Salmosan® Vet

TRUST IN QUALITY

Benchmark Animal Health
In the fight to manage sea lice, your operation looks to a reliable and proven option which delivers effective treatment as part of a strategic de-lousing programme. Through working alongside salmon producers and understanding the needs of every stage in the supply chain, Salmosan® Vet has been continuously developed to become the market leading azamethiphos solution.

Effective, Flexible and Economical
- Optimal clearance — Salmosan® Vet is the only licensed azamethiphos treatment that can be used for a full 1-hour treatment at temperatures up to 15°C
- Greater practicality and efficacy at higher water temperatures
- Delivers exceptional dispersal rates
- Salmon can be treated with confidence and without veterinary deviation from the data sheet
- More effective treatment lessens the chance of resistance occurring
- 36 month shelf life, demonstrating excellent product stability
WE SET THE HIGHEST STANDARDS, ENABLING YOU TO MARKET YOUR FISH WITH 100% CONFIDENCE

Salmosan® Vet has been specifically developed to adhere to the strictest guidelines set by the European Medicines Agency. All the ingredients are fully approved for use in Atlantic salmon, therefore ensuring the integrity of your fish.

Our 5 year long campaign with the US Food and Drug Administration has led to the granting of an Import Tolerance for azamethiphos, this milestone achievement enables you to export Salmosan® Vet treated fish with confidence.
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan® Vet, Azamethiphos 500mg/w powder for suspension for fish treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

- Active substance: Azamethiphos 500mg
- Excipients: For the full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Powder for suspension for fish treatment. Light beige to beige powder.

4. CLINICAL PARTICULARS

4.1 Target species

Farmed Atlantic salmon (Salmosan salmon)

4.2 Indications for use (specifying the target species)

For treatment of pre-adult to adult sea lice (Lepeophtheirus salmonis or Caligus species) on farmed Atlantic salmon.

4.3 Contraindications

Do not use the product in cases of known hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings (for each target species)

The product does not treat juvenile attached sea lice which may be present with the pre-adult and adult stages. These juvenile stages develop into pre-adults and adults in 10 to 20 days when the population count should show whether a second treatment is necessary. All fish on the site should be simultaneously treated.

Resistance is known to occur where incomplete treatments are carried out. To help prevent resistance occurring ensure the correct dose and duration of treatment is accomplished. Only fully enclosed treatments should be used. Repeated use of the same class of chemotherapeutic agent may result in the development of resistance. In order to reduce the risk of resistance to the product developing, the product should be used as part of a rotational strategy in the medicinal treatment of sea lice.

Where there are concerns of decreasing sensitivity of lice to azamethiphos based products the maximum treatment time (60 minutes) should be used to achieve optimum efficacy and limit the opportunity for resistance development (see also section 4.5). If the presence of resistant lice on the farm has been confirmed, the treatment time may be extended to a maximum of 2 hours. Do not use the product prophylactically. Only use when infestation with mature lice has been diagnosed.

4.5 Special precautions for use

1. Special precautions for use in animals

For external use only.

Vigorous oxygenation of the water must be provided during treatment. It is recommended that oxygen addition begins before the tarpsaulins are fitted to the pens. During treatment, careful observation of fish behaviour should be maintained. If signs of distress, e.g., fish suffering balance problems during or shortly after treatment occur flush the treatment area with clean sea water and ensure vigorous oxygenation.

The product should be applied to salmon suffering from infestations with pre-adult and adult sea lice before the stage at which serious skin damage occurs.

A laboratory study was conducted to determine the safety of treatment at temperatures above 10°C for the maximum recommended treatment duration of 60 minutes. Salmon (with bodyweights from 350g) appeared to tolerate exposure to Salmosan® Vet at up to three times the recommended dose rate (i.e., 0.66m), for up to three times the recommended treatment time (i.e., 180 minutes) at both 2°C and 15°C.

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

This product contains azamethiphos. Azamethiphos is an organophosphorus compound. DO NOT USE if under medical advice not to work with such compounds.

THIS PRODUCT MAY CAUSE SENSITISATION (ALLERGY) BY SKIN CONTACT OR INHALATION.

AVOID ALL CONTACT WITH MOUTH, SKIN OR EYES.

ACCIDENTAL SPLASHES ON EXPOSED SKIN OR EYES should be washed off immediately with plenty of water.

WEAR SUITABLE PROTECTIVE CLOTHING SUCH AS WATERPROOF COVERALS, HEAVY DUTY GAUNTLET STYLE NITRILE GLOVES of at least 300 mm length and 0.5 mm thickness, FACE SHIELD AND RESPIRATORY PROTECTION, both when handling the concentrate and when applying the diluted chemical to the pen.

