ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Polypropylene Tub/Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MAQS Formic Acid 68.2g Beehive Strips for Honey Bees

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Each Beehive Strip contains: Formic Acid 68.2g

3. PHARMACEUTICAL FORM

Beehive Strip:

4. PACKAGE SIZE

Polypropylene tubs containing 2 sachets of (4 strips).
Polypropylene tubs containing 10 sachets of (20 strips).

Box containing 2 sachets in plastic liner, packaged in cardboard box (4 strips).
Box containing 10 sachets in plastic liner, packaged in cardboard box (20 strips).
Box containing 30 sachets in a plastic liner, packaged in cardboard box (60 strips).

Not all pack sizes may be marketed.

5. TARGET SPECIES

Honey bee

6. INDICATION(S)

Treatment of Varroosis caused by ***Varroa destructor*** in honey bees *(Apis mellifera)*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
In-hive use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period
Honey: Zero days.
Do not harvest honey during the 7-day treatment period

9. SPECIAL WARNING(S), IF NECESSARY

Take care to disturb the colony as little as possible during the application process. Treat all colonies in the apiary at the same time. Use according to local treatment recommendations, if available.

Natural birth and death rate is 1,000 to 2,000 bees per day during spring and summer. Under the stress of treatment, bees that are fragile due to age or maladies, ones that normally would die away from the hive, may succumb within the hive, and can be observed around the entrance.

The product should only be used as part of an integrated varroa control programme. It is highly recommended to monitor phoretic mite levels monthly during periods of brood rearing and treat when local thresholds are reached.

To ensure sufficient efficacy, do not use when peak temperatures are outside the range of 10 – 29.5°C on the day of application.

• This veterinary medicinal product is irritating to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. When handling and applying the product, wear the usual beekeeping protective clothing. Have water readily available.
• In case of accidental eye contact, flush the eye(s) immediately with clear running water for 10 minutes, seek medical advice and show the package leaflet to the physician.
• Avoid contact with skin by wearing chemical resistant gloves (EN 374). In case of accidental skin contact, wash the exposed skin immediately with water and seek medical advice if irritation persists.
• Avoid inhalation of vapour. Only open the product container and unwrap strips outdoors, standing upwind of the product. In case of accidental inhalation move to fresh air and seek medical advice if irritation persists.
• Keep children well away during application of product.
• Do not eat, drink or smoke whilst handling and applying the product.
• Always wash hands with soap and water directly after use.
• People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution

Other precautions
This product is corrosive. Do not allow product to contact metal surfaces.

10. EXPIRY DATE

EXP: MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Store below 25ºC;

Store in a dry place;

Protect from direct sunlight;

Keep the polypropylene tub or polyethylene bag in carboard box tightly closed to protect from contamination or product spillage.

Store in tightly closed original container in a well-ventilated area, away from sulphuric acid, strong oxidizing agents (e.g. nitric acid, peroxides, perchlorates, chlorites) and sources of ignition.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Do not contaminate ponds, waterways and ditches with the strip or used packaging. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited
Tullow Industrial Estate
Tullow
Co Carlow
Ireland
R93 W0D8

16. MARKETING AUTHORISATION NUMBER

Vm 50769/4000

17. MANUFACTURER'S BATCH NUMBER

Batch: XX-XXX-X

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MAQS Formic Acid 68.2g Beehive Strips for Honey Bees

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each Beehive Strip contains: Formic Acid 68.2g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Contains 1 Dose (2 strips)

4. ROUTE(S) OF ADMINISTRATION

In-Hive use
Sachet opening instructions
Carefully remove the two product strips from the sachet by cutting across one end, then lift the seal so the plastic comes away from the strip, and cut along the seal line the whole length of the sachet. Carefully separate the strips. **DO NOT REMOVE PAPER WRAPS** (This acts as a wick (i.e. it controls the rate of the release of the active substance).

5. WITHDRAWAL PERIOD(S)

Withdrawal period
Honey: Zero days.
Do not harvest honey during the 7-day treatment period.

