[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formivar 85
85 g formic acid /100 g bee-hive solution for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g solution contains:

Active substance: Formic acid 85%, equivalent to 0.85 g formic acid

Excipient:

Qualitative composition of excipients and other constituents
Decalcified water

Clear, colourless, very volatile, corrosive liquid with a pungent smell.

3. CLINICAL INFORMATION

3.1 Target species

Honey bees (*Apis mellifera*)

3.2 Indications for use for each target species

Treatment of varroosis (*Varroa destructor)* and/or tracheal mites *(Acarapis woodi)* on honey bees (*Apis mellifera*).

3.3 Contraindications

Do not use when the daily ambient temperature is beyond the specified range (14-30 °C).

3.4 Special warnings

Treat all colonies in the apiary at the same time to avoid robbery. To ensure a sufficient efficacy the product should be used if the maximum daily temperature is above 14 °C.
Use the product as part of an integrated varroa control program with regular mite monitoring. Treat when local thresholds are reached. Using different substances during the year reduces the risk of building resistance.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Colonies require adequate ventilation during treatment. The flight opening must be at least 15 cm^2. Remove all obstacles in and outside the flight opening. High concentrations of formic acid may lead to bees aggregating in front of the hive entrance. In such a case reduce the evaporation rate of the dispenser and provide a 2 cm in height opening over the entire width of the hive, to lower the concentration of formic acid in the hive. Please read carefully the instructions of the dispenser. Do not disturb the colonies during the treatment period. To ensure a sufficient safety the product should be used if the maximum outside temperature is below 30 °C.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product is harmful especially because of its corrosive properties.
Avoid oral exposure including hand-to-mouth contact, avoid skin- and eye contact including hand-to-eye contact, and avoid inhalation of vapour. Personal protective equipment consisting of **protective clothing, chemical resistant gloves, safety glasses** and **a half – or full-mask with filter type B or E** should be worn when handling the product or cleaning the used equipment. Remove heavily contaminated clothes as soon as possible and wash before re-use. Do not eat, drink or smoke whilst handling and applying the product. Wash hands with soap and water directly after use.
In case of accidental ingestion, rinse mouth and drink plenty of water, but DO NOT induce vomiting.
In case of accidental spillage onto skin, wash the affected areas immediately with running water.
In case of accidental spillage into the eyes, rinse immediately with clear running water for several minutes. Remove contact lenses, if present. In case of accidental inhalation move to fresh air and keep at rest in a position comfortable for breathing. If irritation persists after any type of exposure, seek medical advice and show the package leaflet or the label to the physician.
Keep children away during product application. Used containers should be disposed of immediately in a proper way and not left within the sight or reach of children.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
The product is corrosive to metal parts.

3.6 Adverse events

Honey bee:

Uncommon (1 to 10 colonies / 1,000 colonies treated):	Queen bee death[1]
Rare (1 to 10 colonies / 10,000 colonies treated):	Bee colony death
Undetermined frequency (cannot be estimated from the available data):	Increased mortality rate[2] Bee brood mortality[3]

[1] Queen mortality has been reported more often for short-term treatments or in cases of incorrect adjustment of dispensers.

[2] In the first three days (long-term treatment) or within the first hours (short-term treatment) a higher mortality rate of bees (more than 3 cups (1 cup = 240 ml = 600 bees)) may occur.

[3] Some damage of brood in open or sealed brood cells and hatching young bees may occur after application of the product.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the combined label and package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use with other acaricides.

3.9 Administration routes and dosage

Do not spray or trickle liquid formic acid directly on the bees.
The solution for in-hive use is applied with an appropriate dispenser (e.g. Liebig dispenser) which is generally placed on top of the brood frames. The amount of solution to be administered depends on the dispenser and the duration of the entire treatment. The solution must have ambient temperature when applied.
For the long-term treatment, the formic acid solution should evaporate continuously in a low dose. During one treatment with a duration of 7-10 days, the total amount should not exceed 200 ml. The required dose is 10-15 ml per day for single brood chambers of 35-45 L volume (e.g. DNM, National, Simplex, Swiss Hive, Zander) and 20-30 ml per day for large or double brood chambers of 50-80 L volume (e.g. AZ-hive, Dadant, 2 X DNM, 2 X Simplex, 2 X Zander). It is recommended to repeat the treatment within 4 weeks of the first application if the daily natural varroa mite drop is more than 5 mites/day.
Follow the instructions of your local bee research center for exact dosage and recommended dispensers for the correct treatment according to the local integrated varroa treatment program combining good beekeeping practice with the use of different varroa treatments throughout the year.
For the short-term treatment 2 ml per frame are applied onto a sponge cloth. The sponge cloth is placed on top or below the brood combs. Formic acid evaporation takes place within the 6-10 hours following application. The treatment should be repeated within 3-4 days after the first application for at least one to a maximum of four times. Wash and dry the sponge cloth immediately after use.

