

LEVAMOX DUO POUR-ON FOR CATTLE

Abbey Animal Health Pty Ltd SAFETY DATA SHEET

Section 1- Identification of Product and Supplier

Supplier Company Details: Abbey Animal Health Pty Ltd **Address:** Unit 27/ 1 Maitland place, Norwest NSW, 2153

Telephone Number: 02 8088 0720 **Facsimile Number:** 02 8088 0721

Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour service).

PRODUCT NAME

LEVAMOX DUO POUR-ON FOR CATTLE

PRODUCT USE

Levamox Duo is an endoparasiticide with efficacy in treating and controlling gastrointestinal

parasites in cattle.

Section 2- Hazards Identification

Statement of Hazardous Nature this product is classified as: Hazardous according to the criteria of SWA.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code criteria when transported by road or rail. Refer to Section 14.

GHS Signal word: WARNING

GHS Classification

Acute Toxicity (Dermal) Category 4
Skin Corrosion/Irritation Category 2
Serious Eye Damage/Eye Irritation Category 2A
Hazardous to the Aquatic Environment Acute Hazard Category 3
Hazardous to the Aquatic Environment Long-Term Hazard Category 3
Acute Toxicity (Oral) Category 4

Hazard pictograms





HAZARD STATEMENTS

H302: Harmful if swallowed

H312: Harmful in contact with skin.

H315: Causes skin irritation

H319: Causes serious eye irritation

H412: Harmful to aquatic life with long lasting effects.

PREVENTION

P264: Wash exposed areas thoroughly after handling.

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

P273: Avoid release to the environment.

P280: Wear protective gloves, protective clothing and eye or face protection.

RESPONSE

P301 + P312: IF SWALLOWED: Immediately call a POISON CENTER or doctor if you feel unwell.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

P337+P313: If eye irritation persists: Get medical advice.

P330: Rinse mouth.

P332+P313: If skin irritation occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE

P405: Store locked up.

DISPOSAL

P501: If they cannot be recycled, dispose of contents to an approved waste disposal plant and containers to landfill.

Section 3- Composition / Information on Ingredients

| Ingredients | CAS No | Conc g/L | TWA (mg/m³) | STEL (mg/m ³) |
|--------------------------------------|-------------|----------|-------------|---------------------------|
| Levamisole hydrochloride | 16595-80-5 | 200 | not set | not set |
| Moxidectin | 113507-06-5 | 10 | not set | not set |
| Diethylene glycol monobutyl ether | 112-34-5 | 188 | 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.

Section 4- First Aid Measures

Call Poisons Information Centre Phone Australia 131 126, if you feel that you may have been poisoned or irritated by this product.

Inhalation: No first aid measures normally required. However, if inhalation has occurred, and irritation has developed, remove to fresh air and observe until recovered. If irritation becomes painful or persists more than about 30 minutes, seek medical advice.

Skin Contact: Quickly and gently brush away excess particles. Wash gently and thoroughly with warm water (use non-abrasive soap if necessary) for 10-20 minutes or until product is removed. Under running water, remove contaminated clothing, shoes and leather goods (e.g. watchbands and belts) and completely decontaminate them before reuse or discard. If irritation persists, repeat flushing and seek medical attention.

Eye Contact: Quickly and gently brush particles from eyes. Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes or until the product is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately. 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 no risk of an explosion from this product under normal circumstances if it is involved in a fire.

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

Extinguishing Media: Foam, Dry chemical powder, BCF (where regulations permit), Carbon dioxide, Water spray or fog - Large fires only

Fire Fighting: If a significant quantity of this product is involved in a fire, call the

fire brigade.

Flash point: Combustible solid.

Upper Flammability Limit:No data.Lower Flammability Limit:No data.Autoignition temperature:No data.

Flammability Class: Combustible solid for which no flammability class applies

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Section 6 - Accidental Release Measures

Methods and material for containment and cleaning up

Minor Spills: Remove all ignition sources. Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, 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: Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. No smoking, naked lights or ignition sources. Increase ventilation. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. If contamination of drains or waterways occurs, advise emergency services.

Section 7 - Handling and Storage

Safe handling: DO NOT allow clothing wet with material to stay in contact with skin. The tendency of many ethers to form explosive peroxides is well documented. Ethers lacking non-methyl hydrogen atoms adjacent to the ether link are thought to be relatively safe. DO NOT concentrate by evaporation, or evaporate extracts to dryness, as residues may contain explosive peroxides with DETONATION potential. Any static discharge is also a source of hazard.

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. Store packages of this product in a cool place. Make sure that containers of this product are kept tightly closed. Keep containers dry and away from water. Protect this product from light. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls / 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**.

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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 Levamisole hydrochloride is set at 0.003 mg/kg/day and NOEL is set at 6 mg/kg/day.

The ADI for Moxidectin is set at 0.01 mg/kg/day and NOEL is set at 1 mg/kg/day.

ADI means Acceptable Daily Intake; NOEL means No-observable-effect-level. Data from Australian ADI List, June 2022.

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 in a well-ventilated area. If natural ventilation is inadequate, use of a fan is suggested.