6. BATCH NUMBER

Batch: XX-XXX-X

7. EXPIRY DATE

EXP: MM/YYYY

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited
Tullow Industrial Estate
Tullow
Co Carlow
Ireland
R93 W0D8

10. STATEMENT SIGNPOSTING TO PACKAGE LEAFLET

Read the enclosed package leaflet before use for full instructions and all warnings, including user warnings.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
MAQS Formic Acid 68.2g Beehive Strips for Honey Bees

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
NOD Apiary Ireland Limited
Tullow Industrial Estate
Tullow
Co Carlow
Ireland
R93 W0D8

Manufacturer responsible for batch release:
Lohmann Pharma Herstellung GmbH
Heinz-Lohmann-Straße 5,
27472 Cuxhaven,
Germany

Manufacturer responsible for batch release:
Animal Health Distributor (AHD)
Tullow Industrial Estate,
Tullow, Co Carlow, Ireland
R93 WOD8

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MAQS Formic Acid 68.2g Beehive Strips for Honey Bees

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each Beehive strip contains Formic Acid 68.2g
Each strip is an off-white to caramel coloured gel wrapped in white laminated biodegradable paper. Each strip is approximately 10 x 20 x 0.4 cm, weighing 146g

4. INDICATION(S)

Treatment of Varroosis caused by ***Varroa destructor*** in honey bees (*Apis mellifera*).

5. CONTRAINDICATIONS

Do not use when peak temperatures are outside the range of 10 – 29.5°C on the day of application. See 'Special Warnings' also.

Do not use for treatment of smaller colonies than those listed on the label *(single or double brood-chamber, standard Langstroth equipment or equivalent full-sized honey beehives, honey bee colony cluster covering a minimum of six frames, (approximately 10,000 bees). A smaller colony might not provide sufficient volume to achieve a tolerable formic acid concentration.*

6. ADVERSE REACTIONS

Insufficient ventilation, high ambient temperatures and insufficient hive volume have been identified as particular risk factors for build-up of formic acid concentrations beyond easily tolerated levels. Specific requirements in sections 5. Contraindications and 12. Special Warning(s) should be carefully observed as there is an increased risk of adverse events if these are not followed.
In uncommon cases, increased adult bee mortality, brood mortality and/or queen loss have been observed. Secondary signs including bees absconding, reduced reproduction and/or total colony loss have been noted in consequence.

Moribund bees (e.g. those suffering from a viral infection or a high mite infestation) are more susceptible to toxic effects.

Formic acid will initially disturb colony activities and may, within one day of application, result in queen rejection, triggering queen supersedure activities.

Colonies are expected to expand the cluster as part of controlling vapour concentration during the first 3 days of treatment. Bearding behaviour may be observed.

The frequency of adverse reactions is defined using the following convention.
- *very common (more than 1 in 10 colonies treated displaying adverse reaction(s))*
- *common (more than 1 but less than 10 colonies in 100 colonies treated)*
- *uncommon (more than 1 but less than 10 colonies in 1,000 colonies treated)*
- *rare (more than 1 but less than 10 colonies in 10,000 colonies treated)*
- *very rare (less than 1 colony in 10,000 colonies treated, including isolated reports.)'*

