Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
BOMAC BUTOCIN

SYNONYMS
Product Code: 1370
! 09/01
oxytocin 20iu/ml
20,000USP/Litre
sterile solution for injection

PRODUCT USE
For animal treatment only. To precipitate and accelerate normal parturition and uterine involution. To enhance milk letdown.

SUPPLIER
Company: Bomac Laboratories Ltd
Address:
Cnr. Wiri Station Rd & Hobill Avenue
Manukau City
Auckland,
NZL
Telephone: +64 9 262 3169
Fax: +64 9 262 3008

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to the Criteria of NOHSC, and the ADG Code.

POISONS SCHEDULE
None

RISK

SAFETY

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
oxytocin acetate	50-56-6	0-0.2
preservative		0-1
pH adjuster		0-1
water	7732-18-5	>60

Section 4 - FIRST AID MEASURES

SWALLOWED
- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down

continued...

position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

If this product comes in contact with the eyes:
- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA
- There is no restriction on the type of extinguisher which may be used.

Use extinguishing media suitable for surrounding area.

FIRE FIGHTING
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD
- Non combustible.
- Not considered to be a significant fire risk.
- Expansion or decomposition on heating may lead to violent rupture of containers.
- Decomposes on heating and may produce toxic/ irritating fumes.
- May emit acrid smoke.

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FIRE INCOMPATIBILITY
None known.

HAZCHEM
None

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS
- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Wipe up.
- Place in a suitable labelled container for waste disposal.

MAJOR SPILLS
Minor hazard.
- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact by using protective equipment as required.
- Prevent spillage from entering drains or water ways.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.
- Wash area and prevent runoff into drains or waterways.
- If contamination of drains or waterways occurs, advise emergency services.

EMERGENCY RESPONSE PLANNING GUIDLINES (ERPG)
The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour WITHOUT experiencing or developing

life-threatening health effects is:
water 500 mg/m³

irreversible or other serious effects or symptoms which could impair an individual's ability to take protective action is:
water 500 mg/m³

other than mild, transient adverse effects without perceiving a clearly defined odour is:
water 500 mg/m³

The threshold concentration below which most people. will experience no appreciable risk of health effects:
water 500 mg/m³

American Industrial Hygiene Association (AIHA)

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

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Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

None required when handling small quantities.
OTHERWISE:.
- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- When handling DO NOT eat, drink or smoke.
- Always wash hands with soap and water after handling.
- Avoid physical damage to containers.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.

SUITABLE CONTAINER

50mL multidose vial.

STORAGE INCOMPATIBILITY

Avoid contamination of water, foodstuffs, feed or seed.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

Store below 25 degC.
Shelf Life: 18 months.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

No data available for oxytocin acetate as (CAS: 50-56-6)
No data available for water as (CAS: 7732-18-5)
Not available. Refer to individual constituents.

EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) :93.9261 mg/m³.
Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.
If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.
Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc (%).

Component	Breathing Zone (mg/m³)	Mixture Conc (%)
oxytocin acetate	0.1879	0.2

INGREDIENT DATA

OXYTOCIN ACETATE:
Dusts not otherwise classified, as inspirable dust;
ES TWA: 10 mg/m³.
Particulate (insoluble or poorly soluble *) Not Otherwise Specified (P.N.O.C)

continued...

TLV TWA: 10 mg/m³ Inhalable particulate
TLV TWA: 3 mg/m³ Respirable particulate
OEL-Sweden, United Kingdom: 10 mg/m³ total dust, 5 mg/m³ respirable dust

These "dusts" have little adverse effect on the lungs and do not produce toxic effects or organic disease. Although there is no dust which does not evoke some cellular response at sufficiently high concentrations, the cellular response caused by P.N.O.C.s has the following characteristics:
· the architecture of the air spaces remain intact,
· scar tissue (collagen) is not synthesised to any degree,
· tissue reaction is potentially reversible.
Extensive concentrations of P.N.O.C.s may:
· seriously reduce visibility,
· cause unpleasant deposits in the eyes, ears and nasal passages,
· contribute to skin or mucous membrane injury by chemical or mechanical action, per se, or by the rigorous skin cleansing procedures necessary for their removal. [ACGIH]

This limit does not apply:
· to brief exposures to higher concentrations
· nor does it apply to those substances that may cause physiological impairment at lower concentrations but for which a TLV has as yet to be determined.