Eye Protection: Protective glasses or goggles should be worn when this product is being used. Failure to protect your eyes may cause them harm. Emergency eye wash facilities are also recommended in an area close to where this product is being used.

Skin Protection: If you believe you may have a sensitisation to this product or any of its declared ingredients, you should prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

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

Respirator: As this product is classed as a respiratory sensitiser, special care should be taken with respiratory selection if you are sensitised to this product or any of its declared ingredients. If there is a significant chance that dust is likely to build up in the area where this product is being used, we recommend that you use a suitable dust mask. Otherwise, not normally necessary.

Eyebaths or eyewash stations and safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Section 9 - Physical and Chemical Properties

Physical Description & colour: Liquid

Odour: Not available
Boiling Point: Not available
Freezing/Melting Point: Not available

Volatiles:No dataVapour Pressure:No dataVapour Density:Not available

Specific Gravity: Not available

Water Solubility: Miscible with water

pH: No dataVolatility: No dataOdour Threshold: No data

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Aluminium, Glycols and their ethers undergo violent decomposition in

contact with 70% perchloric acid, oxidising agents

Section 11 - Toxicological Information

Local Effects

Target Organs: There is no data to hand indicating any particular target organs.

Potential Health Effects

Inhalation:

Short Term Exposure: Classified as a potential sensitiser by inhalation. Exposure to a sensitiser, once sensitisation has occurred, may manifest itself as an asthmatic condition, and in some individuals this reaction can be extremely severe. In addition product may be mildly irritating, although unlikely to cause anything more than mild transient discomfort. One case report describes kidney and liver damage in two people working in a closed room with paint containing diethylene glycol monobutyl ether and at the same time consuming large quantities of alcoholic beverages. It has as yet not been established whether the glycol ether and alcohol have synergistic effects but it is possible that oxidation and elimination of both substances probably involves alcohol dehydrogenases; competitive inhibition would be the result

Long Term Exposure: Long term inhalation of high amounts of any nuisance dust may overload lung clearance mechanism. No data for health effects associated with long term inhalation.

Ingestion:

Short Term Exposure: Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. Cyanosis, rapid breathing and heart beat, low blood pressure, muscle tenderness and unconsciousness may follow ingestion of diethylene glycol monobutyl ether. Swallowing large or repeated doses may affect kidney function..

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

Skin Contact:

Short Term Exposure: Classified as a potential sensitiser by skin contact. Exposure to a skin sensitiser, once sensitisation has occurred, may manifest itself as skin rash or inflammation, and in some individuals this reaction can be severe. Examine the skin prior to the use of the material and

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ensure that any external damage is suitably protected. There are indications that diethylene glycol monobutyl ether is absorbed through intact skin. Toxic effects only occur at very high doses.

Long Term ExposureLimited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. .

| INGREDIENT | TOXICITY | IRRITATION | |
|-----------------------------|------------------------------|---------------------------------|--|
| Levamisole hydrochloride | Oral(Rat) LD50; 180 mg/kg | Not Available | |
| Moxidectin | Dermal (rabbit) LD50: >2000 | Eye (rabbit): slight irritant * | |
| | mg/kg | | |
| | Oral(Mouse) LD50; 42 mg/kg | Skin (rabbit): non-irritant * | |
| Diethylene glycol monobutyl | dermal (guinea pig) LD50: | Eye (rabbit): 20 mg/24h | |
| ether | 1920 mg/kg | moderate | |
| | Oral(Guinea) LD50; 1720-2310 | Eye (rabbit): 5 mg - SEVERE | |
| | mg/kg | | |

Acute toxicity: There are adequate oral, inhalation and/or dermal toxicity studies on the category members. Oral LD50 values in rats for all category members are all > 3000 mg/kg bw, with values generally decreasing with increasing molecular weight. Four to eight hour acute inhalation toxicity studies were conducted for all category members except DGPE in rats at the highest vapour concentrations achievable. No lethality was observed for any of these materials under these conditions. Dermal LD50 values in rabbits range from 2000 mg/kg bw (DGHE) to 15000 mg/kg bw (DGEEA). Signs of acute toxicity in rodents are consistent with non-specific CNS depression typical of organic solvents in general. All category members are slightly irritating to skin and slightly to moderately irritating to eyes (with the exception of DGHE, which is highly irritating to eyes). Sensitisation tests with DGEE, DGEEA, DGPE, DGBE and DGBEA in animals and/or humans were negative. Repeat dose toxicity: Valid oral studies conducted using DGEE, DGPE, DGBEA, DGHE and the supporting chemical DGBE ranged in duration from 30 days to 2 years. Effects predominantly included kidney and liver toxicity, absolute and/or relative changes in organ weights, and some changes in haematological parameters. All effects were seen at doses greater than 800-1000 mg/kg bw/day from oral or dermal studies; no systemic effects were observed in inhalation studies with less than continuous exposure regimens.

