



## ADVICE SUMMARY

### APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

**Product name:** BUFFODINE FISH FARMING ANTISEPTIC  
**Applicant:** MALAGUNA PTY LTD  
**Product number:** 62200  
**Application number:** 42590

**Purpose of Application and Description of Use:** Registration of a 1.1% available iodine aqueous liquid product for use as a disinfectant for fish eggs.

**Active Constituent(s):** IODINE

#### **Regulatory Decision:**

To grant the application subject to the following conditions:

#### **Standard Conditions of Registration/Approval**

For full conditions, refer to [http://www.apvma.gov.au/advice\\_summaries/adv\\_summaries.shtml](http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml).

### **ADVICE**

#### **Australian Government Department Of Environment And Heritage**

The Department of Environment, Water, Heritage and the Arts (DEWHA) conducted a risk assessment to take into account the proposed aquacultural use of iodine in the product *Buffodine Fish Farming Antiseptic (P62200)*. DEWHA relied on available literature to complete their assessment.

Environmental fate from literature articles indicate that iodine undergoes rapid reduction with humic substances to give iodide, and after 3.5 h the I<sub>2</sub> component in solutions is completely reduced to iodide. The retention of iodine in soils is due mainly to the organic matter and hydrous oxides of iron and aluminium.

Iodide may be lost from soils by leaching, volatilisation and removal in crops. The amount of iodide in ground water, and in rivers and lakes remote from human activity, suggest some leaching of iodine is widespread. Iodine has a low log Pow <3.0 and thus is not expected to be significantly bioaccumulate.

Iodine is very highly toxic to fish, highly toxic to water fleas and slightly toxic to fungi. DEWHA concluded that iodine, including from the release of spent solution, poses a potential environmental risk to the aquatic compartment. As such, following statements are required on the label: Under the heading **“Protection of Wildlife, Fish, Crustaceans and the Environment”** the following is to be stated: *“Product is extremely toxic to aquatic organisms. DO NOT contaminate streams, rivers or waterways with the chemical or used container. Treatment water from tanks should not be released directly to the aquatic compartment. Prior to disposal, spent solutions should be treated with 10g sodium thiosulphate pentahydrate, left for 30 minutes, and then disposed of at a dedicated disposal site by evenly spreading over flat land, away from natural waterways and in a way that avoids potential run-off into local water bodies”*.

DEWHA recommended that, with the inclusion of these label amendments, the APVMA could be satisfied that the proposed use of iodine in the product ***Buffodine Fish Farming Antiseptic (P62200)***, in accordance with the instructions for use on the product label, would not be likely to have an unintended effect that is harmful to animals, plants, things or the environment.

Based on this advice, the APVMA has determined that use of the product in accordance with label instructions would not be likely to have an unintended effect that is harmful to animals, plants, things or the environment.

## **Veterinary Residues Team**

The Veterinary Residues Team (VRT) of the APVMA evaluated potential residues issues associated with the product ***Buffodine Fish Farming Antiseptic (P62200)***. Iodine is an approved active constituent, however no products containing iodine are currently registered for use in fish or fish eggs.

The applicant proposed that the use of iodine for disinfecting eyed salmonid eggs and newly stripped non-hardened eggs is eligible for a table 5 entry in the *MRL standard*. The VRT considered the requirements for a table 5 entry in making their decision and came to the following conclusions:

Disinfected fish eggs are washed four or five times with clean water after treatment, removing residual iodine. Fertilised eggs are not made available for human consumption. Treated eggs are allowed to hatch, and fish are grown for 12-24 months before being harvested. Residues of iodine are therefore not expected to occur at the time of harvest.

Iodine is an essential trace element that occurs naturally. The foods highest in natural iodine include seaweed, seafood and fish. Therefore any residues in fish are expected to be indistinguishable from naturally occurring iodine.

