Marine Fish Farm: Stulaigh South

Medicine Use

Mowi Scotland Limited

January 2023

Medicine Use

Stulaigh South Marine Pen Fish Farm, South Uist

Scope

This document outlines information requirements requested by SEPA in their standardized application form "Application for a new Permit FORM C-2", which requests –

A list of all chemicals and sea lice medicines which are intended to be used on the site*, including details of:

- the trade name of the medicine or chemical and the manufacturer;
- the active ingredient;
- a copy of the manufacturers data sheet for each medicine or chemical;
- a method statement explaining in detail how each medicine and chemical will be used;
- total quantity of neat medicine or chemical or the total quantity of active ingredient to be used in a single treatment;
- maximum concentration of the active ingredient for each medicine or chemical (where applicable) to be used in a single treatment;
- details of storage arrangements for medicines and chemicals;
- Information regarding any net anti-fouling coatings which may be used.

*You should check product documentation (or if necessary, with the manufacturers) to establish if any of the chemicals listed in Annex 2 of this form are present. If any of these chemicals are present, you must list them and estimate the quantities which will be used.

Table 1. Proposed Medicines - trade name, active ingredient, and manufacturer

Medicine	Active Ingredient	Manufacturer
AlphaMax/AMX	Deltamethrin	Pharmaq AS
Excis*	Cypermethrin	Novartis
Salmosan, Salmosan Vet	Azamethiphos	Benchmark Animal Health Ltd
Azasure		Ground Animal Health Ltd
Slice, Quinafish	Emamectin Benzoate	MSD Animal Health UK Ltd
Note. products which aren't listed on the VMD databased currently include AlphaMax, Salmosan, Excis, and Quinafish.		

Table 2. Summary of proposed treatment quantities

Active Ingredient	Recommended licence limit	No. pens able to be treated per day
Deltamethrin	25g	1.69 pens in 6 hours
Cypermethrin	68g	1.8 pens in 6 hours
Azamethiphos	750g	1 pen in 3-24hours
Emamectin Benzoate	151.0g of EmBZ.	This allows one treatment per cycle across the all pens

Table 3. Treatment Method

Medicine	Method
AlphaMax/AMX	Bath treatments in-situ by enclosing the target pen fully with a large tarpaulin, and bath treatments in well boats. Bath treatments (bath medicines and freshwater) are expected to be administered in wellboats due to the site conditions and proposed equipment.
Excis	
Salmosan, Salmosan Vet or Azasure	
Slice	In-feed

Medicine	Concentration of Active Ingredient	Max Treatment Conc Active Ingredient)	No of Applications Typically Needed for Each Treatment
AlphaMax/AMX	1% w/v	2 ppb (2 mg m^{-3})	1 per pen
Excis	1% w/v	5 ppb (5 mg m^{-3})	1 per pen
Salmosan, Salmosan Vet or Azasure	50% w/w	0.1 ppm (100 mg m^{-3})	1 per pen
Slice	0.2% w/w	50 - 60 µg/kg biomass/d	1 x 7 day treatment
Note: 1. w/v – weight by volume, w/w – weight by weight, ppm – parts per million, ppb – parts per billion; 2. Slice daily dose dependent upon prescription.			

- Details of storage arrangements for medicines and chemicals

Medicines and chemicals are stored at centralised locations registered with the Veterinary Medicines Directorate (VMD) and Royal College of Veterinary Surgeons (RCVS), currently located upon Skye, Uist, and in Fort William at three addresses. Registration is the responsibility of an allocated individual and allows Mowi to store and distribute the medications to it's seawater sites for use. Any medicines that are not used must be returned promptly to the registered stores. Medicines that are no longer required or have expired must be disposed of by an appropriate approved contractor. Monthly internal audits are also undertaken for sustainability reporting.

•Information regarding any net anti-fouling coatings which may be used.

Nets with an anti-fouling coating have not been in use as standard for many years and the company actively works towards zero use of anti-foulants. There have been recent scenarios which have needed the temporary use of anti-foulants during the installation of nylon nets. These nets were installed temporarily to support containment, and whilst further changes were implemented to the site equipment. During installation mitigation was applied, for example operating procedures stipulate that net cleaning is carried out at a lower pressure than nets which do not have anti-foulants, and requires a monitoring program of sampling. This scenario has since been resolved and the nets replace with net without anti-foulant coatings.

