

SAFETY DATA SHEET

Product Name: Ilium Syntocin Injection of Synthetic Oxytocin

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This revision issued: April, 2015

Section 1 - Identification of The Material and Supplier

Troy Laboratories Australia Pty. Ltd ABN: 21 000 283 769 Tel: (02) 8808 3600 (office hours) 31-35 Glendenning Road Fax: (02) 9677 9300

Glendenning NSW 2761

Chemical nature: Water solution of ingredients.

Trade Name: Ilium Syntocin Injection of Synthetic Oxytocin

Product Code: 3700

Product Use: Stimulation of uterine contractions; an aid in the control of minor haemorrhage after

birth, and in the removal of retained placenta in horses, cattle, sheep, pigs, dogs and

cats.

Creation Date: September, 2011

This version issued: April, 2015 and is valid for 5 years from this date.

Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Xn, Harmful. Hazardous according to the criteria of SWA Australia.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA and IMDG/IMSBC criteria.

Risk Phrases: R61. May cause harm to the unborn child.

Safety Phrases: S45. In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre

immediately (show the label where possible).

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated



GHS Signal word: WARNING.

HAZARD STATEMENT:

H360: May damage fertility or the unborn child.

PREVENTION

P102: Keep out of reach of children.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P262: Do not get in eyes, on skin, or on clothing.

P281: Use personal protective equipment as required.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P352: Wash with plenty of soap and water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P308+P313: If exposed or concerned: Get medical advice.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P405: Store locked up.

P402+P404: Store in a dry place. Store in a closed container.

P403+P235: Store in a well-ventilated place. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

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Emergency Overview

Physical Description & Colour: Clear, colourless liquid.

Odour: Mild odour.

Major Health Hazards: may cause harm to unborn children. If injected into pregnant women, premature labour

may be induced. IN ALL SUCH CASES, SEEK IMMEDIATE MEDICAL ADVICE.

Potential Health Effects

This product has no pharmacological effect on the human male. However, if injected into pregnant women, premature labour may be induced. **IN ALL SUCH CASES, SEEK IMMEDIATE MEDICAL ADVICE.**

Inhalation

Short Term Exposure: Significant inhalation exposure is considered to be unlikely. Available data indicates that this product is not harmful. However product may be mildly irritating, although unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be mildly irritating, but is unlikely to cause anything more than mild discomfort which should disappear once contact ceases.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: Exposure via eyes is considered to be unlikely. This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed. **Long Term Exposure:** No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA. **NTP:** No significant ingredient is classified as carcinogenic by NTP. **IARC:** No significant ingredient is classified as carcinogenic by IARC.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Oxytocin	50-56-6	10iu/mL	not set	not set
Other non hazardous ingredients	secret	<10	not set	not set
Water	7732-18-5	to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

AS INDICATED ABOVE, IF INJECTED INTO A PREGNANT WOMAN, SEEK IMMEDIATE MEDICAL ADVICE.

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Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes.

Ingestion: If product is swallowed or gets in mouth, wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: Not Combustible. Use extinguishing media suited to burning materials. **Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Does not burn.

Upper Flammability Limit: Does not burn.

Lower Flammability Limit: Does not burn.

Autoignition temperature: Not applicable - does not burn.

Flammability Class: Does not burn.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits TWA (mg/m³) STEL (mg/m³)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: There is no specific recommendation for any particular protective material type.

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Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: Clear, colourless liquid.

Odour: Mild odour.

Boiling Point: Approximately 100°C at 100kPa.

Freezing/Melting Point: Approximately 0°C. Volatiles: Water component.

Vapour Pressure: 2.37 kPa at 20°C (water vapour pressure).

Vapour Density: No data. Specific Gravity: No data.

Water Solubility: Completely soluble in water.

pH: No data.
Volatility: No data.
Odour Threshold: No data.
Evaporation Rate: No data.
Coeff Oil/water Distribution: No data

Autoignition temp: Not applicable - does not burn.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: No particular Incompatibilities.

Fire Decomposition: Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness. Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

This product has no pharmacological effect on the human male. However, if injected into pregnant women, premature labour may be induced. **IN ALL SUCH CASES, SEEK IMMEDIATE MEDICAL ADVICE.**

Classification of Hazardous Ingredients

Ingredient Risk Phrases

No ingredient mentioned in the HSIS database is present in this product at hazardous concentrations.

Section 12 - Ecological Information

Insufficient data to be sure of status.

Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredients: Oxytocin, are mentioned in the SUSMP.

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Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition

AICS Australian Inventory of Chemical Substances
CAS Number Chemical Abstracts Service Registry Number

Hazchem Code Emergency action code of numbers and letters that provide information to emergency

services especially firefighters

IARC International Agency for Research on Cancer
SWA Safe Work Australia, formerly ASCC and NOHSC

NOS Not otherwise specified

NTP National Toxicology Program (USA)

R-Phrase Risk Phrase

SUSMP Standard for the Uniform Scheduling of Medicines & Poisons

UN Number United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous

Chemicals - Code of Practice" (December 2011) Copyright © Kilford & Kilford Pty Ltd, April, 2015. http://www.kilford.com.au/ Phone (02)9251 4532