



Evaluation Report for Category B, Subcategory 3.2, 3.4 Application

Application Number: 2021-0735
Application: Changes to Product Labels-Application Timing and Method
Product: Salmosan Vet
Registration Number: 32506
Active ingredient (a.i.): Azamethiphos
PMRA Document Number: 3296647

Purpose of application

The purpose of this application was to amend the label of Salmosan Vet by extending the bath treatment time for the control of sea lice on farmed Atlantic salmon from 30-60 minutes to 60-180 minutes in order to maximize the efficacy of the product when populations of sea lice have a reduced sensitivity to azamethiphos, and to amend the directions of use and other text for clarity and to improve safety to treated fish.

Chemistry assessment

A chemistry assessment was not required for this application.

Health assessments

A toxicological assessment was not required for this application.

The amendments to the label of Salmosan Vet for use on Atlantic Salmon reared in marine aquaculture sites is not expected to result in an increase in potential occupational or bystander exposure over that from the registered use of azamethiphos. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Confirmatory data from trials conducted in Norway using known azamethiphos-resistant sea lice populations in Atlantic salmon were sufficient to support the proposed increase in bath treatment time on the Salmosan Vet label from 30-60 minutes to 60-180 minutes. Residues of azamethiphos are not expected to be greater than the established MRL in/on fish. Consequently, dietary exposure to residues of azamethiphos will not pose any health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental assessment

When used according to label directions, the increase in treatment duration, changes to the application dose rate for well boats and the other label changes do not represent an increase in risk the environment. When used according to label directions, the environmental risks from the use of Salmosan Vet are acceptable.

Value assessment

Value information reviewed consisted of four studies, which included two laboratory bioassays on sea lice and two laboratory studies on Atlantic salmon infested with sea lice. The trials were conducted using known resistant sea lice populations collected in Norway. Results from the studies demonstrated that, while a bath time of 60 minutes did not provide adequate control, increased bath times up to 180 minutes provided control of sea lice with reduced susceptibility to azamethiphos.

The reviewed value information was sufficient to support the increase in bath treatment time on the Salmosan Vet label to a minimum of 60 minutes for sea lice populations that are susceptible to azamethiphos and a maximum of 180 minutes for sea lice populations with reduced susceptibility to azamethiphos. Sea lice are an important pest in farmed Atlantic salmon, with significant animal welfare impacts on infested fish. The change in exposure duration will allow continued use of Salmosan Vet when populations of sea lice with reduced sensitivity of azamethiphos are present.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Salmosan Vet.

References

PMRA

Document

Number	Reference
3203470	2021, Value Summary, DACO: 10.1
3203471	2021, Mode of Action, DACO: 10.2.1
3203472	2021, Description of the pest problem, DACO: 10.2.2
3203473	2021, Efficacy summary tables, DACO: 10.2.3.1
3203474	2020, Summary document (Efficacy detailed and critical summary for Salmosan Vet regarding variation treatment time), DACO: 10.2.3.1
3203475	2021, Resistance Management, DACO: 10.5.3
3203483	2021, Data waiver submitted, DACO: 10.2.3.3,10.2.3.4
3203511	2018, Effect of extended exposure of Salmosan Vet on resistant sea lice (<i>Lepeophtheirus salmonis</i>) study protocol, DACO: 10.2.3.3,10.2.3.4
3203512	2018, Effect of extended exposure of Salmosan Vet on resistant sea lice (<i>Lepeophtheirus salmonis</i>), DACO: 10.1,10.2.3.1,10.2.3.3,10.2.3.4,10.5.3
3203505	2012, Testing the safety of Salmosan to Atlantic salmon when used at high temperatures and increased duration., DACO: 10.1,10.2.3.1,10.2.3.3,10.2.3.4
3203512	2018, Effect of extended exposure of Salmosan Vet on resistant sea lice (<i>Lepeophtheirus salmonis</i>), DACO: 10.1,10.2.3.1,10.2.3.3,10.2.3.4,10.5.3.
3225976	2021, Scientific rationale, DACO 7.1.

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