

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dany's BienenWohl powder and solution for 39.4 mg/ml bee-hive dispersion for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One bottle of 375 g solution contains:

Active substance:

Oxalic acid dihydrate 17.5 g (equivalent to 12.5 g of oxalic acid)

Excipients:

For the full list of excipients, see section 6.1

One bottle of 750 g solution contains:

Active substance:

Oxalic acid dihydrate 35.0 g (equivalent to 25.0 g of oxalic acid)

Excipients:

For the full list of excipients, see section 6.1

One sachet of 125 g powder contains:

Excipients:

Sucrose 125 g

For the full list of excipients, see section 6.1

1 ml of mixed bee-hive dispersion contains:

Active substance:

Oxalic acid dihydrate 39.4 mg (equivalent to 28.1 mg of oxalic acid)

Excipients:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solution for bee-hive dispersion.

Solution for bee-hive dispersion (bottle containing the active substance):

Clear and colourless solution.

Powder for bee-hive dispersion (sachet):

White crystalline powder.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees (*Apis mellifera*)

4.2 Indications for use, specifying the target species

For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Dany's BienenWohl must only be applied once in brood-free colonies.

The veterinary medicinal product should be used as a treatment within an Integrated Varroa Management program with mite drop monitored regularly. When possible, rotate the use of this veterinary medicinal product with another approved varroacide with a different mode of action to decrease the potential for Varroa mites to develop resistance.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dose and do not administer this veterinary medicinal product more than once. Repeated treatments are not well tolerated by bees. If worker bees are treated more than once per generation, it can result in damage to the bees and a reduction in the strength of the colony.

All colonies in the same apiary should be treated simultaneously to avoid re-infestation. Avoid disturbing the hives in the days following treatment.

Dany's BienenWohl should not be used when honey supers are present.

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

This veterinary medicinal product is highly acidic and could have irritating and corrosive effects on the skin, eyes and mucous membranes.

Avoid oral exposure, including hand-to-mouth contact. Avoid direct skin and eye contact, as well as hand-to-eye contact.

Personal protective equipment consisting of protective clothing, acid-proof gloves and safety glasses should be worn.

Wash hands and exposed skin with soap and plenty of water immediately.

Do not eat, drink or smoke whilst handling and applying the veterinary medicinal product.

Remove contaminated clothing immediately.

Used measuring devices and empty containers should be disposed of immediately in a proper way.

In case of accidental ingestion, clean the mouth with water and drink water or milk, but do not induce vomiting. In case of eye contact, immediately rinse the eye thoroughly with water (remove contact lenses first). Seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

Dany's BienenWohl has corrosive properties on corrosion-sensitive parts of beekeeping equipment.

4.6 Adverse reactions (frequency and seriousness)

In clinical trials, increased bee mortality was very commonly observed. This did not affect long-term development of colonies.

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 medicinal products and other forms of interaction

None known.

The concomitant use of other acaricidal products should be avoided because increased toxicity to bees might occur.

4.9 Amounts to be administered and administration route

In-hive use.

Dose:

A maximum dose of 5-6 ml of the final bee-hive dispersion should be administered once per seam occupied by bees. The total amount of product administered to a colony should not exceed 54 ml. Therefore, if necessary, the dose per seam should be reduced in order not to exceed the maximum total amount administered per colony (calculation: maximum dose per colony/number of occupied seams= x.x ml/seam).

The use of Dany's BienenWohl with the above dosing scheme only applies to hives with vertical frames that can be accessed from the top, as the treatment of bees in other types of hives has not been investigated.

Advice on correct administration:

The product should be administered using a suitable measuring device with appropriate graduations (e.g. automatic pipette, disposable syringe) onto the bees sitting in seams.