Mowi has made a commitment to work towards certifying our production units in accordance with the most stringent sustainability standard, the Aquaculture Stewardship Council (ASC) standard. Collectively, the ASC requirements related to copper encourage any sites that can do so to not use copper. Simultaneously, they recognise that in some situations phasing out copper usage may not yet be possible. In situations where copper is used, the standard outlines requirements for sustainable use. Broader research and development is being explored to find alternatives to the anti-foulant coatings available today.

For Stulaigh South new HDPE nets is expected to be introduced in the first instance; the specification for all 'high energy' fish farms, including the proposed development, will comprise 100% HDPE 'SealPro' or equivalent standard with Dyneema sinker tube dropper system. Therefore anti-foulants should not be needed as standard at the proposed site. If required, their use would be in response to a specific scenario, justified, mitigated and monitored. Action would be taken to find alternatives so use is temporary.

- a copy of the manufacturers data sheet for each medicine or chemical

Attached below for medicines currently listed on the VMD database.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMX 10 mg/ml Concentrate for solution for fish treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Deltamethrin 10 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for fish treatment
Slightly opaque, pale yellow liquid

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar*) and rainbow trout (*Oncorhynchus mykiss).*

4.2 Indications for use, specifying the target species

For treatment of adult and preadult sea lice (*Lepeophtheirus salmonis*) on Atlantic salmon (*Salmo salar*) and rainbow trout (*Oncorhynchus mykiss)*.

4.3 Contraindications

Do not use on fish with infectious diseases, as treatment against sea lice may aggravate the clinical signs and increase the mortality.

4.4 Special warnings for each target species

The efficacy of this medicinal product declines with water temperatures below 6°C.

Avoid treatment if large amounts of organic material are present in the sea water or if the sea-cage is overgrown, as this may reduce the efficacy of the treatment.

Dead sea lice may remain on the fish for a few days after treatment (depending on the water temperature).

AMX does not prevent reinfestation with sea lice after treatment.

Lack of efficacy and reduced sensitivity to deltamethrin has been observed. Suboptimal treatment regimen and frequent treatments as well as the use of pyrethroids only for sea lice treatment, can induce reduced sensitivity in the sea lice with lack of efficacy as a possible consequence.

4.5 Special precautions for use

Special precautions for use in animals

All fish should be oxygenated during treatment. Ensure that the oxygen level is above 7 mg/l before the treatment is initiated and that it is kept above 7mg/l during the entire duration of the treatment.

At water temperatures below 6°C the product's safety margin is reduced. Extra precautionary measures should be exercised if treatments are performed at low water temperatures.

The risk of intoxication may increase in fish with severe skin lesions.

Overgrowth of algae on the sea-cages/nets may prevent water exchange after treatment. This may extend the exposure period and increase the risk of intoxication of the fish.

Treatment should not be carried out unless some degree of water current is present. Without a current the exposure period may be extended and increase the risk of overdosing. If water currents are low at the time of removal of the tarpaulin the use of an artificial water-current (e.g. a boat motor propeller) is recommended in order to speed up the water exchange in the treatment unit.

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

- Wear protective clothing (i.e. cotton overalls and nitrile rubber or neoprene gloves (0.3mm thick)) and disposable face mask when handling the product and tarpaulins and nets of treated cages.
- Wear protective clothing, gloves, eye protection and a disposable face mask when mixing and administering the product.
- Do not smoke, drink or eat while handling the product.
- Avoid contact with the skin, eyes, nose and mouth. If clothing becomes contaminated remove without delay and wash skin thoroughly with soap and water. Change out of protective clothing and wash hands thoroughly after using the product. Launder protective clothing before re-use.
- The product is of low hazard by oral and dermal routes. Inhalation of product may cause irritation to the mucous membranes and respiratory tract. Skin exposure may cause transient sensations (tingling, numbness) which disappear after a few hours. Obtain medical advice if symptoms persist.
- All equipment which has been in contact with the product should be thoroughly cleaned after completion of treatment.

The product may cause harm to the unborn child. Pregnant women should therefore be extra careful when handling the product.

Other precautions

The substance is toxic to crustaceans and should not be used in sea farms where crabs or lobsters are kept in the close vicinity of the treated sea-cages (<200 m), or when local water-currents increase the likelihood of exposure.

