Summary of product characteristics for a biocidal product

Product name: FAM

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

Authorisation number: 2019-09-24-B02

R4BP 3 asset reference number: MT-0021574-0001

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Administrative information

1.1. Trade names of the product

FAM			

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Evans Vanodine Europe
Address	6-9 Trinity Street D02 EY47 Dublin 2 Ireland

Authorisation number

2019-09-24-B02 1-1

R4BP 3 asset reference number

MT-0021574-0001

Date of the authorisation

24/09/2019

Expiry date of the authorisation

06/03/2029

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	ACF Minera S.A.
Address of the manufacturer	San Martin No 499 None Iquique Chile
Location of manufacturing sites	Lagunas mine None Pozo Almonte Chile
Active substance	1319 - Iodine
Name of the manufacturer	SQM S.A.
Address of the manufacturer	Los Militares 4290, Piso 4, Las Condes None Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, Pedro de Valdivia plant None None Chile
Active substance	1319 - Iodine
Active substance Name of the manufacturer	1319 - Iodine Cosayach Nitratos S.A.
Name of the manufacturer	Cosayach Nitratos S.A.
Name of the manufacturer Address of the manufacturer	Cosayach Nitratos S.A. Hnos Amunátegui 178 None Santiago Chile
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	Cosayach Nitratos S.A. Hnos Amunátegui 178 None Santiago Chile CosayA. Compania de Salitre y Yodo None Not reported Chile
Name of the manufacturer Address of the manufacturer Location of manufacturing sites Active substance	Cosayach Nitratos S.A. Hnos Amunátegui 178 None Santiago Chile CosayA. Compania de Salitre y Yodo None Not reported Chile 1319 - Iodine

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	2,179
Alcohol Ethoxylate	C9-11 Alcohol Ethoxylate (8EO)		68439-46-3	614-482-0	18,575
Sulphuric Acid	Sulphuric Acid		7664-93-9	231-639-5	7,995
Phosphoric Acid	Trihydroxidooxido- phosphorus		7664-38-2	231-633-2	12,495

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hozord	ototomonto
Hazaru	statements

Causes severe skin burns and eye damage.

Harmful to aquatic life with long lasting effects.

May be corrosive to metals.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Store locked up.

Keep out of reach of children.

Do not breathe mist.

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse skin with water.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Wash contaminated clothing before reuse.

Dispose of contents to in accordance with local regulations.

Dispose of container to in accordance with local regulations..

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 (FAM) - animal accommodation surface disinfection - spray or foam application

Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Products used to disinfect the materials and surfaces associated with the housing of animals.

Scientific name: Bacteria Common name: Bacteria Development stage: All

Scientific name: Other Viruses Common name: Viruses Development stage: All

Scientific name: Yeast Common name: Yeast Development stage: All

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Indoor

Indoor

Application method(s)

Spraying -

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate.

Foaming -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled into the reservor of a knapsacksprayer (low pressure foam).

Application rate(s) and frequencies

300 mL/m² (dilute solution) - Dilution ratios - FAM 1:75 -

The disinfection of animal housing takes places as follows:

- Dairy cattle: Once per year
- Veal calves: Every 17-19 weeks
- Fattening pigs: Twice per year
- Laying hens: Once per 12 -18 months
- Broiler: Every 7 weeks

Turkeys: Twice per yearDucks: Every 8 weeksGeese: Twice per yearSheep: Once per yearGoats: Once per year

300 mL/m² (dilute solution) - Dilution ratios – FAM 1:75 - The disinfection of animal housing takes places as follows:

- Dairy cattle: Once per year
- Veal calves: Every 17-19 weeks
- Fattening pigs: Twice per year
- Laying hens: Once per 12 -18 months
- Broiler: Every 7 weeksTurkeys: Twice per year
- Ducks: Every 8 weeks
- Geese: Twice per year
- Sheep: Once per year
- Goats: Once per year

Category(ies) of users

Professional

Pack sizes and packaging material

Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres

4.1.1 Use-specific instructions for use

Clean and rinse surfaces prior to disinfection

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate. Spray the disinfectant making sure surfaces are thoroughly wetted and leave to dry for 30-minutes, porous surfaces should be allowed to dried for a minimum of 4 hours. After disinfection, empty and clean the reservoir and the spray equipment by rinsing with water.

Dilution ratios - FAM 1:75

4.1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

The use of eye protection during handling of the product is mandatory.

Feed and water troughs are to be covered during biocidal treatment

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 Directions for use.		

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

See 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 Directions for use.

4.2 Use description

Use 2 - Use # 2 (FAM) - animal accommodation equipment disinfection - immersion

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Products used to disinfect the materials and surfaces associated with the housing of animals.

Scientific name: Other: Bacteria Common name: bacteria Development stage: All

Scientific name: other yeast Common name: Yeasts Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Indoor

Outdoor

Indoor and outdoor

Application method(s)

Open system: immersion -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled in a clean container and the equipment (e.g. buckets, cages, hatchery trays, drinkers, crates) is placed in the solution. The equipment is left for at least 30 minutes before removing and allowing equipment to drain and dry.