7. TARGET SPECIES

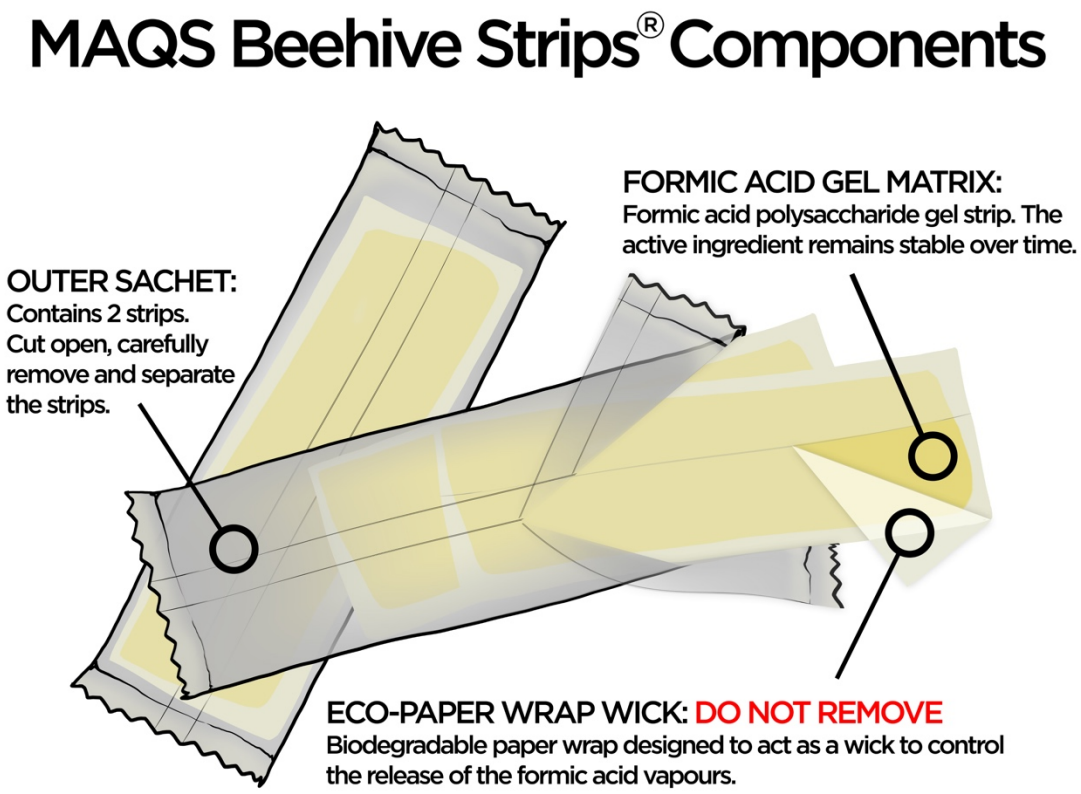
Honey bee

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: 1 sachet (*i.e.* 2 strips) per hive. Treatment period is 7 days. Allow a minimum of one month between applications.

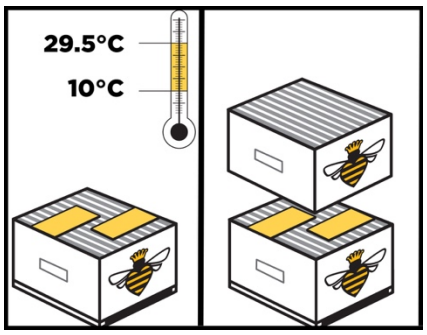
9. ADVICE ON CORRECT ADMINISTRATION

APPLICATION: Colonies should have good food reserves prior to treatment, and should not be in-hive fed during the treatment.
Once the hive is prepared, carefully remove the strips from the sachet and separate the two strips. **DO NOT REMOVE THE ECO-PAPER WRAP** (This acts as a wick (i.e. it controls the rate of the release of the active substance)**.**