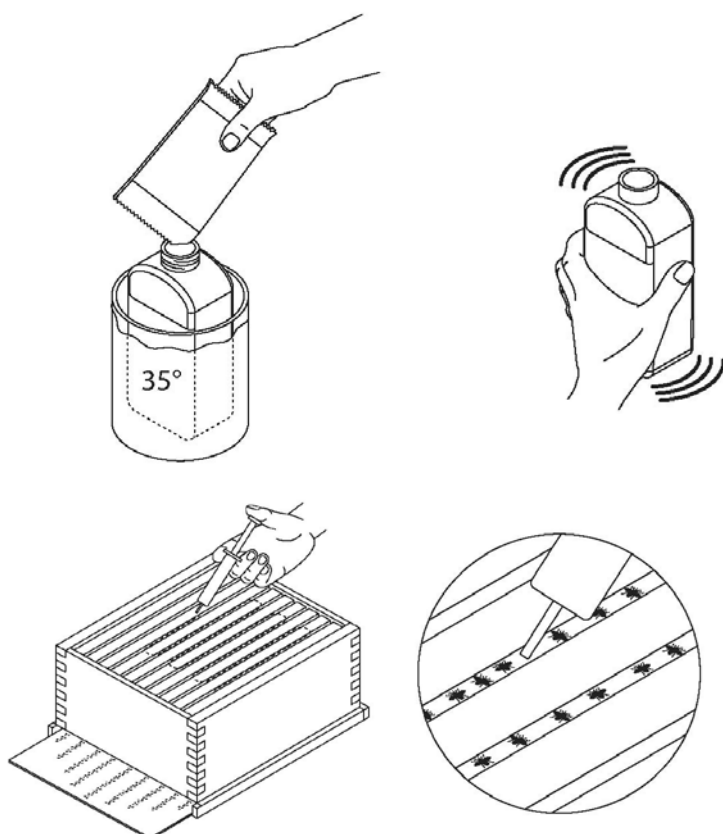
The final bee-hive dispersion is to be trickled onto the bees in the seams. Dosing should be done carefully and overdosing should be avoided.

The dispersion should be warm (30 – 35 °C) during application.

The outside temperature during treatment with Dany's BienenWohl should be at least 3 °C.

Apply only one treatment per hive.

In case the final dispersion had been stored, it should be well shaken before use.



Preparation of the final bee-hive dispersion:

Before use, the contents of the sachet(s) containing the flavoured sucrose powder should be added to the bottle containing the solution for bee-hive dispersion as follows:

Place the bottle containing the oxalic acid dihydrate solution into warm (30 – 35 °C) water. Open the sachet(s) of the sucrose powder with a pair of scissors.

Preparation of the 444 ml final bee-hive dispersion: Pour the content of one sachet into the bottle containing 375 g of the oxalic acid dihydrate acid solution.

Preparation of the 888 ml final bee-hive dispersion: Pour the content of the two sachets into the bottle containing 750 g of the oxalic acid dihydrate acid solution.

The full content of the sachet(s) should be poured into the bottle with the solution.

Close the bottle tightly and shake it until the sucrose is completely dissolved. The final bee-hive dispersion should be a colourless, clear to slightly turbid dispersion.

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

After overdosing, increased bee mortality was very commonly observed. An overdose of 53% of the dispersion per treatment resulted in a temporary, short-term increase in bee mortality. The overdose did not significantly affect the development of the colonies in the long term, as shown by the development of the colonies in spring.

4.11 Withdrawal period(s)

Honey: Zero days.

Do not use during honey flow.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents; Ectoparasiticide for topical use, incl. insecticides

ATCvet code: QP53AG03

5.1 Pharmacodynamic properties

Oxalic acid is an organic acid used for the treatment of *Varroa destructor*. Studies on the mode of action of oxalic acid are not available.

The major contributor to the acaricidal effects is the low pH of the dispersion, as opposed to the volume of dispersion administered. It acts as contact poison against *Varroa destructor*.

The high proportion of sugar in this product increases the viscosity of the dispersion and hence its adhesion to the bees.

5.2 Pharmacokinetic particulars

There is evidence that oxalic acid dihydrate dispersion is able to penetrate keratin, as for a short time after application to bees the concentration of oxalic acid dihydrate is slightly increased in all their tissues.

Oxalic acid dihydrate is externally distributed on the bees through body contact and/or social food exchange (trophallaxis).

Environmental properties

Dany's BienenWohl should not enter water courses as this may be dangerous for fish and other aquatic organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Solution:

Citric acid monohydrate

Glycerol (85%)

Water, purified

Powder:

Sucrose

Anise oil

Eucalyptus oil

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after mixing according to directions: 1 year.

6.4. Special precautions for storage

Keep the bottle and the sachet in the outer carton in order to protect from light.

Final bee-hive dispersion (after mixing): Store in a refrigerator (2 °C – 8 °C).

