

PERMIT TO ALLOW SUPPLY AND EMERGENCY USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT FOR CONTROL OF VARROA MITES IN BEE HIVES

PERMIT NUMBER - PER94609

This permit is issued to the Permit Holder in response to an application granted by the APVMA under section 112 of the Agvet Codes of the jurisdictions set out below. This permit allows a Supplier (as indicated) to possess the product for the purposes of supply and to supply the product to a person who can use the product under permit. This permit also allows a person, as stipulated below, to use the product in the manner specified in this permit in the designated jurisdictions. This permit also allows the Permit Holder, the Supplier (if not one and the same) and any person stipulated below to claim that the product can be used in the manner specified in this permit.

THIS PERMIT IS IN FORCE FROM 11 NOVEMBER 2024 TO 30 SEPTEMBER 2025

Permit Holder:

NSW DEPARTMENT OF PRIMARY INDUSTRIES 105 Prince Street ORANGE NSW 2800

Supplier:

NSW DEPARTMENT OF PRIMARY INDUSTRIES 105 Prince Street ORANGE NSW 2800

ACT ENVIRONMENT, PLANNING AND SUSTAINABLE DEVELOPMENT DIRECTORATE – ENVIRONMENT 480 Northbourne Avenue DICKSON ACT 2602

AGRICULTURE VICTORIA 475 Mickleham Road ATTWOOD VIC 3049

BIOSECURITY QUEENSLAND Level 3C East, Ecosciences Precinct, 41 Boggo Road DUTTON PARK QLD 4102

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Commercial suppliers in all states except TAS, for supply for use in the jurisdictions where use is approved.

Note: As these products are unregistered, an import consent must be requested, and must be in place with the APVMA for each supplier importing product from any overseas country, including New Zealand. This is in addition to any other relevant import permits from other Australian Government Departments.

Persons who can use the product under this permit:

Persons generally, within the designated jurisdictions.

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CONDITIONS OF USE

Products to be used:

API-BIOXAL SOLUTION

AN UNREGISTERED PRODUCT

Containing: 62 g/L OXALIC ACID DIHYDRATE as the only active constituent.

API-BIOXAL POWDER

AN UNREGISTERED PRODUCT

Containing: 886 g/kg OXALIC ACID DIHYDRATE as the only active constituent.

RESTRAINT:

For in-hive use only.

Only to be handled in a well-ventilated area.

Apply only when monitoring indicates treatment is required. Consult State/Territory guidelines and/or experts for monitoring protocols and thresholds for treatment.

DO NOT mix or use simultaneously with other veterinary products, including miticides.

Directions for Use:

Host	Pest	Rate
European honeybees (Apis mellifera)	Varroa mites (Varroa destructor)	Liquid application (Api-Bioxal Powder prepared as a solution, or Api-Bioxal Solution): 5 mL per frame full of bees, up to a maximum dose of 50 mL per hive, administered using a syringe.
		Vaporization application (Api-Bioxal Powder, only): 2.3 g dose of powder per hive, administered via vaporisation.

Critical Use Comments:

- Apply when monitoring indicates that varroa infestations reach or exceed economic treatment thresholds.
- Oxalic acid may be applied in the presence of brood, however, it is expected that there will be a reduction in the efficacy of the products.
- Oxalic acid may be applied when supers are in place.
- Treatment using either method may be repeated up to twice annually, with a minimum interval of 5 days between applications.
 - The toxicity associated with repeated vaporization treatments for bees has not been fully evaluated.
- For further directions, including preparation of the liquid for trickling, or how to use the vaporization application, refer to the relevant product label at **Attachment 1** or **Attachment 2**.

Withholding Period:

Honey: Zero (0) days.

Jurisdiction:

NSW, ACT, VIC and QLD only.

Additional Conditions:

This permit allows for the use of a product in a manner specified on the permit. Persons who wish to prepare for use and/or use products for the purposes specified in this permit must read, or have read to them, the details and conditions of this permit. Unless otherwise stated, the use of the product must be in accordance with the appropriate product label at **Attachment 1** or **Attachment 2**.

Note: The permit over-rides any label statement where there appears to be a conflict in conditions or instructions.