Application rate(s) and frequencies

Immersere for 30-minutes in 100 litres of diluted solution - Dilution ratios - FAM 1:75 - The equipment disinfection in animal accomodation by immersion takes place indoor or outdoor by professional workers as follows:

- Broiler: Every 7 weeks
- Ducks: Every 8 weeks

Category(ies) of users	Professional
Pack sizes and packaging material	Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 -1 000 Litres
4.2.1 Use-specific instruction	ns for use
diluted concentrate and place equipment	tion uipment) the concentrated product and dilute with water. Fill a clean container with the (e.g. buckets, cages, hatchery trays, drinkers, crates) in the solution, leave for at least 30 juipment to drain and dry. Dispose the disinfection solution into STP.
4.2.2 Use-specific risk mitiga	tion measures
Wear protective chemical resistant gloves	s (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN	13034) shall be worn.
The use of eye protection during handling	g of the product is mandatory.
<u>=</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See Directions for use.	
4.2.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See Directions for use.	
4.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See Directions for use.	
1	

4.3 Use description

Use 3 - Use # 3 (FAM) - disinfection of vehicles for transporting animals - spray application

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Products used to disinfect the materials and surfaces associated with transportation of animals.

Target organism(s) (including development stage)

Scientific name: bacteria Common name: bacteria Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: yeast Common name: Yeasts Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Outdoor

Outdoor

Application method(s)

Spraying -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled into the reservoir of a knapsack sprayer (low pressure spray). The surfaces are sprayed with the disinfectant making sure that the surfaces are thoroughly wetted. The product is left on the surfaces until it has dried (porous surfaces should be dried for a minimum of 4 hours).

Application rate(s) and frequencies

300mL/m² diluted solution - Dilution ratios - FAM 1:75 -

Generally, the vehicles for transporting animals are cleaned and disinfected with products which are not iodine-based. Only in in case of disease, the disinfection is done with iodine-based products.

Category(ies) of users

Professional

Pack sizes and packaging material

Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres

4.3.1 Use-specific instructions for use

Clean and rinse surfaces prior to disinfection

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate. First, apply the disinfectant solution to the outside of the vehicle including wheel arches, tyres, mudguards and underside of the vehicle, starting at the top and working down. Thereafter, spray on the inside of the vehicle, starting at the top and working down to the bottom, ensuring that all surfaces including the floor are covered. After

disinfection (at least 30-minutes), empty and clean the reservoir and the spray equipment by rinsing with water. Dilution ratios – FAM 1:75

4.3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

The use of eye protection during handling of the product is mandatory.

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

See Directions for use.

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

See Directions for use.

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

See Directions for use.

4.4 Use description

Use 4 - Use # 4 (FAM) - disinfection of fish farm equipment - immersion

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Products used to disinfect the materials and surfaces associated with the housing of animals.

Scientific name: Bacteria Common name: Bacteria Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: Yeast Common name: Yeasts Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use	Outdoor.
Application method(s)	Open system: immersion - The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled a clean container and the equipment (e.g. buckets, cages, hatchery trays, drinkers, crates) is placed in the solution. The equipment is left for at least 30 minutes before removing and allowing equipment to drain and dry. For larger pieces of equipment such as fish holding tanks, the cleaned containers are filled with the disinfectant. The disinfectant is left for a minimum of 30 minutes, drained, rinsed with clean water and allowed to dry.
Application rate(s) and frequencies	500 L of diluted solution Dilution ratios – FAM 1:75 - The disinfection of equipment in fish farming takes places once a week.
Category(ies) of users	Professional
Pack sizes and packaging material	Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres

4.4.1 Use-specific instructions for use

Clean and rinse surfaces prior to disinfection

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill a clean container with the diluted concentrate and place equipment (e.g. buckets, trays, fish nets, crates) in the solution, leave for at least 30 minutes before removing, drain, rinse the equipment with clean potable water and allow to dry. For larger pieces of equipment such as fish holding tanks, fill cleaned containers with disinfection solution, leave for a minimum of 30 minutes, drain, rinse with clean water and allow to dry.

Dilution ratios - FAM 1:75

4.4.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 6, EN 13034) shall be worn.

The use of eye protection during handling of the product is mandatory.

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

See Directions for use.			

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

See Directions for use.		

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

See Directions for use.

4.5 Use description

Use 5 - Use # 5 (FAM) - boot and wheel disinfection - dipping

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PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: Bacteria Development stage: all

Field(s) of use

Outdoor

Outdoor

Application method(s)

Open system: dip treatment -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The foot and wheel baths are filled with the diluted concentrate and placed at the entrances or exits. A two-minute contact time is to be ensured before moving from one area to another.

