SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan
Powder for suspension for fish treatment containing 50%w/w azamethiphos.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Azamethiphos 50% w/w

3. PHARMACEUTICAL FORM

Powder for suspension for fish treatment.
Wettable powder for dilution in water and subsequent administration by the bath technique.

4. CLINICAL PARTICULARS

4.1 Target species

Farmed Atlantic salmon (Salmo salar)

4.2 Indications for use (specifying the target species)

For the control of mature pre-adult to adult sea-lice (*Lepeophtheirus salmonis*) or (*Caligis* species) on farmed Atlantic salmon.

4.3 Contraindications

None

4.4 Special warnings (for each target species)

If signs of distress, e.g., fish falling on their side, occur after 30 minutes of treatment, remove the tarpaulin and ensure vigorous oxygenation of the water.

4.5 Special precautions for use

i. Special precautions for use in animals

At water temperatures above 10°C it is advisable to limit treatment periods to 30 minutes. Vigorous oxygenation of the water must be provided during treatment.

For external use only.

ii. Special precautions for the person administering the veterinary medicinal product to animals

MAY CAUSE SENSITISATION BY INHALATION AND SKIN CONTACT

The Control of Substances Hazardous to Health Regulations 1988 (COSHH) applies to the use of this product at work.
Salmosan contains azamethiphos. Azamethiphos is an organophosphorus compound. DO NOT USE if under medical advice not to work with such compounds.

WEAR SUITABLE PROTECTIVE CLOTHING (WATERPROOF COVERALLS), SUITABLE PROTECTIVE GLOVES (heavy duty gauntlet style nitrile at least 300mm in length and 0.5mm thick are recommended) AND FACE PROTECTION (FACE SHIELD) when handling the concentrate (i.e., mixing or transferring product from one container to another) and when applying the diluted chemical to the pen. Renew protective clothing and gloves regularly and certainly when cracking or damage has occurred. Initial dilution of the water soluble bags into a small volume of distilled water must be carried out on land, ensure that the drum container is securely closed during this process.

RINSE APPLICATION EQUIPMENT AND CONTAINERS AFTER USE
WASH ALL PROTECTIVE CLOTHING thoroughly after use especially the iinsides of gloves.
REMOVE HEAVILY CONTAMINATED CLOTHING IMMEDIATELY, wash or destroy.
DO NOT EAT, DRINK OR SMOKE without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.
AVOID ALL CONTACT BY MOUTH, WITH THE SKIN OR EYES.
ACCIDENTAL SPLASHES ON EXPOSED SKIN OR EYES should be washed off immediately with plenty of water.
WASH HANDS, FACE AND EXPOSED SKIN after leaving the work area.
KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.

MEDICAL ADVICE TO USERS

- If you have previously felt unwell after using a product containing an organophosphorus compound consult your doctor before working with this product and show your doctor the product label
- If you feel unwell after using this product consult your doctor and show your doctor the product label.
- Treat any cases of heavy contamination as an emergency. You should go straight to hospital after removing contaminated clothing, and rinse with plenty of water areas of skin which came into contact with the product.
- If the product has been swallowed go straight to hospital and take the product label with you.

MEDICAL ADVICE TO DOCTORS

Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, with a resultant over-activity of acetylcholine. Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils and bronchorrhea. These may develop for up to 24 hours after exposure. Severe poisoning can include general muscle twitching, loss of coordination, extreme difficulty with breathing and convulsions which may lead to unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.
Advice on clinical management is available from the National Poisons Information Service.

REPORTING INCIDENTS

Illness suspected to be a result of working with Salmosan may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985. If in doubt contact your local Health and Safety Executive Officer.

Report human or veterinary suspected adverse reactions to the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS.

Further advice can be obtained from: Fish Vet Group, 22 Caresgate Road, Inverness, IV3 8EX, Scotland. Tel: +44 (0) 1463 717774.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amount(s) to be administered and administration route

READ THE OPERATOR PRECAUTIONS AND ENVIRONMENTAL WARNINGS. The prescribing veterinary surgeon must ensure that farm staff have received adequate instruction in the safe use of Salmosan.

Salmosan should be applied to salmon suffering from infestation with mature (pre-adult to adult) sea-lice (*Lepeophtheirus salmonis*) or (*Caligis* species) before the stage at which serious skin damage is evident. The exact timing of a treatment and setting up of a treatment programme is a matter of expertise and judgement; operators must seek the advice of the prescribing veterinary surgeon.

Salmosan does not affect juvenile attached sea-lice which will be present with the pre-adult and adult stages. These juvenile stages will develop into pre-adults and adults in 10 to 20 days, when a population count should show whether a second treatment is necessary. A third treatment may be necessary after another 14 days, after which fish should be lice free for considerable periods, if all fish on the site have been simultaneously treated.

