

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

FORMAL-EA

Product type(s)

PT03: Veterinary hygiene

Authorisation number: BE2024-0014

R4BP asset number: BE-0032455-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	FORMAL-EA
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Elements Advisory
	Address	Antwerpsesteenweg 39/101b 9000 Gent Belgium
Authorisation number	BE2024-0014	
<i>R4BP asset number</i>	BE-0032455-0000	
Date of the authorisation	17/04/2024	
Expiry date of the authorisation	18/04/2029	

1.3. Manufacturer(s) of the product

Name of manufacturer	Synerlogic B.V.
Address of manufacturer	Graafsingel 22 6921 RT DUIVEN Netherlands (the)
Location of manufacturing sites	Synerlogic B.V. site 1 Graafsingel 22 6921 RT DUIVEN Netherlands (the)

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

Active substance	Formaldehyde
Name of manufacturer	Synthite Ltd
Address of manufacturer	Alyn Works, Denbigh Road CH7 1BT Mold United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Synthite Ltd site 1 Alyn Works, Denbigh Road CH7 1BT Mold United Kingdom of Great Britain and Northern Ireland (the)

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Formaldehyde		active substance	50-00-0	200-001-8	42,3

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

<p>Hazard statements</p>	<p>H301+H311+H331: Toxic if swallowed, in contact with skin or if inhaled.</p> <p>H314: Causes severe skin burns and eye damage.</p> <p>H317: May cause an allergic skin reaction.</p> <p>H341: Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.</p> <p>H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.</p> <p>EUH071: Corrosive to the respiratory tract.</p>
<p>Precautionary statements</p>	<p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P260: Do not breathe vapours.</p> <p>P260: Do not breathe mist.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P272: Contaminated work clothing should not be allowed out of the workplace.</p> <p>P280: Wear protective gloves (DIN EN 374)/ protective clothing (DIN EN 14605)/safety goggles/ face-shield.</p> <p>P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</p> <p>P302+P352: IF ON SKIN: Wash with plenty of soap and water..</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a a POISON CENTER or doctor/physician..</p> <p>P333+P313: If skin irritation or rash occurs: Get medical a POISON CENTER or doctor/physician..</p>

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

P501: Dispose of contents to hazardous waste collection point or special requirements in accordance with local, regional or international regulations.

P501: Dispose of container to hazardous waste collection point or special requirements in accordance with local, regional or international regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Disinfection of eggs (disinfection sluice) by fogging

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeast Common name: Yeasts Development stage: no data Scientific name: Fungi Common name: fungi Development stage: no data Scientific name: Viruses Common name: Viruses Development stage: no data
Field(s) of use	indoor use Indoor – in disinfection sluice of hatcheries: Disinfection of hatching eggs
Application method(s)	Method: fogging Detailed description: Cold Ultrasonic Fogging in large enclosures (size room: equal or over 4m ³)
Application rate(s) and frequency	Application rate: Against bacteria, fungi/yeasts and viruses: 5 g Formaldehyde/m ³ (12.32 mL FORMAL-EA/m ³) Dilution (%): The dilution of the product depends primarily on the room size (use 1&2) and the number of eggs (use 1 only) to be disinfected, but the technical characteristics of the equipment used for the cold fogging have as well to be taken into account. See below. Number and timing of application: - The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. - Technical characteristics of the device to be taken into account : · Diffusion principle : Cold Ultrasonic Fogging · The particle size should be in accordance with the size tested (population centered Dv(50) (µm): 5.15 µm; mean diameter D (µm): 8.94 µm; particle population under the threshold of 50 µm: 98.85 %) • Contact time: 1h. The contact time starts when the required total volume of product (see application rate) is nebulized. • Temperature: +20°C

	<ul style="list-style-type: none"> Relative Humidity recommendation: 50-75%
Category(ies) of users	professional
Pack sizes and packaging material	1, 2, 2.5 and 3 kg HDPE (bottle) 5, 10, 20, 22, 25 kg PE (can) 60, 100, 200, 220 kg PE (drum) 1000, 1025 kg HDPE (IBC)

4.1.1. Use-specific instructions

Clean the eggs to be disinfected before application of the product.

Instructions to use the product with the *MS Hatchfog Ultra* device, to be used for disinfection of eggs :

- Determine the volume of the room to be treated.

- If room volume > 154m³, the volume (L) of Formal-EA to be added to the tank of the fogging device is:

VolumeFORMAL-EA (L) = Room volume (m³)*0.0123 (L/m³)+4.6L.

In this case, the product is used pure (100%).

- If room volume < 154m³, the volume (L) of Formal-EA to be added to the tank of the fogging device is :

VolumeFORMAL-EA (L) = Room volume (m³)*0.0421(L/m³)

The rest of the tank should be filled up with water up to 6.5 L (total volume), and thus the dilution ranges between >0% - <100%.

Follow the fogging device manual. Dilute the product accordingly and add the solution to the fogging device. Seal the enclosed space or room and initiate the decontamination cycle. The concentration of formaldehyde should reach 5g/m³. Prevent entry during disinfection process. After the disinfection procedure, ventilation of the room is mandatory at a ventilation rate of 2000m³/h during 20min or until the formaldehyde is below the AEC of 0,12mg/m³. For rooms <154m³ water needs to be added, for rooms > 154m³ pure product is poured into the device.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required during mixing and loading. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

Wear a protective coverall (at least type 6, EN 13034) during mixing and loading.

The use of eye protection during mixing and loading of the product is mandatory.

