
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: Optigentín Antibiotic Ophthalmic Gel

Product Code: 60520

Recommended Use: For the treatment of bacterial infections of the eye, susceptible to gentamicin, in the dog, cat and horse.

Company Identification: Jurox Pty Limited

Address: 85 Gardiner Street
Rutherford NSW 2320
Australia

Email: customerservice@jurox.com.au

Customer Centre: 1800 023 312

National Poisons Information Centre: 131126 (Australia-wide)

Emergency Telephone Number: 1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications: Considered a Hazardous Substance according to the criteria of GHS.
Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

GHS Hazard Classification:*

GHS Category	Hazard code	Hazard Statement
Reproductive Toxicity Category 1B	H360	May damage fertility or the unborn child.

GHS Pictogram:

Health hazard

Signal Word:* DANGER**Precautionary Statements:*****Prevention**

P201 Obtain special instructions before use.
P281 Use personal protective equipment as required.

Response

P308+P313 IF exposed or concerned: Get medical advice/attention.

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/container in accordance with local/national regulations.

* N.B.: These statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Gentamicin sulfate	1405-41-0	<10%
Other non-hazardous components		10 – <30%
Water	7732-18-5	>60%

Section 4: FIRST AID MEASURES

- General information:** Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have product container or label at hand.
- Inhalation:** If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually not necessary.
- Ingestion:** If swallowed, immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
- Skin:** May cause skin rashes in sensitised persons. If skin contact occurs, immediately remove all contaminated clothing, including footwear. Wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.
- Eye:** If eye contact occurs, rinse cautiously with water for at least 20 minutes. If eye irritation persists, get medical advice/attention.
- Advice to Doctor:** Gentamicin is an aminoglycoside antibiotic. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

- Flash Point:** Not flammable.
- Hazardous Combustion Products:** If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.
- Extinguishing Media:** There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
- Protective Equipment:** Protective gloves and boots and breathing apparatus.
- Special Hazards:** Flame Incompatibility: None known.
- HAZCHEM:** None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

- Spills and Disposal:** Slippery when spilt. Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up / absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely.
- Protective Clothing:** For appropriate personal protective equipment see section 8.
- Environmental Precautions:** If contamination of drains and waterways occurs, advise Emergency Services.

Section 7: HANDLING AND STORAGE

- Handling:** Avoid all personal contact, including inhalation. Use personal protective equipment as required.
- Storage:** OptigentIn Antibiotic Ophthalmic Gel is a Scheduled Poison (S4) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Store in original container,

away from foodstuffs. Store below 25°C (air conditioning). Protect from light. Keep out of reach of children.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.

Protective Equipment: Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.

Engineering Controls: Handle in a well ventilated area.

Hygiene Precautions: Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colourless gel.	Vapour Pressure:	No data.
Odour:	No data.	Vapour density:	No data.
Odour threshold:	No data.	Relative density:	Not applicable.
pH:	4.0 -5.0.	Specific Gravity:	~1.01.
Melting Point:	Not applicable.	Solubility in Water:	Soluble.
Boiling Point:	No data.	Partition coefficient:	No data.
Flash Point:	Not flammable.	Auto-ignition temperature:	No data.
Evaporation Rate:	No data.	Decomposition temperature:	Not applicable.
Flammability:	Not applicable.	Viscosity:	No data.
Upper flammability limits:	Not applicable.		
Lower flammability limits:	Not applicable.		

Section 10: STABILITY AND REACTIVITY

Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the labelling

Hazardous Polymerisation: Not known to occur.

Materials to Avoid: None known.

Section 11: TOXICOLOGICAL INFORMATION

Acute toxicity:

Inhalation: Not normally a hazard due to the non-volatile nature of the 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.

Ingestion: 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. Gentamicin is poorly absorbed after oral administration.

Gentamicin sulfate:
LD₅₀ (oral): > 5000mg/kg (rat)

- Skin Irritation/ Corrosion:** The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Gentamicin appears to have a low order of toxicity when applied topically to the skin.
- Serious Eye Damage/ Irritation:** Gentamicin appears to have a low order of toxicity when applied topically to the eye; however, sensitization to the drug may result in some individuals.
- Respiratory or Skin sensitisation:** No data for the mixture is available. Gentamicin appears to have a low order of toxicity when applied topically to the skin; however, sensitization to the drug may result in some individuals.
- Chronic Effects:** May cause allergic reactions, possibly serious in gentamicin sensitive individuals. Long-term exposure to aminoglycoside antibiotics can damage the kidneys.
- STOT** Ototoxicity and nephrotoxicity are the most serious adverse effects of systemic gentamicin administration. Optigent In Antibiotic Ophthalmic Gel is not administered by injection so is unlikely to pose any risk to specific target organs.
- Reproductive Toxicity:** There is some evidence from animal testing that exposure to gentamicin may result in toxic effects to the unborn baby.
- Mutagenicity:** Not known to be mutagenic.
- Carcinogenicity:** Not known to be carcinogenic.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity:

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Gentamicin sulfate	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

- Product Disposal:** Dispose of product only by using according to APVMA approved label or by approved waste collection.
- Container Disposal:** Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

Section 15: REGULATORY INFORMATION

- Poisons Schedule:** S4
- APVMA Registration No:** 36184
- ACIS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Gentamicin, is mentioned in the SUSMP.

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

ADG	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7 th Edition.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
PPE	Personal Protective Equipment.
PVC	Polyvinyl Chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.

References

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Gentamicin sulfate (RN: 1405-41-0).

Environmental Protection Authority, HSNO Chemical Classification and Information Database (CCID), entry for Gentamicin sulphate (CAS No. 1405-41-0).

HSDB <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> Gentamicin (CASRN: 1403-66-3).

THE VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>, entry for Gentamicin.

This version issued: 18 July 2017 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 13 August 2012.

Revision History:

Date of Revision	Reason
18 July 2017	Updates to section 1, 2, 3, 10, 11 & 15; Updates to Legend and addition of Revision History in Section 16.

END OF SDS