ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

VIRBAC
1ère avenue – 2065 m – L.I.D. – 06516 Carros - France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance : Ivermectin.

3. PHARMACEUTICAL FORM

Pour-On solution

4. PACKAGE SIZES

500 ml

5. TARGET SPECIES

Cattle

6. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml per 10 kg bodyweight. Assess bodyweight as accurately as possible before calculating the dosage. Apply along the mid-line of the back in a narrow strip between the withers and tailhead.

7. WITHDRAWAL PERIOD

Meat and offal: 28 days.
Not permitted for use in lactating cows producing milk for human consumption. Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

14. MARKETING AUTHORISATION NUMBER

Vm 05653/5061

15. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 litre bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance : Ivermectin.

3. PHARMACEUTICAL FORM

Pour-On solution

4. PACKAGE SIZES

1 L

5. TARGET SPECIES

Cattle

6. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml per 10 kg bodyweight. Assess bodyweight as accurately as possible before calculating the dosage. Apply along the mid-line of the back in a narrow strip between the withers and tailhead.

7. WITHDRAWAL PERIOD

Meat and offal: 28 days.
Not permitted for use in lactating cows producing milk for human consumption. Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

14. MARKETING AUTHORISATION NUMBER

Vm 05653/5061

15. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

2.5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance : Ivermectin.

3. PHARMACEUTICAL FORM

Pour-On solution

4. PACKAGE SIZES

2.5 L

5. TARGET SPECIES

Cattle

6. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml per 10 kg bodyweight. Assess bodyweight as accurately as possible before calculating the dosage. Apply along the mid-line of the back in a narrow strip between the withers and tailhead.

7. WITHDRAWAL PERIOD

Meat and offal: 28 days.
Not permitted for use in lactating cows producing milk for human consumption. Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

14. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5061

15. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance : Ivermectin.

3. PHARMACEUTICAL FORM

Pour-On solution

4. PACKAGE SIZES

5 L

5. TARGET SPECIES

Cattle

6. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml per 10 kg bodyweight. Assess bodyweight as accurately as possible before calculating the dosage. Apply along the mid-line of the back in a narrow strip between the withers and tailhead.

7. WITHDRAWAL PERIOD

Meat and offal: 28 days.
Not permitted for use in lactating cows producing milk for human consumption. Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

14. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5061

15. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin ..... 0.5 % w/v (5 mg/ml)

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

500 ml

4. WITHDRAWAL PERIOD

Meat and offal: 28 days.

5. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

6. BATCH NUMBER

<Batch> <Lot> <BN>

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 litre bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin ..... 0.5 % w/v (5 mg/ml)

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

1 L

4. WITHDRAWAL PERIOD

Meat and offal: 28 days.

5. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

6. BATCH NUMBER

<Batch> <Lot> <BN>

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

2.5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin ..... 0.5 % w/v (5 mg/ml)

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

2.5 L

4. WITHDRAWAL PERIOD

Meat and offal: 28 days.

5. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

6. BATCH NUMBER

<Batch> <Lot> <BN>

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin ..... 0.5 % w/v (5 mg/ml)

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

5 L

4. WITHDRAWAL PERIOD

Meat and offal: 28 days.

5. SPECIAL STORAGE CONDITIONS

After the first opening of the container : 6 months.
Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed in an upright position. Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

6. BATCH NUMBER

<Batch> <Lot> <BN>

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

B. PACKAGE LEAFLET

PACKAGE LEAFLET

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

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

Marketing authorisation holder

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer

VIRBAC
1ère avenue – 2065 m – L.I.D. – 06516 Carros - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC
Pour-On solution for cattle 5 mg/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE

Ivermectin ..... 0.5 % w/v (5 mg/ml)

4. INDICATION(S)

VIRBAMEC Pour-on is indicated for the treatment of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites, sucking and biting lice of beef and non-lactating dairy cattle.