To prevent toxic effects on local aquatic organisms and to prevent toxic waste of deltamethrin to be washed into the littoral zone, bath treatment should be performed at outgoing tide or during periods with a local outgoing current.
See also 5.3

4.6 Adverse reactions (frequency and seriousness)

The fish tend to move closer to the surface during treatment and increased restlessness and jumping frequency are observed. Occasional mortalities have also been observed after treatment with the recommended treatment regimen. Miscalculation of the treatment volume (overdosing), extended exposure period or low water temperature may increase the frequency of adverse reactions or signs of intoxication (see section 4.10 “Overdose”).

4.7 Use during pregnancy, lactation or lay

Use only in accordance with a benefit/risk assessment by the responsible veterinarian because reproduction toxicity has not been established in the target species.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

The delousing should be performed in a well-boat or in a sea-cage with a raised net enclosed by a tarpaulin. This is to ensure proper control of the treatment volume and the treatment dosage, in addition to reduce the amount of AMX used and the environmental exposure. Calculate the water volume as exactly as possible to ensure correct dosing.

Treatment dose: 0.2 ml AMX per m^3 (1000 l) sea water in the treatment unit.
This corresponds to 2 microgram deltamethrin/litre sea water.
For calculation of the treatment volume in the unit, please refer to the section below; “Treatment volume”.

Treatment period: 30 minutes

Treatment volume:
Well-boat: The dosage is calculated according to the actual volume of the treatment unit.

Tarpaulin:
The dosage is calculated according to the actual volume of the treatment unit (tarpaulin volume).
Method of administration:
The product should be brought to room temperature before use in order to flow more easily out of the bottle. Shake the bottle well before use. Calculate the volume in the treatment unit and the AMX dose. Use a suitable container and dilute the calculated quantity of AMX in seawater. Diluting the product in a large volume of seawater will

ensure a better dispersion and thereby the efficacy of the treatment. After a short period of stirring, the diluted solution must be spread evenly throughout the treatment unit. It is recommended to use a pump with low or moderate pressure to further improve an even dispersion. Do not disperse under high pressure as this may cause atomising and/or foaming.

It may be necessary to repeat the treatment if reinfestation with sea lice occurs, but due to the environmental properties of the product (see section 5.3) the use of the product should be kept to a minimum. As a minimum requirement a period of at least 14 days should elapse between treatments in order to provide a protection of the environment.

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

Equilibrium problems, behaviour disturbances, gasping for air in the water surface, alteration in pigmentation and mortalities are symptoms of an overdose. If any of these symptoms occur, the treatment should be terminated and unmedicated sea water let in. If the fish are treated in a raised net enclosed by a tarpaulin, the tarpaulin should be removed and the net released to normal depth immediately. An artificial water-current in order to speed up the water exchange in the treatment unit is recommended (e.g. by using a boat motor propeller).

The acute toxicity of deltamethrin in fish is high. The toxicity is affected by the dose, exposure period and the water temperature. Signs of intoxication have been seen in laboratory trials with doses 5 times the recommended dose at 30 minutes exposure and doses 3 times the recommended dose at 60 minutes exposure. Experience from clinical use of the product indicates that lower doses and/or other exposure conditions may also cause signs of intoxication.

4.11 Withdrawal period(s)

5 degree days for treated Atlantic salmon
5 degree days for treated rainbow trout

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticide for topical use, Pyrethrins and Pyrethroids.
ATC vet code: QP53AC11

5.1 Pharmacodynamic properties

Deltamethrin is a synthetic pyrethroid with insecticidal effect and acts by affecting the sodium channels after depolarization and thus disturbing the normal repolarization of the cells. This blocking of transmission of impulses in the nervous system of the parasites leads to hyperexcitation, paralysis and death of the parasite. The effect on sea lice is due to direct absorption of deltamethrin through the parasite’s cuticle and not via absorption in the host.

5.2 Pharmacokinetic particulars

Deltamethrin is almost insoluble in water (solubility < 0.002 mg/l at 20°C). The properties of the formulation make it soluble in seawater.

Deltamethrin is mainly absorbed via the gills in fish and is distributed to all organs and tissues.
With a short treatment period (30 minutes), the absorption of deltamethrin in fish is low. The substance is predominantly eliminated through the bile. The metabolism of the substance is less in fish than in mammals. There are no signs of accumulation in tissues.