Store away from food.

6.5 Nature and composition of immediate packaging

Bottle:

High-density polyethylene (HDPE) bottle with an HDPE/ polypropylene (PP) child-proof screw cap containing 375 g or 750 g solution.

Sachet:

Four-layered foil (low-density polyethylene (LDPE)/ aluminium/ LDPE/ clay-coated paper) sealed sachets containing 125 g of flavoured sucrose.

Pack sizes:

One cardboard box containing one HDPE bottle (375 g) and one sachet (125 g), providing 444 ml final bee-hive dispersion after mixing.

One cardboard box containing one HDPE bottle (750 g) and two sachets (each containing 125 g) providing 888 ml final bee-hive dispersion after mixing.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Dany Bienenwohl GmbH
Geyerspergerstr. 27
80689 Munich
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/225/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/06/2018

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Wirtschaftsgenossenschaft deutscher Tierärzte (WDT) eG
Siemensstraße 14
30827 Garbsen
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product not subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Dany's BienenWohl is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Oxalic acid	Not applicable	Bees	No MRL required	Not applicable	No entry	Anti-infectious agent

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

PSUR submissions shall be synchronised and submitted at the same frequency as for the reference product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (for powder and solution for bee-hive dispersion)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dany's BienenWohl powder and solution for 39.4 mg/ml bee-hive dispersion
oxalic acid dihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

17.5 g oxalic acid dihydrate (equivalent to 12.5 g of oxalic acid) (375 g solution)
35 g oxalic acid dihydrate (equivalent to 25.0 g of oxalic acid) (750 g solution)

125 g sucrose
250 g sucrose

3. PHARMACEUTICAL FORM

Powder and solution for bee-hive dispersion

4. PACKAGE SIZE

1 bottle with 375 g oxalic acid dihydrate solution and one sachet (125 g) of sucrose powder, to achieve 444 ml bee-hive dispersion after mixing with sucrose.

1 bottle with 750 g oxalic acid dihydrate solution and two sachets (each containing 125 g) of sucrose powder to achieve 888 ml bee-hive dispersion after mixing with sucrose.

5. TARGET SPECIES

Honey bees (*Apis mellifera*)

6. INDICATION(S)

For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive use
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period (honey): Zero days
Do not use during honey flow.

9. SPECIAL WARNING(S), IF NECESSARY

This product has corrosive properties. Wear personal protective equipment.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once mixed use by...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle and the sachet in the outer carton in order to protect from light.
After mixing the bee-hive dispersion: Store in a refrigerator, away from food.

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

Disposal: read package leaflet.

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

Dany Bienenwohl GmbH
Geyerspergerstr. 27
80689 Munich
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/225/001 (375 g g solution)
EU/2/18/225/002 (750 g g solution)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dany's BienenWohl solution for bee-hive dispersion
oxalic acid dihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

One bottle contains:
17.5 g oxalic acid dihydrate (equivalent to 12.5 g of oxalic acid) (375 g solution)
35 g oxalic acid dihydrate (equivalent to 25.0 g of oxalic acid) (750 g solution)

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

375 g oxalic acid dihydrate solution to achieve 444 ml bee-hive dispersion.
750 g oxalic acid dihydrate solution to achieve 888 ml bee-hive dispersion.

5. TARGET SPECIES

Honey bees (*Apis mellifera*)

6. INDICATION(S)

For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive use
Mix with Dany's BienenWohl powder as instructed, before use.
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period (honey): Zero days
Do not use during honey flow.

9. SPECIAL WARNING(S), IF NECESSARY

This product has corrosive properties. Wear personal protective equipment.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once mixed use by...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.
After mixing the bee-hive dispersion: Store in a refrigerator, away from food.

