ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle (AT, BE, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SI, SK, UK)

Vigophos vet 100 mg / ml + 0.05 mg / ml solution for injection for cattle (SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

Excipients:

Benzyl alcohol (E1519)	10.00 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, reddish to red solution

4. CLINICAL PARTICULARS

4.1 Target species:

Cattle

4.2 Indications for use, specifying the target species

For the supportive treatment of secondary ketosis (e.g in abomasal displacement).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

People with known hypersensitivity to any of the ingredients should avoid contact with the product.

The product might be mildly irritating to the skin or the eye. Dermal and ocular exposure should therefore be avoided. In case of exposure rinse the skin and/or the eye with water.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy and lactation

No negative effects on the use of the product during pregnancy or lactation have been reported. Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intravenous use.

Cattle: 5 mg of butafosfan and 2.5 µg of cyanocobalamin per kg bodyweight (bw) corresponding to 5 ml / 100 kg bw daily with an 24 hour interval for three consecutive days.

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

None known.

4.11 Withdrawal periods

Cattle:
Meat and offal: zero days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Alimentary tract and metabolism, mineral supplements, other mineral supplements, other mineral products, butafosfan.
ATCvet code: QA12CX91

5.1 Pharmacodynamic properties

Cyanocobalamin is a co-enzyme in the biosynthesis of glucose from propionate. Further it serves as a co-factor to enzymes important in fatty acid synthesis and is important for maintenance of normal haemopoiesis, protection of the liver, maintenance of muscle tissue, healthy skin, brain and pancreatic metabolism. It belongs to the class of water-soluble B vitamins synthesized by the microbiotic

flora in the digestive system of the animals (reticulorumen and large intestine). Owing to the microbes' own requirements, the synthesis usually does not produce sufficient quantities to cover the needs of the entire animal organism. Marked deficiencies occur rarely, even in case of an inadequate supply with cyanocobalamin.
Butafosfan is an organic phosphorus source for animal metabolism. Among others phosphorus is relevant for energy metabolism. It is essential for gluconeogenesis since most intermediates of that process need to be phosphorylated. Direct pharmacological effects of butafosfan beyond simple phosphorus substitution have additionally been postulated.

The exact mode of action of cyanocobalamin and butafosfan in combination is not fully understood. Various effects on bovine lipid metabolism of cyanocobalamin and butafosfan in combination have been observed in clinical studies including reduced serum levels of ketosis-related nonesterified fatty acids and β-hydroxybutyric acid.

5.2 Pharmacokinetic particulars

Following intravenous administration of a single dose in cattle, the organophosphorus compound butafosfan is distributed in the extravascular space within minutes and rapidly excreted from the body unchanged. The elimination half-life is 83 minutes. Within twelve hours after intravenous administration, 70-90% of the dose are excreted in the urine, 1% is excreted via the faeces. Only traces of butafosfan are found in the milk. Metabolic degradation was not detected. The metabolism of cyanocobalamin is complex and is associated closely with that of folic acid and of ascorbic acid. Vitamin B12 is stored in significant amounts in the liver, further storage sites include kidney, heart spleen and brain. Tissue half-life of vitamin B12 is 32 days. In ruminants vitamin B12 is excreted primarily in the feces and in smaller amounts in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium hydroxide (for pH adjustment)
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	4 years
Shelf life after first opening of the immediate packaging:	28 days

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

100 ml Type II amber glass vial closed with a coated bromobutyl or chlorobutyl rubber stopper and sealed with an aluminium cap.

Carton of 1 x 100 ml, 6 x 100 ml or 12 x 100 ml

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.

7. MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle (AT, BE, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SI, SK, UK)

Vigophos vet 100 mg / ml + 0.05 mg / ml solution for injection for cattle (SE)

butafosfan, cyanocobalamin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intraveneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period(s):

Cattle:

Meat and offal: zero days
Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening of the immediate packaging: 28 days

Once opened use by……

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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. To be supplied only on veterinary prescription.

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

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

XXXXX

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle (AT, BE, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SI, SK, UK)

Vigophos vet 100 mg / ml + 0.05 mg / ml solution for injection for cattle (SE)

butafosfan, cyanocobalamin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 100 ml, 6 x 100 ml, 12 x 100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intraveneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period(s):

Cattle:

Meat and offal: zero days
Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening of the immediate packaging: 28 days

Once opened use by……

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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. To be supplied only on veterinary prescription.

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

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

XXXXX

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle
Vigophos vet 100 mg / ml + 0.05 mg / ml solution for injection for cattle

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

Marketing authorisation holder:

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

Manufacturers responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle (AT, BE, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SI, SK, UK)

Vigophos vet 100 mg / ml + 0.05 mg / ml solution for injection for cattle (SE)

butafosfan, cyanocobalamin

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

1 ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

Excipients:

Benzyl alcohol (E1519)	10.00 mg

Clear, reddish to red solution.

4. INDICATION(S)

For the supportive treatment of secondary ketosis (e.g in abomasal displacement).

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

For intravenous use

Cattle: 5 mg of butafosfan and 2.5 µg of cyanocobalamin per kg bodyweight (bw) corresponding to 5 ml / 100 kg bw daily with an 24 hour interval for three consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Cattle:

Meat and offal:	zero days
Milk:	zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Shelf life after first opening of the immediate packaging: 28 days

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.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Not applicable.

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

People with known hypersensitivity to any of the ingredients should avoid contact with the product.

The product might be mildly irritating to the skin or the eye. Dermal and ocular exposure should therefore be avoided. In case of exposure rinse the skin and/or the eye with water.

Pregnancy and lactation:

No negative effects on the use of the product during pregnancy or lactation have been reported. Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes:

None known.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
1 x 100 ml, 6 x 100 ml, 12 x 100 ml

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.