

Section 1 - Identification

Alleva Animal Health Ltd
232 Unley Road
Unley SA 5061 AUSTRALIA

Phone: 1800 ALLEVA (1800 255382)

Chemical nature: Injection containing doramectin.
Trade Name: **Doraject Injection**
APVMA Code: 91030
Product Use: Veterinary injection used as antiparasitic and endectocide.
Creation Date: **July, 2022**
This version issued: **July, 2022** 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

SUSMP Classification: S5

ADG Classification: Class 9: Miscellaneous Dangerous Goods.

UN Number: 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.



GHS Signal word: WARNING

Reproductive Toxicity Category 2

Reproductive Toxicity - Effect via lactation

Hazardous to aquatic environment Short term/Chronic Category 1

HAZARD STATEMENT:

H361: Suspected of damaging fertility or the unborn child.

H362: May cause harm to breast-fed children.

H410: Very toxic to aquatic life with long lasting effects.

PREVENTION

P201: Obtain special instructions before use.

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

P260: Do not breathe fumes, mists, vapours or spray.

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

P263: Avoid contact during pregnancy or while nursing.

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

RESPONSE

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

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

P370+P378: In case of fire: Use carbon dioxide, dry chemical, foam, to extinguish.

STORAGE

P410: Protect from sunlight.

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.

Emergency Overview

Physical Description & Colour: Colourless to pale yellow liquid.

Odour: Characteristic odour.

Section 3 – Composition and Information on Ingredients

Ingredients	CAS No	Conc, %	TWA (mg/m ³)	STEL (mg/m ³)
Doramectin	117704-25-3	1	not set	not set

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Sesame oil	8008-74-0	-	not set	not set
Ethyl oleate	111-62-6	-	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 SWA 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 may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated 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 liquid. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

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. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting. 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: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is little risk of an explosion from this product if commercial quantities are involved in a fire.

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

Extinguishing Media: In case of fire, use carbon dioxide, dry chemical or foam. Alcohol resistant foam is the preferred firefighting medium but, if it is not available, normal foam can be used. Try to contain spills, minimise spillage entering drains or water courses.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade. There is little danger of a violent reaction or explosion if significant quantities of this product are involved in a fire. Recommended personal protective equipment is full fire kit and breathing apparatus.

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. Take special care if handling this product over extended periods as it is a cumulative poison.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. 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:

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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.

The ADI for Doramectin is set at 0.002mg/kg/day. The corresponding NOEL is set at 0.1mg/kg/day. ADI means Acceptable Daily Intake

NOEL means No-observable-effect-level. Data from Australian ADI List, March 2017.

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: This product should only be used where there is ventilation that is adequate to keep exposure below the TWA levels. If necessary, use a fan.

Eye Protection: Eye protection such as protective glasses or goggles is recommended when this product is being used.

Skin Protection: You should avoid contact even with mild skin irritants. Therefore you should wear suitable impervious elbow-length gloves and facial protection when handling this product for lengthy periods. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber, PVC, nitrile.

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:	Colourless to pale yellow liquid.
Odour:	Characteristic odour.
Freezing/Melting Point:	No specific data. Liquid at normal temperatures.
Boiling Point:	Not available.
Flash point:	Not flammable.
Upper Flammability Limit:	No data.
Lower Flammability Limit:	No data.
Flammability Class:	No data.
Volatiles:	No data.
Vapour Pressure:	No data.
Vapour Density:	No data.
Specific Gravity:	No data.
Water Solubility:	No data.
pH:	No data.
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	No data.
Coeff Oil/water Distribution:	No data
Particle Characteristics:	Not applicable for liquids.
Autoignition temp:	No data.

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: strong acids, strong bases, oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. 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.

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Section 11 - Toxicological Information

Toxicity: Short-term administration of doramectin in the diet to mice was associated with clinical signs of neurotoxicity, and there was evidence of minor toxic effects on the liver and kidney at and above doses of 100 mg/kg bw/day. Clinical signs of doramectin toxicity were similar in both mice and rats, the most common being decreased activity and respiration, hunched position, shakiness, weakness, tremors, ataxia and weight loss.

Slightly irritating to skin and eyes of rabbits.

LD₅₀ Oral (Rat, male) 1000-2000mg/kg (in aqueous solution) or 500-1000mg/kg in sesame oil.

LD₅₀ Oral (Rat, female) 50-100mg/kg (in aqueous solution) or 100-200mg/kg in sesame oil.

Doramectin is orally active against parasites in cattle in doses of 200(g/kg. In 90 day safety evaluation studies, the no observed effect level was 0.1mg/kg/day in dogs. Mydriasis was noted at higher doses and anorexia, tremors and ataxia occurred at 2mg/kg/day. The NOEL in rats after 90 days was 2mg/kg/day. There was no evidence of mutagenic potential in a standard battery of tests for genetic toxicity. In a multi generation study in rats, the NOEL was 0.3mg/kg/day. Doramectin was not teratogenic in rats and mice at levels up to 6.0mg/kg/day or in rabbits at doses up to 0.75mg/kg/day. Development abnormalities were seen in rabbits at 3.0mg/kg/day, a level that was also maternally toxic. There is no data to hand indicating any particular target organs.

Major Health Hazards: Clinical signs of doramectin toxicity were similar in both mice and rats, the most common being decreased activity and respiration, hunched position, shakiness, weakness, tremors, ataxia and weight loss. suspected of damaging fertility or the unborn child, may cause harm to breast-fed children. This product is a cumulative poison. Minor exposures over a period of time may lead to serious health problems.

Classification of Hazardous Ingredients

Ingredient

Health Hazard Statement Codes

No ingredient mentioned in the HCIS Database is present in this product at hazardous concentrations.

Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

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 irritating, but is unlikely to cause anything more than mild transient discomfort.

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

Eye Contact:

Short Term Exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

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 irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

Long Term Exposure: Long term minor exposures to this product may cause serious health effects.

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 12 - Ecological Information

This product is very toxic to aquatic life with long lasting effects. This product is not readily biodegradable; it may accumulate in the soil or water and cause long term problems.

Doramectin is extremely toxic to aquatic species. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.

Section 13 - Disposal Considerations

Disposal: You should not attempt to reclaim or recycle this product. We suggest that, subject to the regulations in your area, this product should be disposed by controlled incineration, or in landfill. Dispose of empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and

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appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

Not subject to the ADG Code when transported by Road or Rail in Australia, in packages 500kg(L) or less; or IBCs, but classed as Dangerous by IATA and IMDG/IMSBC when carried by Air or Sea transport (see details below).

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Hazchem Code: •3Z

Special Provisions: 179, 274, 331, 335, AU01

Limited quantities: ADG 7 specifies a Limited Quantity value of 5 L for this class of product.

Dangerous Goods Class: Class 9: Miscellaneous Dangerous Goods.

Packing Group: III

Packing Instruction: P001, IBC03, LP01

Class 9 Miscellaneous Dangerous Goods shall not be loaded in the same vehicle or packed in the same freight container with Dangerous Goods of Class 1 (Explosives).

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with AICIS regulations.

The following ingredient: Doramectin, is mentioned in the SUSMP.

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 (7 th edition)
AICS/AIIC	Australian Inventory of Industrial Chemicals
SWA	Safe Work Australia, formerly ASCC and NOHSC
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
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
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" (July 2020) and GHS Revision 7

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