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

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”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dany Bienenwohl GmbH
Geyerspergerstr. 27
80689 Munich
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/225/001 (375 g solution)
EU/2/18/225/002 (750 g solution)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dany's BienenWohl powder for bee-hive dispersion
sucrose

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

125 g

5. TARGET SPECIES

Honey bees (*Apis mellifera*)

6. INDICATION(S)

For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive use.
Mix with Dany's BienenWohl solution before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dany Bienenwohl GmbH
Geyerspergerstr. 27
80689 Munich
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Dany's BienenWohl powder and solution for 39.4 mg/ml bee-hive dispersion 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:

Dany Bienenwohl GmbH
Geyerspergerstr. 27
80689 Munich
Germany

Manufacturer responsible for batch release:

Wirtschaftsgenossenschaft deutscher Tierärzte (WDT) eG
Siemensstraße 14
30827 Garbsen
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dany's BienenWohl powder and solution for 39.4 mg/ml bee-hive dispersion for honey bees

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

One bottle of 375 g of solution contains:

Active substance:

Oxalic acid dihydrate 17.5 g (equivalent to 12.5 g of oxalic acid)
Clear and colourless solution.

One bottle of 750 g of solution contains:

Active substance:

Oxalic acid dihydrate 35.0 g (equivalent to 25.0 g of oxalic acid)
Clear and colourless solution.

One sachet of 125 g of powder contains:

Excipients:

Sucrose 125 g

1 ml of mixed bee-hive dispersion contains:

Active substance:

Oxalic acid dihydrate 39.4 mg (equivalent to 28.1 mg of oxalic acid)
Colourless, clear to slightly turbid dispersion.

4. INDICATION(S)

For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In clinical trials, increased bee mortality was very commonly observed. This did not affect long-term development of colonies.

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 bees (*Apis mellifera*)

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

In-hive use.

Dose:

A maximum dose of 5-6 ml of the final bee-hive dispersion should be administered once per seam occupied by bees. The total amount of product administered to a colony should not exceed 54 ml. Therefore, if necessary, the dose per seam should be reduced in order not to exceed the maximum total amount administered per colony (calculation: maximum dose per colony/number of occupied seams= x.x ml/seam).

The use of Dany's BienenWohl with the above dosing scheme only applies to hives with vertical frames that can be accessed from the top, as the treatment of bees in other types of hives has not been investigated.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered using a suitable measuring device with appropriate graduations (e.g. automatic pipette, disposable syringe) onto the bees sitting in seams.

The final bee-hive dispersion is to be trickled onto the bees in the seams. Dosing should be done carefully and overdosing should be avoided.

The solution should be warm (30 – 35 °C) during application.

The outside temperature during treatment with Dany's BienenWohl should be at least 3 °C.

Apply only one treatment per hive.

In case the final dispersion had been stored, it should be well shaken before use.

Preparation of the final dispersion:

Before use the content of the sachet(s) containing the flavoured sucrose powder should be added to the bottle containing the solution for bee-hive dispersion as follows:

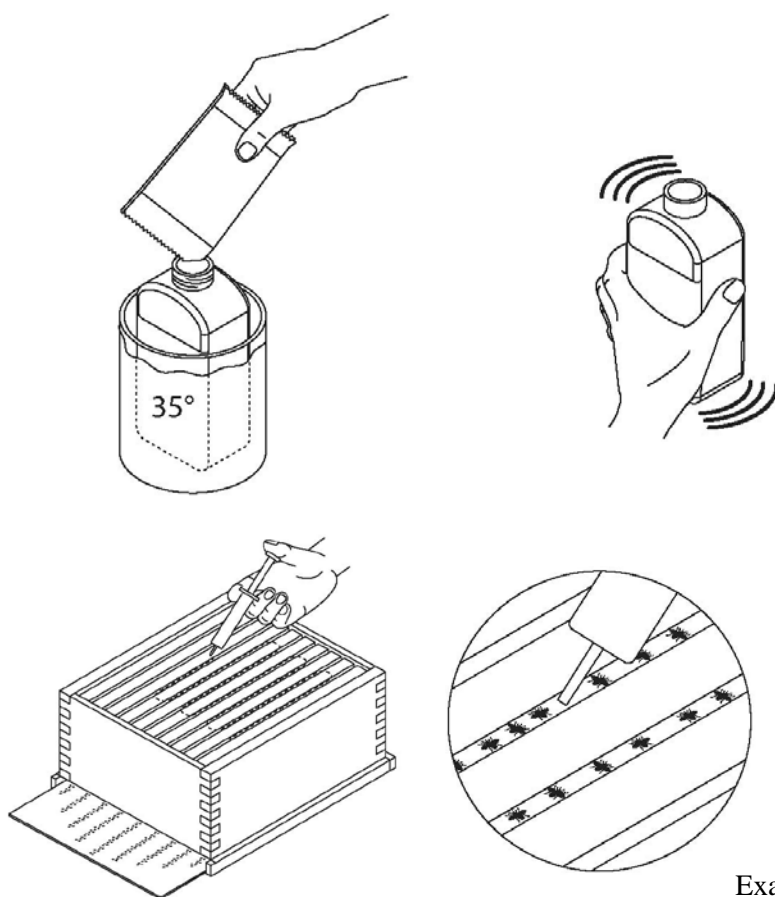
Place the bottle containing the oxalic acid dihydrate solution into warm (30 – 35 °C) water. Open the sachet(s) of the sucrose powder with a pair of scissors.