5.3 Environmental properties

Deltamethrin is toxic to aquatic and sediment living species and may cause adverse effects in the vicinity of treated sea cages. Also at distances of up to 4 kilometers downstream short term effects after treatment can be seen in sensitive organisms. Deltamethrin demonstrates high affinity to organic matter and particles in the water column and in sediments. Deltamethrin is very stable and slowly degradable when bound to sediments, both at aerobic and anaerobic conditions.

The environmental risk assessment of deltamethrin is based on the theoretical use of only a single (annual) application in a single cage at one site. More frequent use and/or 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 AMX 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, must be adhered to. If there is any doubt about safe use, relevant competent authorities should be consulted or professional advice sought accordingly. Please also refer to section 4.9 and 6.6.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogolglycerol ricinoleate
Calcium dodecylbenzene sulphonate in isobutanol
Citric acid anhydrous
N-methylpyrrolidone

6.2 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: 3 years
Shelf life after first opening the immediate packaging: 9 months

Dilute immediately before use, discard any unused solution.

6.4 Special precautions for storage

Protect from frost.

6.5 Nature and composition of immediate packaging

Aluminium bottle with a tamper evident black polypropylene screw cap.
The bottle contains 250 ml or 1000 ml of concentrate.

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.

This formulated product is designed for the treatment of fish. However, at levels greater than the treatment dose, the product could be harmful to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used containers.

7. MARKETING AUTHORISATION HOLDER

PHARMAQ AS
Skogmo Industriområde
7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER

Vm 21714/4004

9. DATE OF FIRST AUTHORISATION

17 December 2008

10. DATE OF REVISION OF THE TEXT

November 2021

Approved: 03/11/21

[redacted]

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azasure 500 mg/g Powder for Suspension for Fish Treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

1g of product contains azamethiphos 500mg

Excipients:

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Powder for suspension for fish treatment.
Fine beige powder in water soluble sachet.

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 (*Caligus* species) on farmed Atlantic salmon.

4.3 Contraindications

None

4.4 Special warnings (for each target species)

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 multi-tactic pest-management program.
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.
Do not use the product prophylactically. Only use when infestation with adult lice has been diagnosed.

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.
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 the tarpaulin and ensure vigorous oxygenation of the water.
The product should be applied to salmon suffering from infestation with sea-lice before the stage at which serious skin damage is evident.

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

The prescribing veterinary surgeon must ensure that farm staff have received adequate instruction in the safe use of the product.

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.
The product 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 insides 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

In the UK

Illness suspected to be a result of working with the medicine may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. If in doubt contact your local Health and Safety Executive Officer.

Report human or veterinary suspected adverse reactions online to the Veterinary Medicines Directorate.

In Norway

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

Further advice can be obtained from: Naqua Limited, Building 500, East Block, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND

iii. Other Precautions

The product is very dangerous to crustaceans and dangerous to fish and other aquatic organisms. Therefore the product should not be used in sea farms where crabs or lobsters are kept in the close proximity of the treated sea cages.
Frequent use 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, must 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. The water movements from a boats propeller may be used to increase water exchange in cases where low water exchange rates cannot be avoided. These measures will help to prevent possible adverse effects on aquatic life.
For countries where an environmental authorisation is not required at each individual site, the following risk mitigation measures should be followed.
At sites with cages ≥ 150m in circumference a maximum of one cage should be treated per day.
At sites with cages 120 – 149m in circumference, a maximum of two cages should be treated per day.

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

No data available

4.9 Amount(s) to be administered and administration route

Fish affected by sea-lice should be bathed in 0.2 ppm of the product (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.

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2g of the powder must be added per cubic metre of water, i.e., 1 x 20g sachet treats 100 cubic meters and 1 x 100g sachet treats 500 cubic metres.

The product 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.

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 the product 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 product).

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 product 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, 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. Oxygen is immediately bled into the system and the product 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 10 degree days after the end of the treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF17

Antiparasitic Products, Insecticides and Repellants

5.1 Pharmacodynamic properties

Azamethiphos is an organophosphorus insecticide.
Resistance of sea lice to azamethiphos, and other organophosphates, can occur through alteration of acetylcholinesterase due to genetic mutation 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 within 1 hour of immersion in a bath containing the maximum recommended dose.