Max. daily temperature	**Start of treatment**
14 – 20 °C	During the day
> 20 – 25 °C	Either in the evening or in the morning
> 25 – 30 °C	In the early morning

Do not start treatment at temperatures below 14 °C and above 30 °C. Do not start a treatment when heavy rains or thunderstorms are expected.
In general, the use of formic acid 60% is recommended for smaller hives and higher temperatures due to its lower partial vapour pressure while formic acid 85% is recommended for larger hives and lower temperatures due to its higher partial vapour pressure which allows a higher evaporation rate per surface unit of the dispenser.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The use of higher dose could lead to excessive brood loss, adult bee mortality, queen loss, and/or absconding. Check the presence of queen 2 weeks after application.
If a higher mortality rate of bees than the natural daily bee fall of summer bees (more than 3 cups (1 cup = 240 ml)) or agitation of the honey bees is observed during the first days (long-term treatment) or hours (short-term treatment) respectively after the application of the product, an overdose may be the cause. The evaporation rate of the dispenser must be reduced, and ventilation must be improved by opening the flight opening to the maximum.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Honey: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP53AG01

4.2 Pharmacodynamics

The mode of action of formic acid is due to the inhibition of the respiratory system of the *V. destructor* mite. The respiratory system of the honey bees is also affected by the formic acid vapours in case of an overdose. Adult bees, larvae and eggs react differently to exposure to formic acid. A correlation between the body mass, the respiratory activity and the sensitivity to formic acid may exist. The mite *V. destructor* seems to be more sensitive to formic acid than the most sensitive development stage of the honey bee due to their lower buffering and metabolizing capacity. The inhibition of the respiratory system in the varroa mite may occur faster than in the honey bee. Efficacy of a treatment is determined by the product (CT) of concentration of the formic acid vapours (C) and the exposure time (T). Concentration during a short-term treatment is thus significantly higher than during a long-term treatment. Long-term treatments can be done with lower concentrations of formic acid over a long period reducing the immediate risk to adult bees. Formic acid kills mites present on bees and in the sealed brood.

4.3 Pharmacokinetics

The pharmacokinetics of formic acid in bees is not known.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life after first opening the immediate packaging: use within the expiry date as printed on the package.

5.3 Special precautions for storage

Store below 30 °C. Do not refrigerate or freeze. Protect from frost. Store in the original container. Keep the bottle tightly closed. Store in an upright position. Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

HDPE bottle with a child-proof PP/PE closure cap.
Package size: 1 litre

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Andermatt BioVet GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

HU: Veterinary medicinal product subject to prescription.
AT, NL, PT, SI: Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

[Not applicable for MRP/DCP/SRP and national procedures]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

HDPE BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formivar 85
85 g formic acid /100 g bee-hive solution for honey bees

2. COMPOSITION

Active substance: Formic acid 85%, equivalent to 0.85 g formic acid /1 g solution
Clear, colourless, very volatile, corrosive liquid with a pungent smell.

3. PACKAGE SIZE

1 L

4. TARGET SPECIES

Honey bees (*Apis mellifera*)

5. INDICATIONS FOR USE

Indications for use
Treatment of varroosis (*Varroa destructor)* and/or tracheal mites *(Acarapis woodi)* on honey bees *(Apis mellifera).*

6. CONTRAINDICATIONS

Contraindications
Do not use when the daily ambient temperature is beyond the specified range (14-30 °C).

7. SPECIAL WARNINGS

Special warnings

<u>Special warnings:</u>
Treat all colonies in the apiary at the same time to avoid robbery. To ensure a sufficient efficacy the product should be used if the maximum daily temperature is above 14 °C.
Use the product as part of an integrated varroa control program with regular mite monitoring. Treat when local thresholds are reached. Using different substances during the year reduces the risk of building resistance.