Mutagenicity: DGEE, DGEEA, DGBE, DGBEA and DGHE generally tested negative for mutagenicity in *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and DGBEA tested negative in E. coli WP2uvrA, with and without metabolic activation. *In vitro* cytogenicity and sister chromatid exchange assays with DGBE and DGHE in Chinese Hamster Ovary Cells with and without metabolic activation and *in vivo* micronucleus or cytogenicity tests with DGEE, DGBE and DGHE in rats and mice were negative, indicating that these diethylene glycol ethers are not likely to be genotoxic.

Reproductive and developmental toxicity: Reliable reproductive toxicity studies on DGEE, DGBE and DGHE show no effect on fertility at the highest oral doses tested (4,400 mg/kg/day for DGEE in the mouse and 1,000 mg/kg/day for DGBE and DGHE in the rat). The dermal NOAEL for reproductive toxicity in rats administered DGBE also was the highest dose tested (2,000 mg/kg/day). Although decreased sperm motility was noted in F1 mice treated with 4,400 mg/kg/day DGEE in

drinking water for 14 weeks, sperm concentrations and morphology, histopathology of the testes and fertility were not affected. Results of the majority of adequate repeated dose toxicity studies in which reproductive organs were examined indicate that DGPE and DGBEA do not cause toxicity to reproductive organs (including the testes). Test material-related testicular toxicity was not noted in the majority of the studies with DGEE or DGEEA.

Results of the developmental toxicity studies conducted with DGEE, DGBE and DGHE are almost exclusively negative. In these studies, effects on the foetus are generally not observed (even at concentrations that produced maternal toxicity). Exposure to 102 ppm (560 mg/m3) DGEE by inhalation (maximal achievable vapour concentration) or 1385 mg/kg/day DGEE by the dermal route during gestation did not cause maternal or developmental toxicity in the rat. Maternal toxicity and teratogenesis were not observed in rabbits receiving up to 1000 mg/kg/day DGBE by the dermal route during gestation; however a transient decrease in body weight was observed, which reversed by Day 21 In the mouse, the only concentration of DGEE tested (3500 mg/kg/day by gavage) caused maternal, but no foetal toxicity. Also, whereas oral administration of 2050mg/kg/day DGBE (gavage) to the mouse and 1000 mg/kg/day DGHE (dietary) caused maternal toxicity, these doses had no effect on the developing foetus.

Section 12 - Ecological Information

Toxicity:

| Ingredient | Endpoint | Test | Species | Value | Source |
|---------------|---------------|---------------|---------------|---------------|---------------|
| | | Duration (hr) | | | |
| Levamisole | Not Available |
| hydrochloride | | | | | |
| Moxidectin | Not Available |
| Diethylene | LC50 | 96h | Fish | 1300mg/l | 2 |
| glycol | EC50 | 72h | Algae or | 1101mg/l | 2 |
| monobutyl | | | other aquatic | | |
| ether | | | plants | | |
| | EC50 | 48h | Crustacea | >100mg/l | 1 |
| | NOEC(ECx) | 96h | Algae or | >=100mg/l | 1 |
| | | | other aquatic | | |
| | | | plants | | |
| | EC50 | 96h | Algae or | >100mg/l | 1 |
| | | | other aquatic | | |
| | | | plants | | |

Persistence and degradability

| Ingredient | Water/Soil | Air |
|-----------------------------------|------------|------|
| Levamisole hydrochloride | HIGH | HIGH |
| Diethylene glycol monobutyl ether | LOW | LOW |

Bioaccumulative potential

Levamisole hydrochloride: LOW (LogKOW=1.84) Diethylene glycol monobutyl ether: LOW (BCF=0.46)

Mobility in soil:

Levamisole hydrochloride: LOW (KOC=8652)
Diethylene glycol monobutyl ether: LOW (KOC=10)

Section 13 - Disposal Considerations

For containers 1L or less: Dispose of container by wrapping with paper and putting in garbage. For containers greater then 1L: Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. Do not dispose of undiluted chemicals onsite. If recycling, replace cap and return clean container to recycler or designated collection point. If the container has the drumMUSTER logo visible, and has been thoroughly cleaned and dried, and is free of any visible residues, it can be recycled at any drumMUSTER collection or similar container management program site. The cap should not be replaced but may be recycled separately with the container. If not recycling, break, crush, or puncture container and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the broken, crushed or punctured containers 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

Section 14 - Transport Information

No specific transport considerations apply since *LEVAMOX DUO POUR-ON FOR CATTLE* is NOT classified as a dangerous good according to Australian Dangerous Goods (ADG) Code.

Section 15 - Regulatory Information

Poisons Schedule: 6

APVMA Approval Number: 93688

Approved pack size: 500mL, 1L, 2L, 2.5L, 5L, 7L (5L+2L), 10L, 15L

For more information, please refer to the APVMA approved product label

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Section 16 – Other Information

Abbey Animal Health Pty Ltd

Telephone Number: 02 8088 0720 Facsimile Number: 02 8088 0721

Emergency Number: Australian Poisons Information Centre: 13 11 26 (24 Hour service).

This Safety Data Sheet (SDS) summary 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 MSDS 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.

*Note: This SDS is valid for 5 years from the effective date.

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