I. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Strep *Sa*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml of vaccine:

Active substance(s)

1.36 x 10^8 bacterial cells of *Streptococcus agalactiae* TI 513

Adjuvant:

ISA 763A VG

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Fish.

4.2 Indications for use

For active immunization of susceptible fish species (see also 4.4) to reduce mortality and disease due to Streptococcosis caused by *Streptococcus agalactiae*[1].

Onset of immunity demonstrated from 3 weeks after vaccination at a water temperature of 28°C. Duration of immunity demonstrated for at least 30 weeks after a single vaccination.

In the field it has been observed that the food conversion rate is significantly improved in vaccinated fish under disease pressure.

4.3 Contraindications

None known.

4.4 Special warnings (for each target species)

The vaccine has been tested for safety and efficacy in Tilapia (*Oreochromis* sp.) as a representative species. The vaccine may be used in other fish species. However, if so, its use should be undertaken with care and it is advisable to test the vaccine on a small number of fish prior to mass vaccination.

4.5 Special precautions for use, including special precautions to be taken by the person administering the veterinary medicinal product to animals

Personal protective equipment consisting of e.g. needle protector should be used when handling the product. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

To the user:

This product contains oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

[1] Previously known as *Streptococcus difficilis*

If pain persists for more than 12 hours after medical examination, seek medical advice again.
To the physician:
This product contains oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions
A small population of treated animals may show very minor lesions.

4.7 Use in broodstock animals
No adverse reaction expected.

4.8 Interaction with other medicinal products and other forms of interaction
No information is available on the compatibility of this vaccine with any other.

4.9 Amounts to be administered and administration route
Inject 0.05 ml intraperitoneally in fish of minimum 15 gram. Ensure the needle penetrates through the muscle wall and ideally deposits the vaccine into the visceral fatty area. For example, in barramundi (*Lates calcarifer*) and tilapia (*Oreochromis spp*) of 15 gram this is between and just before the tip of the pelvic fins. This is to ensure the needle does not penetrate important internal organs such as the liver, stomach and spleen.
Shake the vaccine well before use.
Sterile injection equipment should be used.
For injection, fish should be anaesthetised.
Food should be withheld for a period of 1 day prior to vaccination.
Avoid stress in the period prior to and after vaccination.

4.10 Overdose
No other symptoms expected than those indicated in 4.6.

4.11 Withdrawal period
Zero days.

5. IMMUNONOLOGICAL PROPERTIES

To stimulate active immunity against strains of *Streptococcus agalactiae* covered by the vaccine strain.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
None known.

6.2 Shelf life
Shelf-life of the product as packaged for sale: 3 year
Opened bottles should be used promptly (within 5 hours) and should not be stored.

6.3 Special precautions for storage
Store at 2 - 8°C. Protect from light. Do not freeze.

6.4 Nature and contents of container

PET or glass bottles closed with a rubber stopper and sealed with a coded aluminium cap. Package size: 50 ml (1 000 doses), 100 ml (2 000 doses), 250 ml (5 000 doses), 500 ml (10 000 doses) or 1 000 ml (20 000 doses). Not all pack sizes may be marketed.

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

Any unused vaccine or waste materials should be disposed of in accordance with the local requirements.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV

ANNEX A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AquaVac Strep *Sa*

2. COMPOSITION PER DOSE
The vaccine contains inactivated *Streptococcus agalactiae* cells with oil adjuvant.

3. PACKAGE SIZE
50 ml, 100 ml, 250 ml, 500 ml or 1000 ml

4. INDICATIONS FOR USE
Aid in protection against *Streptococcus agalactiae* (previously known as *Streptococcus difficilis*) infections in susceptible fish species.

5. METHOD AND ROUTE(S) OF ADMINISTRATION
Inject 0.05 ml intraperitoneally in fish of minimum 15 gram.
For details, see package insert.

6. EXPIRY DATE
EXP:

7. SPECIAL STORAGE CONDITIONS
Shake well before use. Store and transport at 2-8°C. Do not freeze.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"
For animal treatment only.

9. THE WORDS "KEEP OUT OF REACH OF CHILDREN"
Keep out of reach of children.

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Product of Intervet International B.V.
Boxmeer - Holland

11. MANUFACTURER'S BATCH NUMBER
LOT: ……..

ANNEX B. PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AquaVac Strep *Sa*

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)
The vaccine contains inactivated *Streptococcus agalactiae* TI 513 cells with oil adjuvant.

3. PRODUCT OF INTERVET INTERNATIONAL
BOXMEER - HOLLAND

4. TARGET SPECIES
Fish.

5. INDICATION(S)
Aid in protection against *Streptococcus agalactiae* infections in susceptible fish species (see also 11 below).

6. DOSAGE FOR EACH SPECIES
Each animal should receive one dose of vaccine.

7. ADVICE ON CORRECT ADMINISTRATION
Inject 0.05 ml intraperitoneally in fish of minimum 15 gram. Ensure the needle penetrates through the muscle wall and ideally deposits the vaccine in the peritoneal cavity where the visceral fat is located. For example, in barramundi (*Lates calcarifer*) and tilapia (*Oreochromis spp*) of 15 gram this is between and just before the tip of the pelvic fins. This is to ensure the needle does not penetrate important internal organs such as the liver, stomach and spleen.
Shake the vaccine well before use.
Sterile injection equipment should be used.
For injection, fish should be anaesthetised.
Food should be withheld for a period of 1 day prior to vaccination.
Avoid stress in the period prior to and after vaccination.

8. CONTRA-INDICATIONS
None known.

9. WITHDRAWAL PERIOD
Zero days.

10. SPECIAL STORAGE CONDITIONS
Store at 2 - 8°C. Protect from light. Do not freeze.

11. SPECIAL WARNINGS
Personal protective equipment consisting of e.g. needle protector should be used when handling the product. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.
<u>To the user:</u>
This product contains oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

The vaccine has been tested for safety and efficacy in Tilapia (*Oreochromis* sp.) as a representative species. The vaccine may be used in other fish species. However, if so, its use should be undertaken with care and it is advisable to test the vaccine on a small number of fish prior to mass vaccination.

12. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED
[Month/Year) ……/…..]

13. OTHER INFORMATION
For animal treatment only.