saxagliptin:

Mobility	:	Remarks: The substance has high mobility in soil. Hydrolysed by water.
Distribution among	:	Remarks: No information available.

environmental compartments

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:

REACH	:	Not listed
DSL	:	This product contains the following components that are not

on the Canadian DSL nor NDSL.

Saxagliptin		945667-22-1
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	:	07.03.2018
Other information	:	New significant SHE information:, 8. New Occupational

		Exposure Limit Value, Minor changes:, 3, 8, 15, 16
Date format	:	dd.mm.yyyy
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

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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