The holder of the permit must notify the APVMA of new information, including relevant information in accordance with section 161 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, in accordance with the obligation imposed by that section.

Supply

The supplier must supply the product in a container that complies with the requirements of section 18 of the Agricultural and Veterinary Chemicals Code Regulations. Attached to this container must be a label which addresses the requirements of the Veterinary Labelling Code, and contains the information included at **Attachment 1** or **Attachment 2**.

Record keeping

Maintain records of all treatments performed under this permit. Details must include the date and locations where treatments occurred, the total amount of product used, and the names and addresses of the persons undertaking the use. These details must be maintained for a minimum period of two years from the date of expiry of this permit, and must be made available to the APVMA or state authorised officials upon request.

Reporting

Users must record any adverse experience associated with the use of the product and report them to the APVMA as soon as possible, ph. 1800 700 583 or aerp@apvma.gov.au.

Issued by the Australian Pesticides and Veterinary Medicines Authority

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POISON

KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING AND USE FOR ANIMAL TREATMENT ONLY

API-BIOXAL SOLUTION

ACTIVE CONSTITUENT: Active constituent: 44.2 mg/mL oxalic acid beehive solution (equivalent 62.0 mg/mL oxalic acid dihydrate)

Excipients - glycerol, purified water.

For the control of Varroa mites in beehives.

<<500 mL>> or <<5 L>>

Api-Bioxal contains oxalic acid for the treatment of varroosis caused by parasitic mites (Varroa destructor) in honeybees (Apis mellifera). Ready-to-use solution.

DIRECTIONS FOR USE

Restraints:

For in-hive use only.

Only to be handled in a well-ventilated area.

Apply only when monitoring indicates treatment is required. Consult State/Territory guidelines and/or experts for monitoring protocols and thresholds for treatment.

DO NOT mix or use simultaneously with other veterinary products, including miticides.

Precautions: Use strictly in accordance with the label directions. Do not use simultaneously with other acaricides.

All colonies in the same apiary should be treated simultaneously to avoid reinfestations. Avoid disturbance to the hives during the days after the treatment.

For greatest efficacy, the product should only be used when the quantity of brood in the colony is non-existent or at its lowest levels. Oxalic acid does not penetrate wax so will not kill mites within capped brood and therefore the presence of brood may noticeably reduce the efficacy of the product. The product should be used in winter or following manipulation of the colony to produce a broodless state in summer (e.g. by queen caging) with a caging period of at least 25 days.

Even with treatment, seriously damaged colonies may not survive due to the effects of varroa infestation.

Resistance management: Use strictly in accordance with label directions to minimise the risk of the development of strains of mites resistant to oxalic acid from intensive use of Api-Bioxal. It is recommended to use products of other chemical groups for treatment in the spring.

Side effects: Slight agitation is very commonly observed (more than 1 in 10 colonies) during treatment with the product. Increased adult bee mortality is very commonly observed (more than 1 in 10 colonies) after treatment with the product.

Attachment 1: Api-bioxal Solution label

Dosage and administration: Supplied as ready-to-use solution. Single 5mL application per beehive frame, administered using a syringe. Maximal dose 50 ml per beehive. Up to two treatments per year (winter and/or spring-summer season in brood-free colonies). DO NOT overdose.

Method of application: Using a syringe, make a single application by trickling the Api-Bioxal solution between frames covered by bees at a rate of 5 mL per frame full of bees.

Timing: Treat hives ideally in the autumn/early winter period after honey supers have been removed (i.e. surplus honey has been removed from the hive) when little or no brood is present. The presence of brood may reduce the effectiveness of the control of the Varroa mite. A repeat application may cause bee mortality or reduce colony build up in the following spring.

Integrated Pest Management Program: Efficacy may vary between colonies due to the conditions of use (residue presence of brood, temperature, reinfestations etc.). The product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite levels regularly monitored.

WITHHOLDING PERIOD:

Honey: Zero (0) days.

SAFETY DIRECTIONS:

Warning Statements:

May cause allergy (contact dermatitis).

Hazards:

Harmful if swallowed. Will irritate the nose and throat. Will damage eyes and skin.

