PACKAGE LEAFLET/LABELLING for: APILIFE VAR bee-hive strip for honey bees

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER CHEMICALS LAIF S.P.A.

V.le dell'Artigianato n° 13, 35010 Vigonza (PD), Italy

NAME AND ADDRESS OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

CHEMICALS LAIF S.P.A.

Via Roma n° 69, 36020 Castegnero (VI), Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

APILIFE VAR bee-hive strip for honey bees

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each bee-hive strip contains:

Active substances: Thymol 8,00 g; Eucalyptus oil 1,72 g; Camphor racemic 0,39 g; Levomenthol 0,39 g;

Excipients: foamed phenolic resin.

4. INDICATION(S)

Treatment of varroosis of the bees caused by Varroa destructor.

5. CONTRAINDICATIONS

Do not use during honey flow in order to avoid tainting the taste of the honey.

Do not use when maximum daytime temperature is above 30°C.

6. ADVERSE REACTIONS

Bees may remove food from directly under the strip.

Treatment at temperatures above 30°C may lead to increased stress and mortality of adult bees and brood.

The colony may become slightly agitated during treatment.

There may be reduced acceptance of the food if feeding at the same time as treatment.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Honey bees (Apis mellifera).

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

Dosage: 1 strip every 7 days for each beehive, complete treatment 4 strips for each beehive. The treatment should be done once per year.

Application: to perform the treatment take one strip from the sachet and place it in one of the four corners above the honeycombs, far away from the brood placed in the centre of the beehive. Close the beehive and let the product work for 7 days.

The strip can also be used by cutting it into 3-4 pieces to be placed in the corners of the beehive. Repeat the treatment for 4 consecutive times. At the end of the treatment, the pieces of strips still present must be removed.

It is not recommended to use the product in multiple storey hives as unsatisfactory efficacy might be expected.

Integrated Pest Management

The efficacy may vary between colonies due to the surrounding conditions (environmental factors connected to the place and climate conditions, temperature, genetic and

infestation level, reinfestation, bee population, strength of the colon, brood area and bee mortality, ec.). The product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite drop regularly monitored. Colonies with an average mite drop of more than 1 mite per day two weeks right after the last treatment have to be subjected to an additional winter or spring treatment for varroa (preferably with another active ingredient).

9. ADVICE ON CORRECT ADMINISTRATION

Not Applicable.

10. WITHDRAWAL PERIOD

Honey: Zero days.

Do not use during honey flow in order to avoid to adulterate the taste of the honey.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Store below 25°C. Do not refrigerate or freeze. Protect sachets from direct sunlight. Protect from frost. Store the strip in the original packaging.

12. SPECIAL WARNINGS

Treatment at temperatures above 30°C lead to increased stress and mortality of adult bees and brood. For maximum efficacy use the product in late summer after the honey harvest, when the amount of bee brood present is diminishing. The ideal outside temperature for a good effectiveness of the product during the treatment ranges between 20-25°C. Insufficient efficacy can be expected if the average outside temperature is lower than 15°C. Do the treatments without supers. Do not perform during honey flow but after the relative honey harvest. All colonies in the same apiary should be treated simultaneously to avoid robbery. Avoid disturbance to the hive. Do not place the strip in the center of the beehive or near the brood. Never place strips near a sugar feeder as this may reduce feeding. It is not recommended to treat hives in cold weather. Because of possible contact dermatitis and irritation of the skin and eyes observed with thymol, direct skin and eye contact should be avoided. When handling the product, wear impermeable gloves as well as the usual protection equipment. After application, wash hands and the material being in contact with the strip with soap and water. In case of skin contact, wash thoroughly the affected area with soap and water. In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water and seek medical advice. Do not inhale. Do not use simultaneously with other acaricides. In the case of an overdose of too many strips, bees can be disturbed, showing increased stress and a change in behaviour. They exit the beehive and remain outside. If dead bees and grubs are found, remove excess strips.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The product should not be allowed to contaminate water courses as this may be dangerous for fish and other aquatic organisms.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

16. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

17. MANUFACTURER'S BATCH NUMBER

Batch n.:

18. EXPIRY DATE

Expiry Date:

After first opening of the sachet all strips should be used immediately.

Marketing authorisation number:

Packaging size: sachet containing 2 strips.