

SAFETY DATA SHEET



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

Product identifier

NEOSTIGMINE SOLUTION FOR INJECTION (0.5 mg/ml)

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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CAS No. : Not applicable
Use : Cholinesteras inhibitor to increase muscle movement.

2. HAZARDS IDENTIFICATION

This mixture is not classified as hazardous for supply/use according to GHS v 4.0. See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.			
Neostigmine methylsulfate	0,05	51-60-5			
			Hazard class #	Category	Hazard statements #
			Acute toxicity	2	H300
			Skin corrosion/irritation	2	H315
			Serious eye damage/eye irritation	2	H319
			Respiratory sensitisation	1	H334
Specific target organ toxicity - single exposure	3	H335			

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 : Wash skin with soap and water.
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.
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) : -
- Special hazards arising from the substance or mixture : If involved in a fire, it may 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.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses.
- Methods and material for containment and cleaning up : Clear up spillages. Absorb spillages with suitable absorbent material. Wash the spillage area with water.

7. HANDLING AND STORAGE

- Precautions for safe handling : In case of accident, avoid contact with skin and eyes.
- Conditions for safe storage, including any incompatibilities : Keep in a dry, cool place. Protect from light.
- Specific end use(s) : Storage temperature : < 25 °C
Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
No Occupational Exposure Limit Assigned.			

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

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.

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.

Respiratory protection

Use a negative pressure air purifying respirator (half face mask) with filter class Ax if the risk assessment does not support the selection of other protection.

Skin protection

Use protective clothing to protect against direct contact with the liquid if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

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 : aqueous solution
Colour : clear

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 : Stable under normal conditions.

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

Eye Contact : No information available.

Ingestion : May cause similar effects as described under single exposure.(STOT)

Specific Target Organ Toxicity (STOT) : **Single exposure**
Exposure routes: Oral, Dermal, Inhalation
Therapeutic doses may produce nausea, abdominal pain, vomiting, diarrhoea and headache.

Repeated exposure
May cause effects as described under single exposure.(STOT)

Sensitisation : No information available.

Carcinogenicity : No information available.

Mutagenicity : No information available.

Reproductive toxicity : No information available.

12. ECOLOGICAL INFORMATION

The following information refers to active ingredient:

Toxicity : No information available.

Effect on Effluent Treatment : No information available.

Persistence and degradability : No degradation data available. The substance is assumed not to be rapidly degradable.

Bioaccumulative potential : The substance has low potential for bioaccumulation.

Mobility in soil : The substance is soluble in water (relates to the water compartment in the environment).

Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods : Disposal should be in accordance with local, state or national legislation. Dispose of contents/ container to an approved incineration plant. Waste, even small quantities, should never be poured down drains, sewers or water courses.

Contaminated Packaging : Empty container will retain 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

This material and its container must be disposed of as hazardous waste.

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

The following sections contain revisions or new statements :

New significant SHE information:

1. Product identifier
3. Composition/information on ingredients
8. Respiratory protection

Minor changes:, 1, 2, 4, 6, 11, 15

GLOSSARY

COM	:	In-house occupational exposure limit
LTCL	:	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.