5.3 Environmental properties

Azamethiphos is highly soluble in water (>1 g/L) with a low octanol/water partition coefficient (log Kow) of 1 g/mL. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not bioconcentrate or bioaccumulate in biota. Azamethiphos has a moderate propensity to adsorb to suspended organic matter (koc 500 l/kg), however it is unstable in saltwater, degrading with a half-life <5 days (12 C) producing non-toxic transformation products. See also 4.5.iii.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulfate
Naphthalene Sulphonic Acid Formaldehyde Concentrate
Kaolin Light
Silica, colloidal anhydrous

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
2 years.

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

20g pack size;
Heat-sealed polyvinylalcohol water soluble bag containing 20g of product contained in a sealed aluminium/polyethylene sachet.
Either 2 x 20g packages in an outer carton or 5 x 20g packages in an outer carton.

100g pack size;
Heat-sealed polyvinylalcohol water soluble bag containing 100g of product contained in a sealed aluminium/polyethylene sachet.
Either 1 x 100g package in an outer carton or 5 x 100g packages in an outer carton.

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, if appropriate

This 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 veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ground Animal Health Ltd
Unit 8 Dock Offices
Surrey Quays Road
London
England
SE16 2XU

8. MARKETING AUTHORISATION NUMBER

Vm 49145/4000

9. DATE OF FIRST AUTHORISATION

04 December 2013

10. DATE OF REVISION OF THE TEXT

November 2020

Approved 10 November 2020

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SLICE 2 mg/g premix for medicated feeding stuff.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Emamectin benzoate (equivalent to 1.76 mg of Emamectin)	2.00 mg

Excipient(s):

Propylene glycol	25 mg
Butylated Hydroxyanisole	0.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
A white to off-white free flowing powder

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar*)

4.2 Indications for use, specifying the target species

For the treatment and prevention at group level of infestations of all parasitic stages of sea lice (*Lepeophtheirus* sp. and *Caligus* sp.) on Atlantic salmon (*Salmo salar*) ranging in size from smolts in freshwater (just prior to transfer to seawater) to market weight fish in seawater.

4.3 Contraindications

Do not use in adult Atlantic salmon intended for broodstock.
Do not use for treatment of smolts in freshwater cages due to potential environmental risks.

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

Wear gloves, protective work clothing, dust mask and safety glasses with side shields when handling SLICE in the preparation of medicated fish feed.
Wash hands thoroughly with soap and water after handling the product or medicated feed and before eating or smoking.
Do not smoke or eat while handling the medicated feed.

4.6 Adverse reactions (frequency and seriousness)

At the recommended dose emamectin benzoate produced no undesirable effects in the clinical trials, apart from a slight reduction in appetite during the medication period in two trials. A change in the source and pellet size of the medicated diet may have contributed to this effect.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Not applicable

Lactation:
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Administer medicated feed to fish at the recommended feeding rate of 0.5% biomass/day for 7 days which will yield a dose rate of 50 micrograms/kg biomass/day. If the feeding rate differs from 0.5% biomass/day, then the concentration of SLICE in feed must be adjusted proportionately. The following table is provided for reference.

Feeding rate (% biomass of fish)	Concentration of emamectin benzoate in feed medicated with SLICE (mg/kg)	Quantity of SLICE per 1,000 kg of medicated feed (kg)	Quantity of SLICE-medicated feed per 1,000 kg of fish per day (kg)
0.25	**20.0**	**10.0**	**2.5**
0.5	**10.0**	**5.0**	**5.0**
1.0	**5.0**	**2.5**	**10.0**
2.0	**2.5**	**1.25**	**20.0**
3.0	**1.67**	**0.833**	**30.0**
4.0	**1.25**	**0.625**	**40.0**

SLICE-medicated fish feed is to be prepared only at commercial fish feed mills and not at fish farms. SLICE is to be coated onto feedstuff of the following type: Extruded cylindrical pellets of varying thickness and length, e.g., 3.5 mm, 5.0 mm, 7.0 mm and 10.0 mm.

Recommended Method of Incorporation:
SLICE may be coated onto the surface of non-medicated fish feed in the following manner:

a. Standard feed is transported by a conveyor belt to a fractioning sieve where dust and fragments are sorted out.
b. The sorted pellets are transferred to an intensive mixer.
c. The pellets are dry-mixed/coated with a pre-determined amount of SLICE for up to 2 minutes.
d. 0.5% to 1% fish or vegetable oil is added and mixing continued for up to 5 minutes. The added oil seals the premix powder to the feed pellet.
e. At the completion of mixing, the product is transferred to a feeder tank for packaging into sacks.