Precautions:

Avoid contact with eyes and skin. Do not inhale dust or vapour.

Mixing and using instructions:

When opening the container, preparing and using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), gauntlet-length chemical resistant gloves and goggles.

After Use:

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles, and contaminated clothing.

Re-entry or Re-handling Statement:

DO NOT perform clean-up or other hive maintenance activities (including harvesting honey) until 48 hours after treatment, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves and goggles.

Clothing must be laundered after each day's use.

FIRST AID INSTRUCTIONS: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26. If swallowed, do NOT induce vomiting. If skin contact occurs, remove contaminated clothing and wash skin thoroughly. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

ADDITIONAL USER SAFETY: Additional information is listed in the safety data sheet (SDS) available from the Australian Distributor.

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Attachment 1: Api-bioxal Solution label

ENVIRONMENTAL PROTECTION: DO NOT contaminate wetlands or watercourses with this product or used containers. ECOTOXIC. Toxic to terrestrial and aquatic life. Chemical not to be applied onto or into water.

DISPOSAL:

500 mL (<1 L) bottles:

Dispose of unused product or container by wrapping with paper and putting in garbage.

5 L HDPE/LDPE containers:

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 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 at the drumMUSTER collection site. 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.

STORAGE: Do not refrigerate or freeze. Store locked up, in the original sealed package, in a cool, dry place, out of direct sunlight and away from foodstuffs and stockfeed. Keep out of reach of children. Do not use after the expiry date stated on the label. Shelf life after first opening the container: 12 months.

Marketing Authorization Holder:

CHEMICALS LAIF SPA Viale dell'Artigianato 13, 35010 Vigonza (PD), Italy.

Distributed by:

iWOOHOO PTY LTD Unit 1A, 1 Swaffham Rd, Minto NSW 2566, Australia. Ph: 02 9731 7400 www.beekeeping.iwoohoo.com.au

Manufactured by:

CHEMIFARMA SPA Via Don Eugenio Servadei 16, 47122 Forlì (FC), Italy.

APVMA Permit No: PER94609

Expiry Date: <<Month/Year>>
Batch No: <<Enter Batch No>>

Attachment 2: Api-bioxal Powder label

POISON

KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING AND USE FOR ANIMAL TREATMENT ONLY

API-BIOXAL POWDER (TM)

ACTIVE CONSTITUENT: 886 mg/g oxalic acid dihydrate as a soluble powder (equivalent 632.70 mg of oxalic acid)

For the control of Varroa mites in beehives.

<<35 g>> or <<175 g>> or <<350 g>>

Api-Bioxal contains oxalic acid for the treatment of varroosis caused by parasitic mites (Varroa destructor) in honeybees (Apis mellifera). A water-soluble formulation suitable for dissolving in a sugar syrup solution.

DIRECTIONS FOR USE

Restraints:

For in-hive use only.

Only to be handled in a well-ventilated area.

Apply only when monitoring indicates treatment is required. Consult State/Territory guidelines and/or experts for monitoring protocols and thresholds for treatment.

DO NOT mix or use simultaneously with other veterinary products, including miticides.

Precautions: Use strictly in accordance with the label directions. Do not use simultaneously with other acaricides.

All colonies in the same apiary should be treated simultaneously to avoid reinfestations. Avoid disturbance to the hives during the days after the treatment.

For greatest efficacy, the product should only be used when the quantity of brood in the colony is non-existent or at its lowest levels. Oxalic acid does not penetrate wax so will not kill mites within capped brood and therefore the presence of brood may noticeably reduce the efficacy of the product. The product should be used in winter or following manipulation of the colony to produce a broodless state in summer (e.g. by queen caging) with a caging period of at least 25 days.

Even with treatment, seriously damaged colonies may not survive due to the effects of varroa infestation.

Resistance management: Use strictly in accordance with label directions to minimise the risk of the development of strains of mites resistant to oxalic acid from intensive use of Api-Bioxal. It is recommended to use products of other chemical groups for treatment in the spring.

Side effects: Slight agitation is very commonly observed (more than 1 in 10 colonies) during treatment with the product. Increased adult bee mortality is very commonly observed (more than 1 in 10 colonies) after treatment with the product.