The concentration of iodine used in the proposed product (0.01%) is considerably less than the acceptable concentrations used in pre-milking and post-milking teat dips (0.1% and 0.5%, respectively) that are already entries in table 5. As such, the risk to human health is significantly lower for the proposed product than the teat dip applications.

The use of iodine as a disinfectant in fish eggs is therefore included in table 5 of the *MRL standard*.

The following restraint and WHP statements are to be applied to the label:

#### **RESTRAINT**

**DO NOT USE in fish eggs intended for human consumption**

#### **WITHHOLDING PERIODS**

**MEAT: NIL**

**EGGS: DO NOT USE in fish eggs intended for human consumption**

It was concluded that use of the product according to label instructions would not be harmful or an undue hazard to the safety of people exposed to residues in food, and would not unduly prejudice trade and commerce between Australia and places outside Australia.

#### **State Efficacy Reviewer**

An external state reviewer evaluated the efficacy and safety of the product *Buffodine Fish Farming Antiseptic (P62200)*. The reviewer assessed data provided by the applicant, including scientific literature and fact sheets from an Australian State Authority.

A considerable body of published scientific work exists to indicate that iodophor disinfection of salmonid eggs is useful in limiting infections by saprophyte fungi such as *Saprolegnia* spp and can aid in controlling other important viral and bacterial pathogens.

The specific studies provided show diminishment of suspended viral titre after exposure to the antiseptic, decrease in colony forming units in bacteria after exposure to the antiseptic, safety of the product to the eggs of the two main farmed salmonids worldwide, and a fact sheet from a State Competent Authority that indicates that iodophor disinfection is a desirable and standard procedure in salmonid farming.

Study 15775 demonstrates that the product is effective in deactivating infectious salmon anaemia virus, with a greater than 4 log<sub>10</sub> reduction in viral titre.

Study 15777 examined the effects of the product on infectious pancreatic necrosis virus and viral haemorrhagic septicaemia virus and demonstrated large decreases in viral titre.

Two studies examined mortality of Atlantic salmon and Rainbow trout (studies 15779 and 15780). These tolerance tests showed that there was no significant differences between hatching rates of eggs in the control eggs or treated eggs, for various times and concentrations. These studies demonstrate that Atlantic salmon and Rainbow trout eggs are not harmed by treatment conducted as recommended and that there is a significant safety margin in terms of time and concentration of the product.

Based on the advice of the state reviewer and the relied-on data, the APVMA determines that use of the product in accordance with label instructions would not be likely to have a significant harmful effect in target animals, and that use of the product in accordance with the recommendations for its use would be effective.

#### Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
15777	S	PF Dixon	Efficacy test of new formulation of BUFFODINE against viral haemorrhagic septicaemia virus and infectious pancreatic necrosis virus.	July 1999	Efficacy and Safety	Efficacy	Applicant	
15778	S	V. Fotheringham	Bactericidal activity of BUFFODINE under low level soiling conditions	July 2006	Efficacy and Safety	Efficacy	Applicant	
15775	S	DL Smail et al	Disinfectants against cultured Infectious Salmon Anaemia (ISA) virus: the virucidal effect of three iodophors, chloramine T, chlorine dioxide and peracetic acid/hydrogen peroxide/acetic acid mixture	2004	Efficacy and Safety	Efficacy	Public	
15776	S	Anon	Disinfection of Salmonid eggs using povidone-iodine solutions	May 2007	Efficacy and Safety	Efficacy	Tasmania Department of Primary Industries, Water and Environment	
15780	S	Dr DJ Alderman	Tolerance test for Rainbow trout (Onchorhynchus mykiss) eggs to new formulation of Buffodine	Jan 1999	Efficacy and Safety	Target Animal Safety Studies	Applicant	

15779	S	M. Algoet	Tolerance test for Atlantic Salmon ( <i>Salmo salar</i> L) eggs to a new formulation of Buffodine	March 2001	Efficacy and Safety	Target Animal Safety Studies	Applicant	
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\* *S* = Data submitted with the application

*I* = Data inherited (that is, referenced) from another application