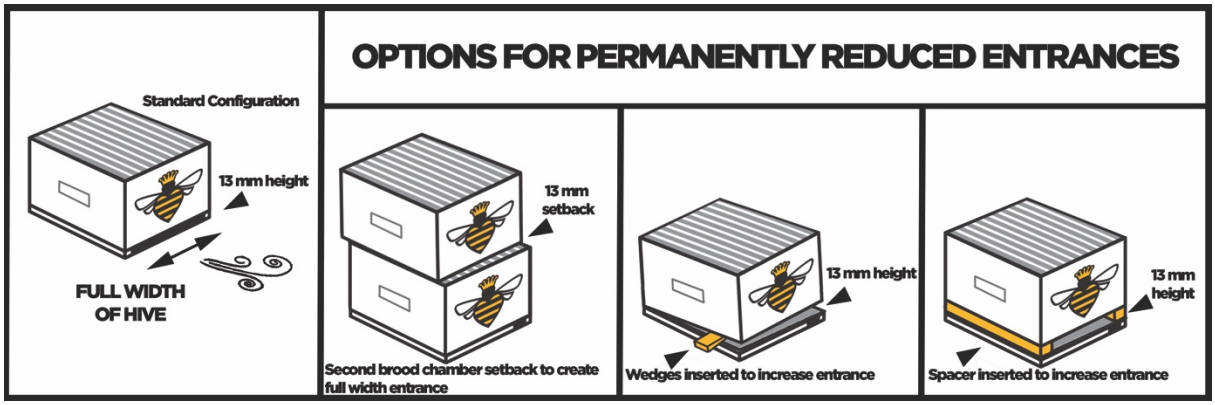


For hives with single or double brood chambers place treatment on the top bars of the frames of the lower brood chamber. No additional rim should be used.
Lay two strips, staggering them so they lay flat and across the full width of the brood chamber, with approximately 5 cm between strips and 10 cm between the ends of the brood chamber and the outer edges of the strips. Refer to the Application Options pictogram.

Placement: Correct application of the beehive strips is shown below in the pictograms.



The bottom hive entrance needs to be open the full width of the hive, minimum 13 mm high, for the entire duration of the treatment (7 days), with no barriers into the brood chamber.
In hives with permanently reduced entrances take appropriate measures to provide equivalent ventilations slots. Examples are provided in the pictogram.



The strips may be applied during honey flow. Put on a honey super complete with frames at time of application if necessary to provide adequate space for strong colonies to expand, or if a honey flow is expected. It is acceptable to have queen excluders in place.
The bulk of the formulation ingredients/excipients are food grade sugar and starch with a biodegradable/compostable paper wrap. The strips do not need to be removed from the hive after the application period of 7 days as the honey bees dispose of the spent strips. If they are removed, dispose of by composting.

10. WITHDRAWAL PERIOD(S)

Withdrawal period
Honey: Zero days.
Do not harvest honey during the 7-day treatment period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC;
Store in a dry place;

Protect from direct sunlight;
Keep the polypropylene tub or polyethylene bag in carboard box tightly closed to protect from contamination or product spillage.
Store in tightly closed original container in a well-ventilated area, away from sulphuric acid, strong oxidizing agents (e.g. nitric acid, peroxides, perchlorates, chlorites) and sources of ignition.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf-life after opening the immediate packaging (sachet): use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Take care to disturb the colony as little as possible during the application process.

Treat all colonies in the apiary at the same time. Use according to local treatment recommendations, if available.

The product should only be used as part of an integrated varroa control programme. It is highly recommended to monitor phoretic mite levels monthly during periods of brood rearing and treat when local thresholds are reached.
To ensure sufficient efficacy the product should be used when outside daytime temperatures exceed 10°C.

Special precautions for use in animals:

The strips may be applied during honey flow; put on honey supers if honey flow is anticipated, to allow adequate space for colony expansion.

Natural birth and death rate is 1,000 to 2,000 bees per day during spring and summer. Under the stress of treatment, (bees that are fragile due to age or maladies), ones that normally would die away from the hive, may succumb within the hive, and can be observed around the entrance.

Do not disturb the colony during the treatment period (7 days). If the colony is disturbed during the treatment period, there is an increased risk of brood and/or adult bee (inc. queen) mortality, and absconding may also occur.

Temperatures: Do not use when peak temperatures are outside the range of 10 – 29.5°C on the day of application. Temperatures above this range during the first three days of treatment may cause increased brood mortality and a higher risk of queen loss, particularly in fragile queens. If such temperatures coincide with a dearth period (where food is in short supply), there is an elevated risk of queen loss, sudden supercedure, or delay in egg laying. Treatment should be postponed until temperatures drop or nectar flow resumes.

To avoid an intolerable formic acid concentration, it is essential to ensure sufficient ventilation over the entire treatment period.

An entrance must be provided that is the full width of the hive (typically the bottom board entrance), with a minimum height 13 mm. The bottom entrance must be fully open for the entire duration of treatment. Any restriction on the entrance into the brood chamber (e.g. reducer or mouse guard) must be removed to prevent excessive damage to the colonies.