This exposure standard applies to particles which
· are insoluble or poorly soluble* in water or, preferably, in aqueous lung fluid (if data is available) and
· have a low toxicity (i.e.. are not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, and do not emit ionizing radiation, cause immune sensitization, or cause toxic effects other than by inflammation or by a mechanism of lung overload)
* Notice of intended change.

WATER:
No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION

EYE

No special equipment for minor exposure i.e. when handling small quantities.
- OTHERWISE:
- Safety glasses with side shields.
- Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them.

HANDS/FEET

No special equipment needed when handling small quantities.
OTHERWISE: Wear chemical protective gloves, eg. PVC.

OTHER

No special equipment needed when handling small quantities.
OTHERWISE:
- Overalls.
- Barrier cream.
- Eyewash unit.

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:
"Forsberg Clothing Performance Index".
The effect(s) of the following substance(s) are taken into account in the

continued...

computer-generated selection: water

Protective Material CPI *.

BUTYL	A
NEOPRENE	A
VITON	A
PVA	C
NATURAL RUBBER	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

RESPIRATOR

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Breathing Zone Level ppm (volume)	Maximum Protection Factor	Half-face Respirator	Full-Face Respirator
1000	10	-AUS P	-
1000	50	-	-AUS P
5000	50	Airline *	-
5000	100	-	-2 P
10000	100	-	-3 P
	100+		Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

None required when handling small quantities.
OTHERWISE:.
General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Colourless, clear liquid with a characteristic odour; mixes with water.

PHYSICAL PROPERTIES

Liquid.

continued...

Mixes with water.

Molecular Weight: Not Applicable
Melting Range (°C): Not Available
Solubility in water (g/L): Miscible
pH (1% solution): Not Available
Volatile Component (%vol): Not Available
Relative Vapour Density (air=1): Not Available
Lower Explosive Limit (%): Not Applicable
Autoignition Temp (°C): Not Applicable
State: Liquid

Boiling Range (°C): Not Available
Specific Gravity (water=1): Not Available
pH (as supplied): Not Available
Vapour Pressure (kPa): Not Available
Evaporation Rate: Not Available
Flash Point (°C): Not Applicable
Upper Explosive Limit (%): Not Applicable
Decomposition Temp (°C): Not Available

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Oxytocin is rapidly absorbed from the mucous membrane when administered bucally.

EYE

Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

Not normally a hazard due to non-volatile nature of product.
The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

continued...

CHRONIC HEALTH EFFECTS

Principal routes of exposure are usually by inadvertent ingestion and skin contact. Excess oxytocin may cause violent uterine contraction leading to rupture and extensive soft issue laceration; maternal and foetal deaths have been reported as a result. Maternal deaths from severe hypertension and subarachnoid hamorrhage have occurred. Water retention and intoxication with convulsions, coma and death may result from long-term intravenous injection. Anaphylactic shock and other allergic reaction, pelvic haematomas may also result from exposure.

TOXICITY AND IRRITATION

MATERIAL	CARCINOGEN	SENSITISER	SKIN	MUTAGEN	REPROTOXIN
Bomac Butocin oxytocin acetate water					

Not available. Refer to individual constituents.
unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

OXYTOCIN ACETATE:

TOXICITY	IRRITATION
Oral (rat) LD50: 20.52 mg/kg	Nil reported
Subcutaneous (rat) LD50: >20.52 mg/kg	
Intravenous (rat) LD50: 2.275 mg/kg	

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

WATER:
No significant acute toxicological data identified in literature search.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

OXYTOCIN ACETATE:

No data for oxytocin acetate.

WATER:

No data for water.

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: Burial in a licenced land-fill or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

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Section 14 - TRANSPORTATION INFORMATION

Shipping Name:
None
Dangerous Goods Class: None, None
UN/NA Number: None
ADR Number: None
Packing Group: None
Labels Required:
Additional Shipping Information:
International Transport Regulations:
IMO: None

HAZCHEM

None

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE

None

REGULATIONS

oxytocin acetate (CAS: 50-56-6) is found on the following regulatory lists:
Australian Inventory of Chemical Substances (AICS)
Australian Poisons Schedule

water (CAS: 7732-18-5) is found on the following regulatory lists:
Australian Inventory of Chemical Substances (AICS)

Section 16 - OTHER INFORMATION

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