

Summary of product characteristics for a biocidal product

Product name: Buffodine

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number:

R4BP 3 asset reference number:

DRAFT

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Administrative information

1.1. Trade names of the product

Buffodine

1.2. Authorisation holder

Name and address of the authorisation holder	Name	
	Address	
Authorisation number		
R4BP 3 asset reference number		
Date of the authorisation		
Expiry date of the authorisation		

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Evans Vanodine International
Address of the manufacturer	Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom
Location of manufacturing sites	Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom

1.4. Manufacturer(s) of the active substance(s)

Active substance	1319 - Iodine
Name of the manufacturer	"As an IRG member, Evans Vanodine International is committed to using only iodine from sources approved under the BPR EU 528/2012 or demonstrated as being technically equivalent; they will comply with > 99.5% purity set by EU 94/2014"
Address of the manufacturer	see above see above see above European Union
Location of manufacturing sites	see above see above see above European Union

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1.114

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - Fish egg disinfection - immersion

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	<p>Haemorrhagic septicaemia virus (VHSV)-Haemorrhagic septicaemia virus (VHSV)-not applicable</p> <p>Infectious Pancreatic Necrosis Virus (IPNV)-Infectious Pancreatic Necrosis Virus (IPNV)-not applicable</p> <p>Infectious Salmon Anaemia Virus (ISAV)-Infectious Salmon Anaemia Virus (ISAV)-not applicable</p>
Field(s) of use	<p>Indoor</p> <p>DISINFECTATION FOR VETERINARY HYGIENE: Fish egg disinfection</p>
Application method(s)	<p>EYED EGGS: Disinfection by immersion - The concentrated product has to be diluted 1:100 by decanting or pumping. The eggs are immersed in solution for 10 minutes. After treatment, eggs must be washed gently four or five times in clean fresh water and placed in trays. All egg washings should be poured into drains and not into watercourses leading to fish farms or streams.</p> <p>NEWLY STRIPPED EGGS: Disinfection by immersion - The milt from the fertilized eggs is washed with a solution containing 90 g sodium chloride in 10 L water. The concentrated product is diluted 1:100 by decanting or pumping in 10L water and 90 g sodium chloride (edible quality salt) is added. The washed eggs are immersed in the prepared solution for a period of 10 minutes. Thereafter, the eggs must be washed gently four or five times in a solution containing 90 g sodium chloride in 10 L water, cleaned in fresh water and placed in trays. All egg washings should be poured into drains and not into watercourses leading to fish farms or streams.</p>
Application rate(s) and frequencies	<p>10 L - 1 - Timing - once per day. It is dependent on the number of eggs: 1 litre of diluted solution per 2000 egg.</p> <p>10 L - 1 - Timing - once per day. It is dependent on the number of eggs. 1 litre of diluted solution per 2000 eggs.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Bottle, Plastic: HDPE , 1- 5 L</p> <p>1 L HDPE with HDPI lid. The pack specification is provided in IUCLID, section 13.</p>

The pack specification is provided in IUCLID, section 13.

4.1.1 Use-specific instructions for use

EYED EGGS: Dilute the concentrated product 1:100 in 10 L water. Place eggs in solution for 10 minutes. Wash gently the disinfected eggs in clean fresh water and place in trays.
NEWLY STRIPPED EGGS: Dissolve 9 parts sodium chloride (edible quality salt) in 1000 parts water and add 10 parts Buffodine (90 g sodium chloride and 100 mL Buffodine per 10 L water). Mix thoroughly. Wash the milt from the fertilized eggs with a solution of 9 parts sodium chloride to 1000 parts water (90 g per 10 L) until the eggs are clean. Immerse eggs in the prepared solution of Buffodine for a period of 10 minutes. Thereafter, wash the eggs gently four or five times in a solution of 9 parts sodium chloride to 1000 parts water. Wash the eggs in clean fresh water and place in trays.
Use the mixed solution only once. Pour the disinfection solution into drains and not into watercourses leading to fish farms or streams.

4.1.2 Use-specific risk mitigation measures

Not applicable.

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

not applicable

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Mentioned in the SDS:

Description of first aid measures:

Inhalation: Unlikely route of exposure as the product does not contain volatile substances.

Ingestion: Do not induce vomiting. Give plenty of water to drink. Get medical attention.

Skin contact: Wash with plenty of water.

Eye contact: Rinse immediately with plenty of water. get medical attention promptly if symptoms occur after washing.

Most important symptoms and effects, both acute and delayed:

Inhalation: No specific symptoms known.

Ingestion: No specific symptoms known. But - May cause discomfort if swallowed.

Skin contact: No specific symptoms known.

Eye contact: Prolonged contact may cause redness and/or tearing.

Stability and reactivity:

Reactivity: The following materials may react with the product: Oxidising materials.

Chemical stability: No particular stability concerns.

Conditions to avoid: Avoid exposure to high temperatures or direct sun light.

Incompatible materials: Materials to avoid: Oxidising agents.

Hazardous decomposition products: When heated, vapours/gases hazardous to health may be formed.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the SDS:

Discharge used solutions to drain. Small amounts (less than 5 liters) of unwanted product may be flushed with water to sewer. Larger volumes must be sent for disposal as specific waste. Consign empty container to normal waste.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

24 months shelf-life

Keep only in original containers in a cool, well-ventilated place. Protect from light. Store away from the following materials: Oxidising materials.

6. Other information

The exact composition of the biocidal product Buffodine is provided in the IUCLID file as well as in the confidential Annex of the PAR.

The following information applies for the Danish label for the approved product:

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Desinfektionsmiddel

Må kun anvendes professionelt som desinfektionsmiddel til bekæmpelse af Infektøus pankreas nekrose virus (IPNV), Viral hæmorrhagisk septikæmi (VHS) og Infektøus lakseanæmi (ISA) i fiskeæg."

2) I advarselsfeltet:

"FORSIGTIG

Sikkerhedsdatablad kan på anmodning rekvireres". (EUH210)

"Bær kemisk resistente beskyttelsehandsker ved håndtering af koncentreret produkt." Handskematerialet skal tillige angives af godkendelsesindehaveren i produktdatabladet.

"Vask huden grundigt efter brug."

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

"Må kun anvendes professionelt som desinfektionsmiddel til bekæmpelse af Infektøus pankreas nekrose virus (IPNV), Viral hæmorrhagisk septikæmi (VHS) og Infektøus lakseanæmi (ISA) i fiskeæg.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer

Levnedsmidler og foderstoffer må ikke forurennes."

Evt. oplysninger om førstehjælp.

"Opbevares ved temperatur under 30°C

Opbevares adskilt fra oxidationsmidler.

Undgå kontakt med oxidationsmidler.

Beskyttes mod direkte sollys"

3) I deklarationsfeltet:

a) Teksten "Desinfektionsmiddel BPR-reg. nr. 798-2. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "Væske" for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C

e) Udløbsdatoen skal anføres. Denne dato må højst være 18 måneder år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.

f) Batchnummer eller – betegnelse skal anføres.

g) Pakningsstørrelse i L.

h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse:

Der skal mærkes med sikkerhedssætning P501: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

"Tom emballage og rester kan bortskaffes med dagrenovationen."