RENEW PROTECTIVE CLOTHING AND EQUIPMENT REGULARLY and certainly when cracking or splashing occurs.

WASH ALL PROTECTIVE CLOTHING thorougly after use, especially inside of gloves.

REMOVE HEAVILY CONTAMINATED CLOTHING IMMEDIATELY after a spill; wash or destroy.

Ensure that the drum/container is securely closed during the dissolving process.

DO NOT EAT, DRINK OR SMOKE without washing away from the work area, removing protective clothing and washing hands, face and exposed skin.

WASH HANDS, FACE AND ANY EXPOSED SKIN immediately after leaving the work area.

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.

RINSE APPLICATION EQUIPMENT AND CONTAINERS AFTER USE.

MEDICAL ADVICE TO USERS

- If you have previously experienced a reaction 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, if necessary, consult your doctor before working with this product and show your doctor the product label.

MEDICAL ADVICE TO DOCTORS

Poisoning from organophosphorus compounds results from blockade of acetylcholinesterase, with a resulting 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, diaphoresis, constriction of pupils and bronchoconstriction. These may develop for up to 24 hours after exposure.

Severe poisoning can involve 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

In the UK:

In Norway:

Adverse reactions, including human reactions, should be reported to the Norwegian Medicines Agency, www.noma.no.

Further advice can be obtained from: Fish Vet Group, Tel: +44 (0) 1463 717774, 24 hour emergency number 0845 0093342, or directly to the Veterinary Medicines Directorate online at http://www.vmd.defra.gsi.gov.uk/adverseeventreporting/

In Norway:

Adverse reactions, including human reactions, should be reported to the Norwegian Medicines Agency, www.noma.no.

further advice can be obtained from: Fish Vet Group, Tel: +44 (0) 1463 717774, info@fishvetgroup.com

II Other precautions

The product is very dangerous to crustaceans and is dangerous to fish and other aquatic organisms; therefore the product should not be used in seas where crabs and lobsters are kept in close proximity of the treated cages.

Use product and/or use on a larger scale may pose an increased risk to the environment. In order to ensure safe use (including large scale and multiple treatments) of the product under a combination of different environmental conditions (e.g. low water current speeds, shallow waters, short distance to the shore etc.), local environmental regulations governing discharges, where applicable, may be required to be adhered to. If there is any doubt about safe use, relevant competent authorities should be consulted or professional advice sought accordingly.

The most important mechanism for removal of the product in coastal waters is dilution which is increased by water movements including the flushing effects in sea lochs. After treatment, care should be taken to provide sufficient water exchange through the net to dilute residual azamethiphos.

Poisoning from organophosphorus compound...
When fish are ready to be treated, the diluted suspension of the product should be further diluted into approximately 200 to 1000 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 sea water dilution tank. This latter mixture should then be immediately and carefully added to the cage by pouring, or pumping the mixture into the water as evenly and efficiently as possible 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 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. The volume of water to be treated should be estimated as accurately as possible, restrictive tarpaulins can be used to give a better management of water volume and reduce the amount of product needed depending on biomass of fish to be treated. Oxygenation should begin before the tarpaulin is fitted and continue until the tarpaulin is fully removed after treatment. Once the tarpaulin is in place the product (in the seawater dilution) should be immediately added. When the addition of product diluted in seawater to the tarpaulined cage is completed the treatment time begins. At the end of the treatment time the tarpaulin should be removed as quickly as possible allowing the exchange of clean seawater into the cage. The Bath Technique is designed to ensure the product is used in a totally enclosed volume of water.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
During a study exposing salmon to up to three times the recommended dose rate for up to 180 minutes no adverse events were observed during the treatment period. However, a small percentage of fish showed reversible changes in colour after the 180 minute treatment period and a very small percentage of fish showed an irreversible loss of equilibrium (at doses of two and three times the recommended treatment dose). It is reported that prolonged exposure to azamethiphos 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 and the tarpaulin removed to aid recovery.

4.11 Withdrawal period(s)
Withdrawal period: 10 degree days.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Organophosphorus insecticide, acting by anticholinesterase activity. Resistance to azamethiphos and other organophosphates has been demonstrated in some sea-lice populations. Although the mechanism is not fully elucidated, it is probable that resistance is due to a genetic alteration of the enzyme acetylcholinesterase influenced by natural selection.

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 1 hour after immersion for 60 minutes in a bath containing the maximum recommended dose.

5.3 Environmental properties
Azamethiphos is highly soluble in water (>1g/l) with a low octanol/water partition coefficient (log Kow) of 1.0 g/ml. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not enter the sediments. Azamethiphos has a moderate propensity to adsorb to suspended organic matter; however it is unstable in salt water, degrading with a half-life of ~6.6 days (at 12°C), producing non-toxic transformation products. Hydrolytic degradation is the primary breakdown route but photolysis and microbial action will also hasten the process.

