

## Evaluation Report for Category B, Subcategory 3.13 Application

**Application Number:** 2008-0659  
**Application:** B.3.13 – New Label Precaution  
**Product:** Bayluscide Granular Sea Lamprey Larvicide  
**Registration Number:** 25563  
**Active ingredients (a.i.):** Niclosamide  
**PMRA Document Number** 2575210

### Purpose of Application

The purpose of this application was to amend the precautions and the first aid sections of the subject product label.

### Chemistry Assessment

Chemistry assessment not required.

### Health Assessments

Bayluscide Granular Sea Lamprey Larvicide is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is mildly irritating to the eye, but is not considered to be irritating to the skin. Bayluscide Granular Sea Lamprey Larvicide is not considered to be a dermal sensitizer.

For the requested uses of niclosamide, a new health based risk assessment was conducted using the selected toxicology end point and use information provided. Target margins of exposure were achieved for mixer/loader/applicators. The exposure potential for postapplication workers was assumed to be much lower than the mixer/loader/applicators and was considered acceptable. Based on the measures implemented by U.S. Fish and Wildlife Service to restrict the public access to treatment areas, the bystander exposure was assumed to be minimal. No additional mitigation measures were required for acute hazards and formulants. Therefore, the requested precautionary label amendments for Bayluscide Granular Sea Lamprey Larvicide were supported.

### Environmental Assessment

The EAD has no outstanding data requirements for the active ingredient, niclosamide and its end-use product Bayluscide Granular Sea Lamprey Larvicide. Additional environmental precautionary statements are required on the proposed label to indicate that this product will be used only by certified applicators of the U.S. Fish and Wildlife Service, and Fisheries and Oceans Canada in programs approved by the Great Lakes Fishery Commission.

## Value Assessment

Value assessment not required.

## Conclusion

PMRA has reviewed information provided in support of the amendments as described above. Based on this review, the updated precautions and the first aid sections of the subject product label are acceptable.

## References

- 1553196 Rivera, Jane E./U.S. Environmental Protection Agency, 2001, Correspondence/PR Notice 2001-2, Acute toxicity requirements for granular pesticide products, DACO: 0.17.1,0.8.1,4.6.1,4.6.2,4.6.5,4.6.6
- 1553198 2008, Bayluscide Acute Toxicity Summary Table, DACO: 4.6
- 1553199 2008, Acute oral bridging rationale and waiver request, DACO: 0.17.1,0.8,4.6,4.6.1
- 1553200 2008, Acute dermal bridging rationale and waiver request, DACO: 0.17.1,0.8,4.6,4.6.2
- 1553201 2008, Data summary and waiver request, DACO: 0.8,4.6,4.6.3
- 1553202 2002, Bayluscide 3.2% Granular formulation: Single exposure (nose-only) toxicity in the rat, DACO: 4.6,4.6.3
- 1553203 2008, Primary eye irritation data summary, DACO: 0.8,4.6,4.6.4
- 1553204 2002, Primary eye irritation/corrosion study of Bayluscide 3.2% Granular formulation in rabbits, DACO: 0.8,4.6,4.6.4
- 1553205 2008, Primary dermal irritation bridging rationale and waiver request, DACO: 0.17.1,0.8,4.6,4.6.5
- 1553206 2008, Dermal sensitization bridging rationale and waiver request, DACO: 0.17.1,0.8,4.6,4.6.6

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