<u>Special precautions for safe use in the target species:</u>
Colonies require adequate ventilation during treatment. The flight opening must be at least 15 cm^2. Remove all obstacles in and outside the flight opening. High concentrations of formic acid may lead to bees aggregating in front of the hive entrance. In such a case reduce the evaporation rate of the dispenser and provide a 2 cm in height opening over the entire width of the hive, to lower the concentration of formic acid in the hive. Please read carefully the instructions of the dispenser. Do not disturb the colonies during the treatment period. To ensure a sufficient safety the product should be used if the maximum outside temperature is below 30 °C.

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This product is harmful especially because of its corrosive properties. Avoid oral exposure including hand-to-mouth contact, avoid skin- and eye contact including hand-to-eye contact, and avoid inhalation of vapour. Personal protective equipment consisting of **protective clothing, chemical resistant gloves, safety glasses** and **a half – or full-mask with filter type B or E** should be worn when handling the product or cleaning the used equipment. Remove heavily contaminated clothes as soon as possible and wash before re-use. Do not eat, drink or smoke whilst handling and applying the product. Wash hands with soap and water directly after use.
In case of accidental ingestion, rinse mouth and drink plenty of water, but DO NOT induce vomiting. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eyes, rinse immediately with clear running water for several minutes. Remove contact lenses, if present. In case of accidental inhalation move to fresh air and keep at rest in a position comfortable for breathing. If irritation persists after any type of exposure, seek medical advice and show the package leaflet or the label to the physician.
Keep children away during product application. Used containers should be disposed of immediately in a proper way and not left within the sight or reach of children.

Other precautions:
The product is corrosive to metal parts.

Interactions with other medicinal products and other forms of interaction:
Do not use with other acaricides.

Overdose:
The use of higher dose could lead to excessive brood loss, adult bee mortality, queen loss, and/or absconding. Check the presence of queen 2 weeks after application. If a higher mortality rate of bees than the natural daily bee fall of summer bees (more than 3 cups (1 cup = 240 ml)) or agitation of the honeybees is observed during the first days (long-term treatment) or hours (short-term treatment) respectively after the application of the product, an overdose may be the cause. The evaporation rate of the dispenser must be reduced, and ventilation must be improved by opening the flight opening to the maximum.

Major incompatibilities:
None known.

8. ADVERSE EVENTS

Adverse events
Honey bee:

Uncommon (1 to 10 colonies / 1,000 colonies treated):
Queen bee death[1]
Rare (1 to 10 colonies / 10,000 colonies treated):
Bee colony death
Undetermined frequency (cannot be estimated from the available data):
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[2] In the first three days (long-term treatment) or within the first hours (short-term treatment) a higher mortality rate of bees (more than 3 cups (1 cup = 240 ml = 600 bees)) may occur.

[3] Some damage of brood in open or sealed brood cells and hatching young bees may occur after application of the product.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Do not spray or trickle liquid formic acid directly on the bees.
The solution for in-hive use is applied with an appropriate dispenser (e.g. Liebig dispenser) which is generally placed on top of the brood frames. The amount of solution to be administered depends on the dispenser and the duration of the entire treatment. The solution must have ambient temperature when applied.
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> 25 – 30 °C	In the early morning

Do not start treatment at temperatures below 14 °C and above 30 °C. Do not start a treatment when heavy rains or thunderstorms are expected.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods
Honey: Zero days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C. Do not refrigerate or freeze. Protect from frost. Store in the original container. Keep the bottle tightly closed. Store in an upright position. Protect from direct sunlight.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
HU: Veterinary medicinal product subject to prescription.
AT, NL, PT, SI: Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
1L HDPE bottle with a child-proof PP/PE closure cap

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Andermatt BioVet GmbH, Franz-Ehret-Str. 18, 79541 Lörrach, Germany

Local representatives and contact details to report suspected adverse reactions: *To be completed nationally.*

18. OTHER INFORMATION

Other information

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.**Additional information in sole responsibility of the marketing authorisation holder.**
Regional honey legislations: regarding the maximum acidity limits approved at European level, these are complied with following a 0-day withdrawal period. However, beekeepers are reminded that single regional honey types may require particular ranges of acid content. The authorization holder recommends the treatment to be carried out without honey supers or after the honey harvest.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within the expiry date.

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

(All the information is included in the labelling)