1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac® Strep Sa1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)
Inactivated bacterial cells of *Streptococcus agalactiae* TI 1422 (serotype Ia)
Inactivated bacterial cells of *Streptococcus agalactiae* TI 1428 (serotype III)

Adjuvant:
Oil adjuvant

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 due to Streptococcosis caused by *Streptococcus agalactiae* Biotype I (serotype Ia and III).

Onset of immunity has been demonstrated from 1 week after vaccination at a water temperature of 28°C (196 degree days). Duration of immunity has been demonstrated for at least 12 weeks after a single vaccination and in the field protection was demonstrated for the entire grow-out period.

Under field conditions the feed conversion rate is significantly improved in vaccinated fish under disease pressure.

4.3 Contraindications

None known.

4.4 Special warnings (for each target species)

Fish should be healthy and free of disease at the time of vaccination. Sick or weak fish may not develop adequate immunity.

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.
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

The first week after vaccination fish may show loss of appetite, resulting in growth retardation in the first three weeks compared to non-vaccinated fish. A small population of treated animals may show very minor local reactions.

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 safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Food should be withheld for a period of 1 day prior to vaccination.
Avoid stress in the period prior to and after vaccination.
Sterile injection equipment should be used.
For injection, fish should be anaesthetised.
Shake the vaccine well before use.
Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram.

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 strains.

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 within a day 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

Plastic bottles closed with a rubber stopper and sealed with an aluminium cap.
Package size: 50 ml (1 000 doses), 100 ml (2 000 doses), 250 ml (5 000 doses), or 500 ml (10 000 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
Wim de Korverstraat 35
5831 AN Boxmeer
the Netherlands

ANNEX A. LABELLING

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AquaVac® Strep Sa1

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
The vaccine contains inactivated bacterial cells of *Streptococcus agalactiae* TI 1422 (serotype Ia) and *Streptococcus agalactiae* TI 1428 (serotype III)

3. INDICATIONS FOR USE
Vaccine against Streptococcosis caused by *Streptococcus agalactiae* Biotype I (serotype Ia and III).

4. PACKAGE SIZE
1 000 doses, 2 000 doses, 5 000 doses, or 10 000 doses

5. METHOD AND ROUTE(S) OF ADMINISTRATION
Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram.
For details, see package insert.

6. EXPIRY DATE
EXP:

7. SPECIAL STORAGE CONDITIONS
Shake well before use. Store dark 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 AND SIGHT OF CHILDREN"
Keep out of reach and sight of children

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Product of Intervet International B.V.
Boxmeer – the Netherlands

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

ANNEX B. PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AquaVac® Strep Sa1

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)
The vaccine contains inactivated bacterial cells of *Streptococcus agalactiae* TI 1422 (serotype Ia) and *Streptococcus agalactiae* TI 1428 (serotype III) with oil adjuvant.

3. PRODUCT OF INTERVET INTERNATIONAL
BOXMEER – THE NETHERLANDS

4. INDICATION(S)
For active immunization of susceptible fish species (see also section 12 below) to reduce mortality due to Streptococcosis caused by *Streptococcus agalactiae* Biotype I (serotype Ia and III).

Onset of immunity has been demonstrated from 1 week after vaccination at a water temperature of 28°C (196 degree days). Duration of immunity has been demonstrated for at least 12 weeks after a single vaccination and in the field protection was demonstrated for the entire grow-out period.

Under field conditions the feed conversion rate is significantly improved in vaccinated fish under disease pressure.

5. CONTRA-INDICATIONS
None known.

6. ADVERSE REACTIONS
The first week after vaccination fish may show loss of appetite, resulting in growth retardation in the first three weeks compared to non-vaccinated fish. A small population of treated animals may show very minor local reactions.

7. TARGET SPECIES
Fish.

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

9. ADVICE ON CORRECT ADMINISTRATION
- Food should be withheld for a period of 1 day prior to vaccination.
- Avoid stress in the period prior to and after vaccination.
- Sterile injection equipment should be used.
- For injection, fish should be anaesthetised.
- Shake the vaccine well before use.
- Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram.

10. WITHDRAWAL PERIOD
Zero days.

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

12. SPECIAL WARNINGS, IF NECESSARY

Special precautions for use in animals

Fish should be healthy and free of disease at the time of vaccination. Sick or weak fish may not develop adequate immunity.

The vaccine has been tested for safety and efficacy in Tilapia (*Oreochromis* sp.) as 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.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

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.
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.

13. OTHER INFORMATION

For animal treatment only.