METHOD BY TRICKLING:

Dosage and administration: Single 5mL application per beehive frame, administered using a syringe. Maximal dose 50 ml per beehive. Up to two treatments per year (winter and/or spring-summer season in brood-free colonies). DO NOT overdose.

Attachment 2: Api-bioxal Powder label

Mixing directions: Prepare sugar syrup solution (1:1 ratio of water and sucrose) at the concentration of 35 g Api-Bioxal in 500 mL of syrup <<or 175 g in 2.5 litres syrup>> or 350 g in 5 litres syrup>>. Open the corresponding sachet containing the powder. Dissolve the powder in the prepared solution and mix until dissolved. Shelf life 24 hours after reconstitution.

Method of application: Using a syringe, make a single application by trickling the Api-Bioxal sugar syrup between frames covered by bees, at a rate of 5 mL per frame full of bees.

METHOD BY VAPORISATION:

Dosage and administration: Single 2.3g dose administered via vaporisation per beehive. One treatment per year. DO NOT overdose.

Method of application: Use an electric resistance device for vaporisation. Follow the manufacturer instructions in order to achieve maximum sublimation. Fill the pan of the vaporiser with 2.3 g powder. Place the appliance through the entrance of the hive under the bees, avoiding contact with the frames. Seal the entrance of the hive and any other ventilation points (e.g. screened bottom boards) to avoid escape of the bees and smoke. Turn on the vaporiser following the manufacturer's instructions for about 3 minutes and keep the hive shut for another 15 minutes. Cool down and clean the vaporiser after use to remove possible residue (max 6%, around 0.140 g). Use drinkable water for cooling and/or cleaning.

Timing: Treat hives ideally in the autumn/early winter period after honey supers have been removed (i.e. surplus honey has been removed from the hive) when little or no brood is present. The presence of brood may reduce the effectiveness of the control of the Varroa mite. A repeat application may cause bee mortality or reduce colony build up in the following spring.

Integrated Pest Management Program: Efficacy may vary between colonies due to the conditions of use (residue presence of brood, temperature, reinfestations etc.). The product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite levels regularly monitored.

WITHHOLDING PERIOD:

Honey: Zero (0) days.

SAFETY DIRECTIONS:

Warning Statements:

May cause allergy (contact dermatitis).

Hazards:

Harmful if swallowed. Will irritate the nose and throat. Will damage eyes and skin.

Precautions:

Avoid contact with eyes and skin. Do not inhale dust or vapour.

Mixing and using instructions:

When opening the container, preparing and using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), gauntlet-length chemical resistant gloves and goggles. In addition, if applying by the vaporisation method, wear a half facepiece respirator with combined particulate and acid gas cartridge.

After Use:

Attachment 2: Api-bioxal Powder label

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles, respirator and contaminated clothing.

Re-entry or Re-handling Statement:

DO NOT perform clean-up or other hive maintenance activities (including harvesting honey) until 48 hours after treatment, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves and goggles.

Clothing must be laundered after each day's use.

FIRST AID INSTRUCTIONS: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26. If swallowed, do NOT induce vomiting. If skin contact occurs, remove contaminated clothing and wash skin thoroughly. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

ADDITIONAL USER SAFETY: Additional information is listed in the safety data sheet (SDS) available from the Australian Distributor.

ENVIRONMENTAL PROTECTION: DO NOT contaminate wetlands or watercourses with this product or used containers. ECOTOXIC. Toxic to terrestrial and aquatic life. Chemical not to be applied onto or into water.

DISPOSAL:

Dispose of unused product or container by wrapping with paper and putting in garbage.

STORAGE: Do not refrigerate or freeze. Store locked up, in the original sealed package, in a cool, dry place, out of direct sunlight and away from foodstuffs and stockfeed. Keep out of reach of children. Do not use after the expiry date stated on the label. Once opened and reconstituted, use prepared solutions within 24 hours. Once opened, dry powder may be stored for up to 3 months.

Marketing Authorization Holder:

CHEMICALS LAIF SPA Viale dell'Artigianato 13, 35010 Vigonza (PD), Italy.

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