The use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during mixing and loading.

Treated rooms/buildings shall be labelled with a warning sign.

Ventilate the room at the maximum rate (>2000m³/h) when the required contact time has passed.

Re-entry into the treated area is allowed only 20 minutes after the treatment is completed and a ventilation rate of at least 2000m³/h is used for 20 minutes or until the formaldehyde is below the AEC of 0,12mg/m³.

4.1.4. 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

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

See general directions for use

4.1.6. 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

4.2. Use description

Table 2. Disinfection of animal housing by fogging

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: no data</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: no data</p> <p>Scientific name: Fungi Common name: fungi Development stage: no data</p> <p>Scientific name: Viruses Common name: Viruses Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Indoor – in Animal housing: Disinfection of hard/porous & non-porous surfaces, with mandatory prior cleaning</p>
Application method(s)	<p>Method: fogging</p> <p>Detailed description: Cold Ultrasonic Fogging in large enclosures (size room: equal or over 4m³)</p>
Application rate(s) and frequency	<p>Application rate: Against bacteria, fungi/yeasts and viruses: 5 g Formaldehyde/m³ (12.32 mL FORMAL-EA/m³)</p> <p>Dilution (%): The dilution of the product depends primarily on the room size (use1&2) and the number of eggs (use 1 only) to be disinfected, but the technical characteristics of the equipment used for the cold fogging have as well to be taken into account. See below.</p> <p>Number and timing of application:</p> <ul style="list-style-type: none"> - The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. - Technical characteristics of the device to be taken into account : <ul style="list-style-type: none"> · Diffusion principle : Cold Ultrasonic Fogging · The particle size should be in accordance with the size tested (population centered Dv(50) (µm): 5.15 µm; mean diameter D (µm): 8.94 µm; particle population under the threshold of 50 µm: 98.85 %) • Contact time: 2h. The contact time starts when the required total volume of product (see application rate) is nebulised. • Temperature: +20°C

	<ul style="list-style-type: none"> Relative Humidity recommendation: 50-75%
Category(ies) of users	professional
Pack sizes and packaging material	1, 2, 2.5 and 3 kg HDPE (bottle) 5, 10, 20, 22, 25 kg PE (can) 60, 100, 200, 220 kg PE (drum) 1000, 1025 kg HDPE (IBC)

4.2.1. Use-specific instructions

All animals are removed from the stable before disinfection. The stables are thoroughly cleaned before disinfection.

The stables must be heated to reach +20°C before disinfection.

Instructions to use the product with the *MS Hatchfog Ultra* device, to be used for disinfection of animal housing :

- Determine the volume of the room to be treated.

- If room volume > 154m³, the volume (L) of Formal-EA to be added to the tank of the fogging device is:

VolumeFORMAL-EA (L) = Room volume (m³)*0.0123 (L/m³)+4.6L.

In this case, the product is used pure (100%).

- If room volume < 154m³, the volume (L) of Formal-EA to be added to the tank of the fogging device is :

VolumeFORMAL-EA (L) = Room volume (m³)*0.0421(L/m³)

The rest of the tank should be filled up with water up to 6.5 L (total volume), and thus the dilution ranges between >0% - <100%.

A fogging device is loaded with a disinfectant outdoors. The device is placed in the unit and the fogging process is started using a time delay to make sure the operator can leave the room. The concentration of formaldehyde should reach 5g/m³. Prevent entry during the disinfection process. After the disinfection procedure, keep the stable closed and heated during 2-4 days while ventilating. After ventilation, or until the formaldehyde is below the AEC of 0,12mg/m³, the stable is opened, and the device is removed from the room (the device is not cleaned after application). For rooms <154m³ water needs to be added, for rooms > 154m³ pure product is poured into the device.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

Mixing and loading should be done outdoor

The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required during mixing and loading and during removal and cleaning of equipment. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. Wear a protective coverall (at least type 6, EN 13034) during mixing and loading and during removal and cleaning of equipment.

The use of eye protection during mixing and loading and during removal and cleaning of equipment is mandatory.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during mixing and loading and during removal and cleaning of equipment

Assure animals are not present in the rooms/buildings/structures/spaces/areas during fumigation.

Feeding troughs must be covered during application.

Treated rooms / buildings shall be labelled with a warning sign.

Ventilate the room when the required contact time has passed.

Re-entry of humans or animals into the fumigation area is allowed only after 2-4 days after the treatment is completed or until the formaldehyde is below the AEC of 0,12mg/m³.

Apply only in stables which are sealed and heated.

After application: keep the stable closed and heated during 2-4 days while ventilating stable.

4.2.4. 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

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

See general directions for use

4.2.6. 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 USE¹

5.1. Instructions for use

See use-specific instructions for use

- Follow the instructions of the equipment suppliers to obtain a sufficient diffusion time.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

5.2. Risk mitigation measures

See use-specific risk mitigation measures

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

INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED:

Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse.

Continue to wash the skin with water

for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112/ambulance for medical assistance.

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

Disposal of product, packaging and product left in the fogging device should be in accordance with local/national/international authority regulations.

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

Store in original container. Keep locked up or in an area accessible only to qualified or authorised persons.

Keep containers tightly closed and locked up.

Protect from heat and direct sun light.

Do not store at temperature above 30°C.

Protect from frost.

Shelf-life: 12 months

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION

The product contains Formaldehyd (CAS No.: 50-00-0), for which a European reference value (AEC_{inhalation} = 0.12 mg/m³) for the professional user was agreed and used for the risk assessment of the product.