Application rate(s) and frequencies

Wheel bath (250 litres) – once per week (based upon the risk assessment up to 400 litres may be used). Boot bath (10 litres) - every day - Dilution ratios - FAM 1:75 -Wheel bath (250 litres) - once per week

(based upon the risk assessment up to 400 litres may be used)

Boot bath (10 litres) - every day

Category(ies) of users

Professional

Pack sizes and packaging material

Container, Plastic: HDPE, 5-1000 L

4.5.1 Use-specific instructions for use
Clean and rinse surfaces prior to disinfection Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill foot/wheel bath with the dilute concentrate and place at the entrances/ exits and ensure a two minute contact time before moving from one area to another. Dispose of used solutions to wastewater. Empty, clean and refill wheel baths, up to a maximum volume of 400L Footbath must be kept indoors/under roof in order to prevent dilution by rain. Dilution ratios – FAM 1:75
4.5.2 Use-specific risk mitigation measures
Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)
A protective coverall (at least type 6, EN 13034) shall be worn.
The use of eye protection during handling of the product is mandatory.
See Directions for use. 1.5.4 Where specific to the use, the instructions for safe disposal of the product and its
oackaging
See Directions for use.
5.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See Directions for use.
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5. General directions for use
5.1. Instructions for use

See Authorised uses. 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment Description of first aid measures inhalation: Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, proceed follows. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing, inspection: Do not induce vomiting. Rinse mouth thoroughly with water. Gwe plenty of water for drink. Get medical attention immediately. Shir contact: Wash with plenty of water. Get medical attention promptly if symptoms occur after washing. Eye contact: Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse. Get medical attention immediately. Most important symptoms and effects, both acute and delayed inhalation: Intitation of nose, throat and alrway; indication of nose, throat and alrway; indication of nose, throat and alrway. Indication	See Authorised uses.	
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Most important symptoms and effects, both acute and delayed nhalation: Irritation of nose, throat and airway. ngestion: May cause chemical burns in mouth and throat. Skin contact: Burning pain and severe corrosive skin damage. May cause serious chemical burns to the skin. Eye contact: Severe irritation, burning and tearing. Prolonged contact causes serious eye and tissue damage. Stability and reactivity: Reactivity: Reacts with alkalis and generates heat. Chemical stability: No particular stability concerns. Conditions to avoid: Avoid exposure to high temperatures or direct sunlight. ncompatible materials: Materials to avoid: Aluminium, Tin, Zinc and their alloys. Concentrated alkaline materials. Chlorine releasin naterials will liberate toxic chlorine gas. Oxidising agents as lodine vapour may be evolved Hazardous decomposition products: When heated, vapours/gases hazardous to health may be formed Environmental precautions - Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body Hush away spillage with plenty of water. Small Spillages: Contain and absorb spillage with sand, earth or other non-combustible material. Collect and place in suitable waste disposal containers and seal securely. - A. Instructions for safe disposal of the product and its packaging - At the end of the treatment used solutions can be flushed to the municipal sewer or disposed to the manure deposit depending on ocal requirements. Avoid release to an on-site waste water treatment plant Dispose unused product and the packaging in accordance with local and/or national requirements. 5. Conditions of storage and shelf-life of the product under normal conditions of storage - Months shelf-life	nhalation: Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, profollows. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. ngestion: Do not induce vomiting. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention mmediately. Skin contact: Wash with plenty of water. Get medical attention promptly if symptoms occur after washing. Eye contact: Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rice.	
Reactivity: Reacts with alkalis and generates heat. Chemical stability: No particular stability concerns. Conditions to avoid: Avoid exposure to high temperatures or direct sunlight. Incompatible materials: Materials to avoid: Aluminium, Tin, Zinc and their alloys. Concentrated alkaline materials. Chlorine releasing materials will liberate toxic chlorine gas. Oxidising agents as lodine vapour may be evolved. Independent of the products: When heated, vapours/gases hazardous to health may be formed. Invironmental precautions Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body. Flush away spillage with plenty of water. Small Spillages: Contain and absorb spillage with sand, earth or other non-combustible material. Collect and place in suitable waste disposal containers and seal securely. Instructions for safe disposal of the product and its packaging At the end of the treatment used solutions can be flushed to the municipal sewer or disposed to the manure deposit depending on ocal requirements. Avoid release to an on-site waste water treatment plant. Dispose unused product and the packaging in accordance with local and/or national requirements. 5. Conditions of storage and shelf-life of the product under normal conditions of storage of months shelf-life	Most important symptoms and effects, both acute and delayed nhalation: Irritation of nose, throat and airway. ngestion: May cause chemical burns in mouth and throat. Skin contact: Burning pain and severe corrosive skin damage. May cause serious chemical burns to the skin.	
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36 months shelf-life	ocal requirements. Avoid release to an on-site waste water treatment plant.	ng on
	5. Conditions of storage and shelf-life of the product under normal conditions of sto	orage
Avoid exposure to high temperatures or direct sunlight.	Keep only in the original container in a cool, well-ventilated place. Store away from the following materials: Oxidising materia	ls.

None.