

Kit SDS Cover Sheet

Silensomes™ CYP3A4 Kit with Control

Version 3.0

Revision Date 30.04.2024

Print Date 06.05.2024

Product Information

Product name : Silensomes™ CYP3A4 Kit with Control

Material number : SIL200K

Components

Silensomes CYP3A4

SDS attached

Silensomes CYP3A4 Control

SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Silensomes CYP3A4

Version 3.0

Revision Date 30.04.2024

Print Date 06.05.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Silensomes CYP3A4

Manufacturer or supplier's detailsCompany : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, AustraliaLonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR
ANIMAL IN VIVO OR DIAGNOSTIC USE.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURESIf inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical

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	advice. If symptoms persist, call a physician.
In case of skin contact	: Wash with water and soap as a precaution. If on clothes, remove clothes. In the case of skin irritation or allergic reactions see a physician.
In case of eye contact	: Flush eyes with water as a precaution. Remove contact lenses. Keep eye wide open while rinsing. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: Heating or fire can release toxic gas.
Specific extinguishing methods	: Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment.
Environmental precautions	: No special environmental precautions required. Try to prevent the material from entering drains or water courses.
Methods and materials for containment and cleaning up	: Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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SECTION 7. HANDLING AND STORAGE

- | | | |
|---|---|---|
| Advice on protection against fire and explosion | : | Normal measures for preventive fire protection. |
| Advice on safe handling | : | No special precautions required.
For personal protection see section 8. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |
| Conditions for safe storage | : | Keep container tightly closed.
Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight. |
| Materials to avoid | : | No special restrictions on storage with other products. |
| Further information on storage stability | : | No decomposition if stored and applied as directed. |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
In the case of vapour formation use a respirator with an approved filter.

Hand protection

Remarks : Wear protective gloves. Break through time : > 480 min

Eye protection : Safety glasses

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Lightweight protective clothing

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

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Colour	: light brown
Odour	: No data available
Odour Threshold	: No data available
pH	: 6,8 - 7,2
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Flammability (liquids)	: 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
Density	: No data available
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No decomposition if stored and applied as directed.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions.

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No hazards to be specially mentioned.

Conditions to avoid : Heat

Incompatible materials : Oxidizing agents
Strong acids and strong bases

Hazardous decomposition products : No decomposition if used as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available

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Skin corrosion/irritation

Remarks : No data available

Serious eye damage/eye irritation

Remarks : No data available

Respiratory or skin sensitisation

Remarks : No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks : No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks : No data available

STOT - repeated exposure

Remarks : No data available

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish :
Remarks: No data available

Persistence and degradability

Biodegradability : Result: no data available

Bioaccumulative potential

Bioaccumulation : Remarks: No data available

Mobility in soil

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

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Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

IMDG

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable
Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable
Environmental hazards : no

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RID	:	Not dangerous goods
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Transport hazard class	:	Not applicable
Packing group	:	Not applicable
Environmental hazards	:	no
Special precautions for user	:	none
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	:	Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.04.2024

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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; 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)

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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; TECI - Thailand Existing Chemicals Inventory; 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

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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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Silensomes CYP3A4 Control

Manufacturer or supplier's detailsCompany : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, AustraliaLonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR
ANIMAL IN VIVO OR DIAGNOSTIC USE.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURESIf inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical

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	advice. If symptoms persist, call a physician.
In case of skin contact	: Wash with water and soap as a precaution. If on clothes, remove clothes. In the case of skin irritation or allergic reactions see a physician.
In case of eye contact	: Flush eyes with water as a precaution. Remove contact lenses. Keep eye wide open while rinsing. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: Heating or fire can release toxic gas.
Specific extinguishing methods	: Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment.
Environmental precautions	: No special environmental precautions required. Try to prevent the material from entering drains or water courses.
Methods and materials for containment and cleaning up	: Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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SECTION 7. HANDLING AND STORAGE

- | | | |
|---|---|---|
| Advice on protection against fire and explosion | : | Normal measures for preventive fire protection. |
| Advice on safe handling | : | No special precautions required.
For personal protection see section 8. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |
| Conditions for safe storage | : | Keep container tightly closed.
Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight. |
| Materials to avoid | : | No special restrictions on storage with other products. |
| Further information on storage stability | : | No decomposition if stored and applied as directed. |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
In the case of vapour formation use a respirator with an approved filter.

Hand protection

Remarks : Wear protective gloves. Break through time : > 480 min

Eye protection : Safety glasses

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Lightweight protective clothing

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

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Colour	: light brown
Odour	: No data available
Odour Threshold	: No data available
pH	: 6,8 - 7,2
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Flammability (liquids)	: 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
Density	: No data available
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No decomposition if stored and applied as directed.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions.

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No hazards to be specially mentioned.

Conditions to avoid : Heat

Incompatible materials : Oxidizing agents
Strong acids and strong bases

Hazardous decomposition products : No decomposition if used as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available

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Skin corrosion/irritation

Remarks : No data available

Serious eye damage/eye irritation

Remarks : No data available

Respiratory or skin sensitisation

Remarks : No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks : No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks : No data available

STOT - repeated exposure

Remarks : No data available

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish :
Remarks: No data available

Persistence and degradability

Biodegradability : Result: no data available

Bioaccumulative potential

Bioaccumulation : Remarks: No data available

Mobility in soil

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

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Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable

IMDG

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable
Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable
Environmental hazards : no

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RID	:	Not dangerous goods
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Transport hazard class	:	Not applicable
Packing group	:	Not applicable
Environmental hazards	:	no
Special precautions for user	:	none
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	:	Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.04.2024

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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; 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)

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