The recommended maximum number of marine treatments is 5 per 2 year growth cycle and not more than 3 per 12 month period.

Smolts should only be treated when raised either in tanks or in flowing waterways (see contra-indications).
Smolts should be transferred to seawater 1 - 2 days after the seven day treatment period has ended.

To reduce the possibility of resistance development in sea lice it is recommended that emamectin benzoate is used in integrated control programmes with the following considerations:

- Administration of the correct dosage rate over the full seven day period
- Medication of an appropriate amount of feed to ensure complete and homogeneous consumption
- Careful feeding practices to monitor feeding behaviour
- Use of the product in the absence of any intercurrent disease affecting appetite
- Simultaneous medication of all fish on a site
- Coordination of treatments of all farms in a loch or bay system to reduce cross-infestation

- Use of good management practices such as single age sites, all-in-all-out systems and fallowing between production cycles
- Use in rotation with other authorised therapeutic agents and/or in collaboration with other natural agents such as cleaner fish.

It is important that the level of infestation and the effectiveness of control measures are monitored by routine counting of sea lice stages on samples of representative fish. Counts should be conducted on at least five fish from each of 20% of cages on the farm at weekly intervals in summer and every second week in winter. Treatment should only be initiated when the number of sea lice per fish reaches a level so that effective sea lice population control can be established.

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

Emamectin benzoate administered to Atlantic salmon smolts in freshwater at 5.4 times the recommended dose produced dark skin colouration and incoordination during the treatment period.

Emamectin benzoate administered to Atlantic salmon in seawater at seven times the recommended dose produced lethargy, dark skin colouration and incoordination commencing on the fifth day of medication and inappetance commencing two days after treatment.

Recovery was not evident in the week following treatment, in either fish treated in freshwater or in seawater. There is no known antidote.

4.11 Withdrawal period

Zero days.

To ensure that tissue residues do not exceed the MRL, fish must not be treated more than once in the 60 days prior to the first fish being harvested for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Avermectin class of endectocides
ATC vet code: QP54AA06

5.1 Pharmacodynamic properties

Emamectin benzoate is a semi-synthetic avermectin. Avermectins are macrocyclic compounds produced by the soil microorganism *Streptomyces avermitilis* and are characterised by a 16-membered lactone ring with an attached dioleandrosyl group.

The precise mechanism by which emamectin benzoate kills the various sea lice species has not been elucidated. However, extensive research on the mode of action of avermectin compounds against invertebrate species has shown that the avermectins competitively bind to glutamate-gated chloride channels on invertebrate nerves. The distribution of glutamate-gated chloride channels in the invertebrate may be localised to specific muscles such as those of the pharyngeal pump.

5.2 Pharmacokinetic particulars

Emamectin benzoate is relatively slowly absorbed but it is also widely distributed to the tissues. Excretion is also relatively slow.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Butylated hydroxyanisole
Maize starch
Maltodextrin M-100

6.2 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: 3 years
Shelf life after incorporation into meal or pelleted feed: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Container: Laminate Foil Pouch (12” x 15” or 13” x 16”) composed of polypropylene/low density polyethylene/aluminium foil. Fill weight 2.5 kg/pouch.

Closure: Pouch is heat sealed on three sides

Package Size: 2.5 kg pouch
Fibre Drum containing 8 x 2.5 kg pouches

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4580

9. DATE OF FIRST AUTHORISATION

13 January 2000

10. DATE OF REVISION OF THE TEXT

November 2021

Approved 02 November 2021

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmosan Vet, 500 mg/g Powder for Suspension for Fish Treatment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Azamethiphos 500 mg

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 (*Salmo salar*)

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 will 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).

Do not use the product prophylactically. Only use when infestation with mature lice has been diagnosed.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.

Careful management and monitoring of oxygen levels is critical during Salmosan Vet treatments. A minimum oxygen level should be set by the prescriber prior to treatment. In order to maintain oxygen levels, vigorous oxygenation of the water must be provided during treatment. It is recommended that oxygen addition begins before the tarpaulins are fitted to the pens.