In hives with permanently reduced bottom entrances take appropriate measures to provide an equivalent level of ventilation (i.e. provision of alternative brood chamber entrances to act as ventilation slots). Refer to section 9. Application, for further information.

Colonies should have good food reserves at time of treatment, and should not be fed during treatment.
Do not destroy queen cells that may be observed prior to or post treatment. Supercedure, even if thought to be set in motion by treatment, is a natural process, and should be allowed to proceed for the health of the colony. Verify the colony is queen-right one month after treatment. Mother and daughter queens present post treatment are not uncommon.

Special precautions to be taken by the person administering the medicinal product to animals:

- This veterinary medicinal product is irritating to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. When handling and applying the product, wear the usual beekeeping protective clothing. Have water readily available.
- In case of accidental eye contact, flush the eye(s) immediately with clear running water for 10 minutes, seek medical advice and show the package leaflet to the physician.
- Avoid contact with skin by wearing chemical resistant gloves (EN 374). In case of accidental skin contact, wash the exposed skin immediately with water and seek medical advice if irritation persists.
- Avoid inhalation of vapour. Only open the product container and unwrap strips outdoors, standing upwind of the product. In case of accidental inhalation move to fresh air and seek medical advice if irritation persists.
- Keep children well away during application of product.
- Do not eat, drink or smoke whilst handling and applying the product.
- Always wash hands with soap and water directly after use.
- People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.

Other precautions:
This product is corrosive. Do not allow product to contact metal surfaces.

Interaction with other medicinal products and other forms of interaction:
Do not use with other acaricides against varroosis.

Overdose (symptoms, emergency procedures, antidotes):
Excessive mortality of adult bees and brood as well as absconding are typical overdose symptoms. These signs can be caused by exceeding the recommended dose, insufficient ventilation, high temperatures and/or inappropriate hive volume. In case of overdose, increase hive ventilation by creating additional entrances from top to bottom. Check for presence of the queen 2 weeks after application. See also section 9. Application.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Do not contaminate ponds, waterways and ditches with the strip or used packaging. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Pharmacodynamic properties

Formic acid from the product acts by fumigation, or vapour action.
Formic acid is active against mites on adult bees and is known to kill mite nymphs within capped brood cells. In addition, activity against male and female adult mites under the brood cap has been shown which may have consequences for mite reproduction since mating and fertilization take place within cells.
The mode of action of formic acid has not been fully elucidated. The available data suggest that impairment of Varroa destructor may result from local effects that are due to the corrosive action of formic acid vapours. In addition, absorbed formic acid may cause acidosis and may impair the mite's energy supply through inhibition of the mitochondrial respiratory chain.

Pharmacokinetic particulars

The pharmacokinetics of formic acid in honeybees has not been studied.

Distribution and elimination in the beehive:
The formic acid volatilises slowly from the strips into the hive cavity. The honeybees determine the concentration of formic acid in the hive air by ventilating the brood area

to their comfort level. Excess levels of formic acid vapour in the hive air are quickly replaced by fresh incoming air to the hive.

Formic acid is naturally occurring in honey. Formic acid is not lipophilic and so does not leave residues in the honeycomb.

Additional Information in Sole Responsibility of the Marketing Authorisation Holder.

Regional Honey Legislations

The 0-Day withdrawal period refers to the relevant maximum acidity limits approved on the European level, which ensures consumer safety. However, beekeepers are reminded that single regional honey types may require particular ranges of acid content and that customised monitoring prior to harvesting could be necessary. This is not reflected in the SPC.

Pack Size:
Polypropylene tubs containing 2 sachets of 2 strips.
Polypropylene tubs containing 10 sachets of 2 strips

Box containing 30 sachets in a plastic liner, packaged in cardboard box
Box containing 10 sachets in plastic liner, packaged in cardboard box
Box containing 2 sachets in plastic liner, packaged in cardboard box

Not all pack sizes may be marketed.

Approved 15 June 2022