6. PHARMACOLOGICAL PARTICULARS

6.1 List of excipients
Sodium Lauryl Sulphate
Kaolin Light
Silicic Acid Precipitated

6.2 Incompatibilities
None known.

6.3 Shelf life
S half-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage
Do not store above 25°C
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 Pk 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
The product 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.
Any unused veterinary medicinal product or waste materials derived from such products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
FVS (Fish Vet Group) Limited
22 Carsegate Road
Inverness IV3 8EX
Scotland

8. MARKETING AUTHORISATION NUMBER
UK — Vm 33459/4001

9. DATE OF FIRST AUTHORISATION
10 December 2014

10. DATE OF REVISION OF THE TEXT
November 2018

Salmosan® Vet is supported by a team of professionals that offers extensive knowledge of sea lice control and salmonid aquaculture. Our support services include bioassays and on-site training and administration advice.

SERVICE AND SUPPORT
To discuss sea lice treatment programmes with the Salmosan® Vet team please contact: salmosanvet@bmkanimalhealth.com
Pharmacovigilance: info@bmkanimalhealth.com

IMPROVING AQUACULTURE HEALTH, WELFARE AND SUSTAINABILITY BY DEVELOPING PRODUCTS, GENETICS, SERVICES AND TRAINING
Benchmark Animal Health is part of Benchmark plc.

Working in aquaculture, the fastest growing segment of the food industry, we focus on tackling the main challenges such as disease, quality, profitability and sustainability.

Our aim is to be aquaculture’s leading provider of solutions in genetics, health and specialist nutrition.
Our mission is to enable food producers to improve their sustainability and profitability.

We bring together technology and fundamental biology to deliver products and solutions that support farmers throughout the growth cycle. We do this by improving the genetic make-up, health and nutrition of their stock — from broodstock and hatchery through to nursery and grow out.

By optimising the genetics, health and nutrition of our customers’ stock, as well providing them with the knowledge to determine livestock performance and understand disease threats, we can increase the productivity and sustainability of their business.

Malcolm Pye  
CEO, Benchmark

Being close to our customers is key

We have large-scale production facilities in seven countries, covering the main aquaculture regions, supported by a network of R&D and commercial operations in an additional 20 countries.

Our R&D facilities and farms are strategically located throughout the world, ensuring we are close to our customers. We have a strong commitment to innovation and the development of new products and solutions that meet the needs of our clients.

Benchmark at a Glance

Leading market positions  
Unique product offering  
Innovative technology  
Established track record

1066 Employees  
42 Nationalities

Malcolm Pye  
CEO, Benchmark

We know that biological control is key to the performance, productivity and long-term growth of our clients’ businesses.
**BENCHMARK’S OFFERING**

**OUR TECHNOLOGY**

- **Genetics**
  Improved genetics are the best start for disease resistance.

- **Advanced Nutrition**
  Specialist feed promotes growth and immunity.

- **Animal Health**
  New vaccines prevent disease and targeted treatments manage disease outbreaks.

- **Knowledge Services**
  Our offering includes industry education through accredited courses, training, conferences and publications and data and consultancy solutions.

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<tr>
<th>Eggs, breeding (parent stock) animals for salmon, shrimp and tilapia</th>
<th>Hatchery stage fish and shrimp</th>
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<td>Genetic improvement services to a broad range of industry players across 12 species</td>
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- **Probiotics**

- **Broodstock diets**

- **Hatchery diets**

- **Enrichment diets**

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- **Sea lice treatment**

- **Purification system**

**OUTPUTS**

- **Employees**
  Our growth and continued success is down to the hard work, talent and dedication of every member of our team. Our people strategy ensures that we offer rewarding careers where employees are motivated and inspired to make a difference.

- **Customers**
  Investment in our products and services has a high return relative to the substantial costs resulting from major disease challenges. Our offering drives consistency in supply and supports the long-term growth and sustainability of our customers’ business — improving yield, quality and animal health and welfare.

- **Shareholders**
  We are securing the technology at the heart of the ‘blue revolution’ — driving shareholder value as the industry grows.

- **Environment**
  We care for our planet by operating our business responsibly and by developing sustainable solutions that tackle some of the key environmental challenges in our industry. For example, Benchmark’s CleanTreat® purification system eliminates the discharge of medicinal bath treatments into the ocean and the development of modern probiotics and vaccines is reducing the need for antibiotics.

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*For marine species and shrimp*
COMMITTED TO THE SUSTAINABLE DEVELOPMENT OF THE AQUACULTURE INDUSTRY