SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MAQS Formic Acid 68.2g Beehive Strips for Honey Bees
MAQS 68.2g Beehive Strips for Honey Bees (IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each strip contains:

Active Substance:
Formic Acid: 68.2g

Excipients:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Beehive strip.
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. CLINICAL PARTICULARS

4.1 Target species

Honey bee

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use when peak temperatures are outside the range of 10 – 29.5°C on the day of application. See sections 4.4 and 4.5i 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.*

4.4 Special warnings for 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 temperatures exceed 10°C. See the temperature range given in section 4.3 "Contraindications".

4.5 Special precautions for use

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.

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.

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.

Temperatures: Outside daytime temperature highs should be in the temperature range given in section 4.3 "Contraindications".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 4.9 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 veterinary 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.

4.6 Adverse reactions (frequency and seriousness)

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 of section 4.3 and 4.5 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.)'*

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medical products and other forms of interaction

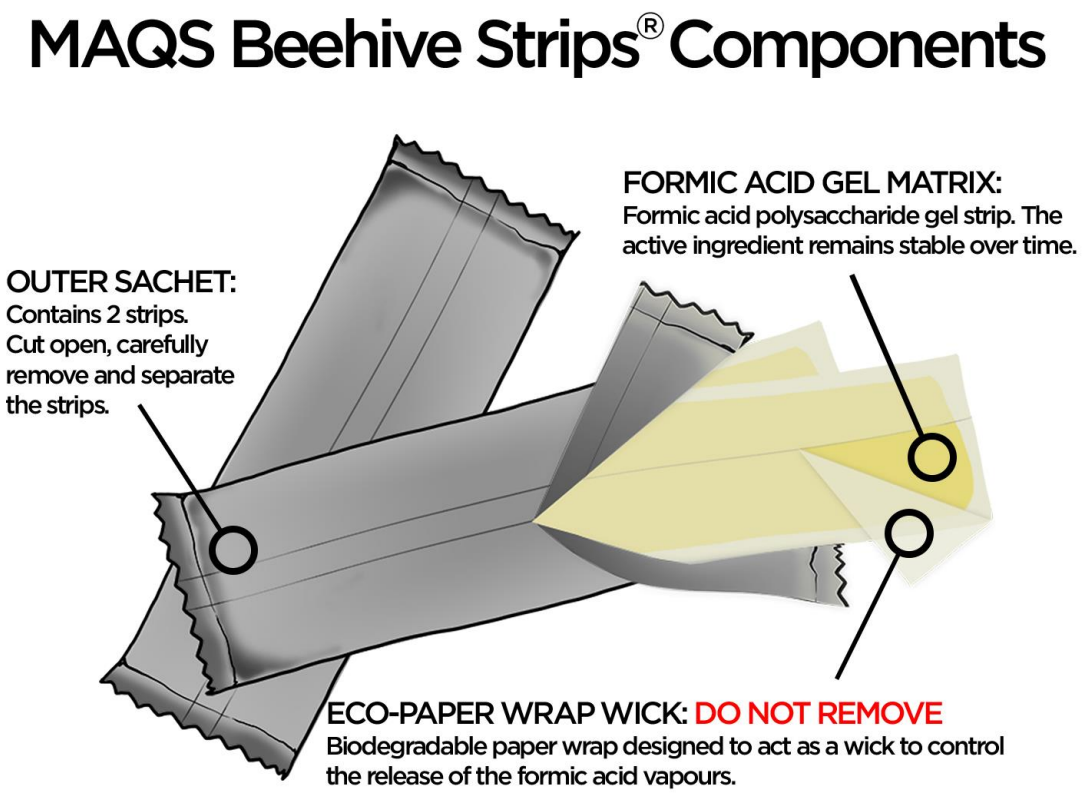
Do not use with other acaricides against varroosis.

4.9 Amounts to be administered and administration route

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

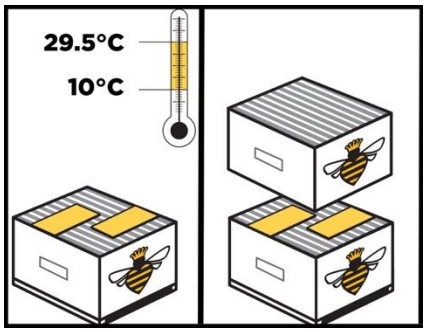
APPLICATION: Colonies should have good food reserves prior to treatment, and should not be in-hive fed during the treatment.

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)**.**



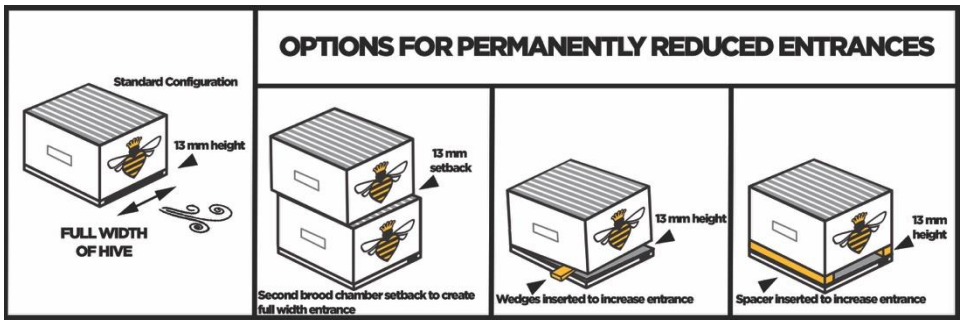
For hives with single or double brood chambers place treatment on the top bars of the frames of the lower brood chamber. No additional rim should be used.
Lay two strips, staggering them so they lay flat and across the full width of the brood chamber, with approximately 5 cm between strips and 10 cm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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 sections 4.5 and 4.9.

4.11 Withdrawal period

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents, organic acids, formic acid

ATCvet code: **QP53AG01**

5.1 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 fertilisation 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.

5.2 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.

5.3 Environmental properties

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch
Liquid Sugar
Potable Water
Laminated paper containing biodegradable polymers

6.2 Major Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 12 months
Shelf-life after the first opening of the immediate packaging: use immediately

6.4 Special precautions for storage

Store below 25ºC;
Store in a dry place;
Protect from direct sunlight;
Keep the polypropylene tub or polyethylene bag in cardboard box tightly closed to protect from contamination or product spillage.
Store in tightly closed original containers in a well-ventilated area, away from sulphuric acid, strong oxidizing agents (e.g. nitric acid, peroxides, perchlorates, chlorites) and sources of ignition.

6.5 Nature and composition of immediate packaging

A polypropylene/aluminium foil/polypropylene laminated sachet containing two strips.

Pack 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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.

7. MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Ltd.,
Tullow Industrial Estate,
Tullow, Co Carlow, Ireland
R93 W0D8

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

February 28th, 2022