Fish affected by sea-lice should be bathed in 0.2 ppm Salmosan (0.1 ppm azamethiphos) for a period of not less than 30 minutes and not more than 60 minutes. At water temperatures above 10°C it is advisable to limit treatment periods to 30 minutes. Assess water volume as accurately as possible.

During treatment, careful observation of fish behaviour must be maintained. If signs of distress, e.g., fish falling on their side, occur after 30 minutes of treatment, remove tarpaulin and ensure vigorous oxygenation of the water. Oxygenation must be provided during treatment. Vigorous oxygenation is recommended in the treatment cage. Where several cages are to be treated a large reservoir of oxygen bottles should be available.

On dry land, not more than 48 hours prior to treatment, operators wearing suitable equipment and protective clothing, (See OPERATOR PRECAUTIONS), should place the required number of water soluble bags of Salmosan required for the dosage of an individual cage into a labelled screw-topped polyethylene container, together with a quantity of distilled water (1 litre or more of distilled water for every 200g of Salmosan).

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2g of Salmosan powder must be added per cubic metre of water, i.e., 1 x 20g sachet treats 100 cubic metres.

Screw the lid tightly onto the container and gently shake this intial dilution for up to 5 minutes. When fish are ready to be treated, the diluted suspension of Salmosan should be further diluted into approximately 200 litres of sea water and gently stirred for 5 minutes. The polyethylene container, in which the first dilution was prepared, should be rinsed with sea water and the rinsing from this should be added to the next dilution. This latter mixture should then be immediately and carefully added to the cage by pouring or pumping the

mixture into the water at the oxygen diffuser points using the Bath Technique.

THE BATH TECHNIQUE

In this technique, the depth of the fish cage net is reduced to a known depth at the centre, e.g., 2 metres, and a tarpaulin placed around the net so that it is totally enclosed. Ensure the base of the cage is not drooping when in the raised position as fish may congregate and come to harm. Oxygen is immediately bled into the system and Salmosan is added. After 30 to 60 minutes the tarpaulin is removed.

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

Azamethiphos induces little change in brain acetylcholinesterases at therapeutic concentrations but some fish may show hyperactivity. At concentrations in excess of 0.1ppm signs of stress, stupor and in extreme cases death may occur. If acute toxicity is seen the treatment should be stopped and oxygenation increased to aid recovery.

4.11 Withdrawal period(s)

Fish for human consumption may be taken only after 24 hours after the end of the treatment.

5. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP 53 AF 17

Antiparasitic Products, Insecticides and Repellants

5.1 Pharmacodynamic properties

Organophosphorus insecticide, acting by anticholinesterase activity.

5.2 Pharmacokinetic properties

Radiolabelled metabolism studies in salmon have shown azamethiphos residues in tissues and organs are depleted quickly and are below the limit of detection within 1 hour of immersion in a bath containing the maximum recommended dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lauryl Sulphate
Naphthalene Sulphonic Acid Formaldehyde Concentrate
Kaolin Light
Silicic Acid Precipitated

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
18 months

6.4 Special precautions for storage

Do not store above 25ºC
Store in the original unopened packaging
Store in a dry place
Store away from food, drink and animal feedingstuff

6.5 Nature and composition of immediate packaging

Heat-sealed PVA water soluble bag containing 20g or 100g of product contained in a sealed polyethylene lined paper sachet.
5 x 20g or 2 x 100g packages in a box.

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

Salmosan is dangerous to many organisms. The fastest and therefore most important detoxification mechanism in coastal waters is dilution which is increased by water movements including the flushing effect in sea lochs.

Do not use Salmosan prophylactically. Only use when infestation with adult lice has been diagnosed.

Salmosan is dangerous to fish and other aquatic organisms in the concentrated form. Do not contaminate ponds, streams, lochs or inlets with product or used packaging.

Do not re-use packaging for any purpose.

Salmosan is a Prescription Only Medicine under the Medicines Act (1968). Use of this product at certain sites with lower water movements may be restricted or prohibited. The user must therefore apply for and obtain discharge consent at each individual site from the Scottish Environment Protection Agency (Environment Agency in England and Wales, Environmental Division of the Department of the Environment for Northern Ireland) prior to the use of this product.

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

7. MARKETING AUTHORISATION HOLDER

Fish Vet Group Limited
22 Carsegate Road
Inverness
IV3 8EX
Scotland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 33459/4000

9. DATE OF FIRST AUTHORISATION

24th December 1996

10. DATE OF REVISION OF THE TEXT

March 2011