Preparation of the 444 ml final bee-hive dispersion: Pour the content of one sachet into the bottle containing 375 g of the oxalic acid dihydrate acid solution.

Preparation of the 888 ml final dispersion: Pour the content of the two sachets into the bottle containing 750 g of the oxalic acid oxalic dihydrate acid solution.

The full content of the sachet(s) should be poured into the bottle with the solution.

Close the bottle tightly and shake it until the sucrose is completely dissolved. The final bee-hive dispersion should be a colourless, clear to slightly turbid dispersion.



Example of measuring device

10. WITHDRAWAL PERIOD(S)

Honey: Zero days.

Do not use during honey flow.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the bottle and the sachet in the outer carton in order to protect from light.

After mixing the bee-hive dispersion: Store in a refrigerator (2 °C – 8 °C).
Store away from food.

Do not use this veterinary medicinal product after the expiry date which is stated on the labels and the cardboard box. The expiry date refers to the last day of that month.

Shelf life after mixing according to directions: 1 year.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Dany's BienenWohl must only be applied only once in brood-free colonies. The veterinary medicinal product should be used as a treatment within an Integrated Varroa Management program with mite drop monitored regularly.

When possible, rotate the use of this product with another approved varroacide with a different mode of action to decrease the potential for *Varroa* mites to develop resistance.

Special precautions for use in animals:

Do not use higher doses than the recommended dose, and do not administer this veterinary medicinal product more than once. Repeated treatments are not well tolerated by bees. If worker bees are treated more than once per generation, it can result in damage to the bees and a reduction in strength of the colony.

All colonies in the same apiary should be treated simultaneously to avoid re-infestations. Avoid disturbance to the hives the days after treatment.

Dany's BienenWohl should not be used when honey supers are present.

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

This veterinary medicinal product is highly acidic and could have irritating and corrosive effects on skin, eyes and mucous membranes.

Avoid oral exposure, including hand-to-mouth contact.

Avoid direct skin and eye contact, as well as hand-to-eye contact.

Personal protective equipment consisting of protective clothing, acid-proof gloves and safety glasses should be worn.

Wash hands and exposed skin with soap and plenty of water immediately. Do not eat, drink or smoke whilst handling and applying the veterinary medicinal product.

Remove contaminated clothing immediately. Used measuring devices and empty containers should be disposed of immediately in a proper way.

In case of accidental ingestion, clean the mouth with water and drink water or milk, but do not induce vomiting. In case of eye contact, immediately rinse the eye thoroughly with water (remove contact

lenses first). Seek medical advice immediately and show the package leaflet or the label to the physician.

Dany's BienenWohl has corrosive properties on corrosion-sensitive parts of beekeeping equipment.

Interaction with other medicinal products and other forms of interaction:

None known.

The concomitant use of other acaricidal products should be avoided because increased toxicity to bees might occur.

Overdose (symptoms, emergency procedures, antidotes):

After overdosing, increased bee mortality was very commonly observed. An overdose of 53% of the dispersion per treatment resulted in a temporary, short-term increase in bee mortality. The overdose did not significantly affect the development of the colonies in the long term, as shown by the development of the colonies in spring.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Dany's BienenWohl should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

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

Pack sizes:

One cardboard box containing one 500 ml bottle (containing 375 g oxalic acid dihydrate solution) and one sachet (containing 125 g sucrose powder), providing 444 ml of the final bee-hive dispersion after mixing.

One cardboard box containing one 1000 ml bottle (containing 750 g oxalic acid dihydrate solution) and two sachets (each containing 125 g sucrose powder), providing 888 ml of the final bee-hive dispersion after mixing.

Not all pack sizes may be marketed.