Impaired gill health and concurrent diseases such as pancreas disease and cardiomyopathy syndrome has been shown to increase fish mortality post treatment, due to stress related to the treatment and/or treatment procedure.

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 is evident.

During treatment, fish should be monitored for, but not limited to, signs of stress (lethargy, gasping, orientation problems, balance problems and abnormal swimming behaviour). If any of these signs are observed during or shortly after treatment, flush the treatment area with clean sea water and ensure vigorous oxygenation.

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 350 g) appeared to tolerate exposure to Salmosan Vet at up to three times the recommended dose rate (i.e. 0.6 ppm), for up to three times the recommended treatment time (i.e. 180 minutes), at both 6°C and 15°C.

ii. Special precautions to be taken by 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 COVERALLS, 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 damage has occurred.
WASH ALL PROTECTIVE CLOTHING thoroughly after use, especially the insides 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 first withdrawing 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 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 areas of skin which came into contact with the product with plenty of water.
- 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 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, 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.

iii. 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 sea farms where crabs and lobsters are kept in close proximity of the treated cages.

Frequent use 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, must be adhered to. **If there is any doubt about safe use in the environment, 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. The water movements from a boat's propeller may be used to increase water exchange in cases where low water exchange rates cannot be avoided. These measures will help to prevent possible adverse effects on aquatic life.

From a practical use position, 'restrictive tarpaulins' are commonly available now and can be used to reduce the volume of larger net pens for bath treatments. Depending on biomass, these tarpaulins can reduce the size of larger pen nets by >60%. This is good practice which not only allows for better measurement of the water volume to be treated but also reduces the amount of product needed to be used and therefore released at the end of

treatment.

For countries where an environmental authorisation is not required at each individual site, the following risk mitigation measures should be followed:

At sites with cages ≥ 150 m in circumference, a maximum of one cage should be treated per day.

At sites with cages 120-149 m in circumference, a maximum of two cages should be treated per day.

4.6 Adverse reactions (frequency and seriousness)

Signs of hyperactivity or distress may be seen if fish are not adequately oxygenated during treatment.

Mortalities of treated fish is uncommonly observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the product with regard to reproduction toxicity has not been assessed. Therefore, only use in maturing brood stock in accordance with the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

READ THE OPERATOR PRECAUTIONS AND ENVIRONMENTAL WARNINGS (see Sections 4.5.ii and 5.3 of the SPC).

Fish affected by sea-lice should be bathed in 0.2 ppm of the product (0.1 ppm azamethiphos) for a period of not less than 30 minutes and not more than 60 minutes.

Assess water volume as accurately as possible when calculating the amount of product needed for treatment to avoid under- or over- dosing.

To achieve a final concentration of 0.1 ppm azamethiphos, 0.2 g of the product must be added per cubic metre of water, i.e., 1 x 100 g sachet treats 500 cubic metres.

Oxygenation must be provided during treatment, ideally continuously while the fish are crowded in the net and the tarpaulin is fitted to and removed from the cage. Vigorous oxygenation is recommended in the treatment cage. Where several cages are to be treated a large reservoir of oxygen bottles should be available.

Initial preparation of the treatment concentrate should take place in a dry and sheltered location, not more than 48 hours prior to treatment. Operators wearing suitable equipment and protective clothing, (See Section 4.5.ii of the SPC), should place the number of water soluble bags of the product required for the dosage of an individual cage into a labelled screw-topped polyethylene container, together with a quantity of fresh water (1 litre or more of water for every 200 g of the product). 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 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 0.1 ppm signs of stress, stupor and in extreme cases death may occur. If acute toxicity is seen the treatment should be stopped, oxygenation increased, and the tarpaulin removed to aid recovery.

4.11 Withdrawal period(s)

Withdrawal period: 10 degree days.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP53AF17

Ectoparasiticides for topical use, organophosphorus compounds.

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 K_{ow}) 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 <5.6 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. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulfate
Kaolin Light
Silicic Acid Precipitated

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

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 20 g or 100 g of product contained in a sealed polyethylene lined paper sachet.
5 x 20 g or 2 x 100 g 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 veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Benchmark Animal Health Limited
Highdown House
Yeoman Way
Worthing
West Sussex
BN99 3HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 43684/4002

9. DATE OF FIRST AUTHORISATION

10 December 2014

10. DATE OF REVISION OF THE TEXT

December 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved 22 December 2022