Gastro-intestinal roundworms (adults and 4th stage larvae):

Ostertagia ostertagi	(L4, adults and inhibited stages)
Haemonchus placei	(L4, adults)
Trichostrongylus axei	(L4, adults)
Trichostrongylus colubriformis	(L4, adults)
Cooperia spp.	(adults)
Cooperia puntacta	(adults)
C*ooperia oncophora*	(adults)
Oesophagostomum radiatum	(L4, adults)

Strongyloides papillosus	(adults)
Trichuris spp.	(adults)

Lungworms (adults and 4th stage larvae):

Dictyocaulus viviparus

Warbles (parasitic stages):

Hypoderma bovis
Hypoderma lineatum

Mites:

Sarcoptes scabiei var bovis
Chorioptes bovis

Lice:

Sucking lice
Linognathus vituli
Haematopinus eurysternus

Biting lice
Damalinia bovis

VIRBAMEC Pour-On, at the recommended use level of 500 mcg ivermectin per kg bodyweight, has a persistent activity on:

Dictyocaulus viviparus:	for up to 28 days
Ostertagia spp:	for up to 21 days
Oesophagostomum radiatum:	for up to 21 days
Cooperia spp.:	for up to 14 days
Trichostrongylus axei:	for up to 14 days

Virbamec Pour on helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

VIRBAMEC Pour-On has also a persistent activity on the horn Fly (*Haematobia irritans)* for 28 days, partial efficacy may last for up to 35 days post application.

Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia spp*, *Trichostrongylus axei* and *Trichostrongylus colubriformis.*

To obtain optimal benefit of VIRBAMEC Pour-on, the product is recommended to be used as part of treatment programs, based on the epidemiology of the parasites in question

5. CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to the active substance.
This product is for application to skin surface only, do not inject or give orally.
Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption.
Do not use in pregnant dairy heifers within 60 days prior to calving.

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Posology:
1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg ivermectin per kg bodyweight).

Administration:
Topical administration.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

9. ADVICE ON CORRECT ADMINISTRATION

<u>500 ml and 1L VIRBAMEC Pour-on bottles</u>

Both are equipped with a Squeeze-Measure-Pour System.

Attach the metering cup firmly to the bottle.

Set the dose by turning the top section of the cup to align the correct bodyweight. When bodyweight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

When the pressure is released, the dose automatically adjusts to the correct level. Tilt the bottle and dispense the solution.

Important- Keep upright when filling and during storage.

Close container when not in use and store in an upright position.

2.5 litre backpack and 5 litre backpack

These presentations are equipped with straps and a vented cap.

They should be used in conjunction with an appropriate dosing gun.

Connect the Pour-On applicator to the pack as follows:

Attach the open end of the draw-off tubing to the Pour-On applicator.

Attach draw-off tubing to the cap with the stem. Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.

Gently prime the Pour-On applicator, checking for leaks.

Follow manufacturer's directions for correct use and care of the equipment.

10. SPECIAL PRECAUTIONS FOR USE IN ANIMALS

Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

Cattle should not be treated when the hair or hide is wet. Rain falling on animals less than two hours after dosing may result in reduced efficacy. However, under such conditions efficacy of VIRBAMEC Pour-On against infections of *Ostertagia ostertagi* or *Dictyocaulus viviparus* in cattle may be maintained. The influence of extreme weather conditions on the long-term performance (persistent activity) of VIRBAMEC Pour-On is not known.

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Frequent and repeated use may lead to the development of resistance.

The product is effective in all hypodermosis stages, however, it is very important to treat on time (at the end of warble fly season). The elimination of *Hypoderma* larvae may cause negative reactions on the host, when they are found in vital areas. Killing *Hypoderma lineatum*, if found in perioesophageal tissue, may cause salivation and tympanism. Killing *Hypoderma bovis*, if found in the vertebral canal, may cause unsteadiness or paralysis. Cattle should be treated before or after those stages of warble flies.

11. WITHDRAWAL PERIOD

Meat and offal: 28 days.

Not permitted for use in lactating cows producing milk for human consumption. Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

12. SPECIAL STORAGE PRECAUTIONS

Highly flammable - Do not smoke. Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container and keep tightly closed.
Keep the container in the outer carton in order to protect from light.
The container should be stored in an upright position.
Storage temperature: none.
If stored at low temperatures below 0°C, VIRBAMEC Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

13. SPECIAL WARNINGS

Care should be taken to avoid the following practices because they increase the risk of the development of resistance and could ultimately result in ineffective therapy:

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin (an avermectin) has been reported in *Cooperia oncophora* in cattle within the EU, in *Teladorsagia* in cattle in developed countrie such as New Zealand and *Haemonchus* in cattle outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

VIRBAMEC Pour-On may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves, rubber boots and a waterproof coat when applying the product. Protective clothing should be washed after use.

If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well ventilated areas or outdoors.

HIGHLY FLAMMABLE.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 13 November 2024
Gavin Hall