Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

FORMAL-EA

Product type 3

Formaldehyde

Case Number in R4BP: [BC-JX073084-12]

Competent Authority: [BE CA]

Date: [17/04/2024]

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1 Conclusion

Formal EA is a soluble concentrate biocidal product containing formaldehyde as active substance. The product is used as a PT3 by professional users for the control of bacteria, virus, fungi and yeast.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the uses *1 and 2* as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product does not contain any non-active substances (so called "co-formulant(s)") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

Based on the available information, the biocidal product does not contain any non-active substances.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains Formaldehyde which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution and exclusion based on the following criteria: presence of classification carc. 1B

Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[1]. The assessment is presented under section 3.10 of the PAR. The competent authority concluded that use 1 and use 2 can be authorized in Belgium (chemical diversity not met yet).

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

Conclusions of the assessments for each area

[1] The document is available in CIRCABC at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

The intended use(s) as applied for by the applicant [has / have] been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substance (formaldehyde), relevant impurities (methanol and formic acid) are available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

Activity of the product FORMAL-EA is demonstrated against bacteria (mycobacteria & spore-forming bacteria excluded), fungi, yeasts and viruses with 12.32 mL formaldehyde/m3 for applications via Cold Ultrasonic Fogging (particle population under the threshold of 50 µm: 98.85 %) in > 4 m^3 rooms at +20°C and 50-75% RH, under clean conditions:

- Use #1 - Airborne disinfection of hatching eggs in the disinfection sluice: one hour contact time.

- Use #2 - Airborne disinfection of hard/porous & non-porous surfaces in animal housing: two hours contact time.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

No substances of concern regarding human health were identified as there are no additional co-formulants added to the active substance. The human health risk assessment is based on the active substance formaldehyde.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional user and professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1	Disinfection of eggs (disinfection sluice) by fogging	**Acceptable** when using mask (APF 20), coverall, eye protection/face shield and gloves	- 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. 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 (>2000m^3/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 2000m^3/h is used for 20 minutes or until the formaldehyde is below the AEC of 0,12mg/m.
2	Disinfection of animal housing by fogging	**Acceptable** when using mask (APF 40), coverall, eye protection/face shield and gloves	- 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 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 removal and cleaning of equipment. - The use of eye protection during mixing and loading and 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 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.

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
			- 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. - Mixing and loading should be done outdoor - Apply only in stables which are sealed and heated - -After application: keep the stable closed and heated during 2-4 days while ventilating

Dietary risk assessment

Regarding the disinfection of eggs hatcheries, based on a literature search and an EFSA publication we can expect that the levels found in the albumen of the egg will be low and the residues remaining in the chicks would not exceed the acceptable levels of formaldehyde ingestion by humans, particularly if we take into account that the level of endogenous formaldehyde is more important than the exogenous intake of formaldehyde. Furthermore, formaldehyde is known to show high reactivity with proteins so a negligible residue level can be expected.

Regarding the animal housing disinfection, it can be expected that the relative exposure of livestock, following animal housing disinfection and allowing re-entry only after 2-4 days, will be negligeable because of its high reactivity and volatility. In addition, as stated above, the level of endogenous formaldehyde is more important than the exogenous intake of formaldehyde. Therefore, we do not expect any risk for the consumers.

Risk assessment for animal health

A risk assessment for animal health has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.7 of the PAR.

Based on the risk assessment, it is unlikely that the intended use (animal housing disinfection) causes any unacceptable risk for livestock animals, if the re-entry time claimed will be **2-4 days.**

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is only based on the active substance formaldehyde.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2-1 Product type(s) and type(s) of formulation

Product type(s)	PT3
Type(s) of formulation	SL-Soluble Concentrate

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2-2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
[1]	Airborne disinfection of hatching eggs (in disinfection sluice)	PT3	Bacteria Yeasts Fungi Viruses	Cold Ultrasonic Fogging	5g formaldehyde/ m^3	*Professional*	*[R]*	• Acceptable when using mask (APF 20), coverall, eye protection/face shield and gloves during mixing and loading. - - [Additional RMM (human health): - 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 during mixing and loading.of the product is mandatory.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.

[2]	Airborne disinfection of animal housing	PT3	Bacteria Yeasts Fungi Viruses	Cold Ultrasonic Fogging	5g formaldehyde/ m^3	*Professional*	*[R]*	• Acceptable when using mask (APF 40), coverall, eye protection/face shield and gloves during mixing and loading and removal and cleaning of equipment *[Additional RMM (human health)] :* - - 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 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 removal and cleaning of

								equipment. - The use of eye protection during during mixing and loading and removal and cleaning of equipment of the product is mandatory.Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during mixing and loading and 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.. • Mixing and loading should be done outdoor • The stable should be heated to reach +20°C before disinfection -Apply only in stables which are sealed and heated • -After application: keep the stable closed and heated during 2-4 days while ventilating

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The identity and composition of the biocidal product are

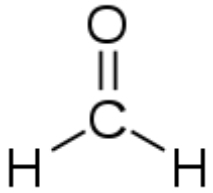
identical ☒
not identical ☐

to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2-3 Identity of the active substance(s)

Main constituent(s)	
Common name	Formaldehyde
Chemical name	Methanal, formaldehyde
EC number	200-001-8
CAS number	50-00-0
Index number in Annex VI of CLP	605-001-00-5
Minimum purity / content	25-55.5% (as provided in the implementing regulation of the active substance approval)
Structural formula	

2.5 Information on the source(s) of the active substance(s)

Is the source of formaldehyde the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

2.6 Candidate(s) for substitution

Formaldehyde meets at least one of the exclusion criteria listed in Article 5(1)(a), classified as Carcinogenicity: Category 1B

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product contains the active substance Formaldehyde, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. formaldehyde already fulfils the exclusion criteria; thus, the regulatory outcome will not change. The endocrine disrupting properties will be assessed in full detail in the scope of

the renewal of the approval.

No other co-formulants are present. Therefore, an assessment of the endocrine-disrupting properties of the co-formulants is not applicable.

2.8 Classification and labelling

Table 2-4 Classification and labelling of the biocidal product

The BP consists of 100% premix of the active substance. This premix contains 37% formaldehyde solution, < 7% methanol and 56% water. (See also confidential annex for a more detailed composition.) This premix of the active substance falls within the limits set up in the Assessment report for formaldehyde. There are no human health data available for the product. So for human health classification and labelling are based on the current harmonised classification of the a.s. formaldehyde (6th ATP). However, there is a new RAC opinion from 2022 (CLH-O-0000007130-88-01/F) which would have an impact on the acute toxicity endpoints and would lead to a different classification and labelling of the product (new: Acute Tox. 4, H302, Acute Tox. 2, H330, acute dermal toxicity no longer required) when the new ATP with classification from the RAC Opinion is released.

	Classification	**Labelling**
Hazard Class and Category code	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1 STOT SE 3 Muta. 2 Carc. 1B	
Hazard Pictograms	GHS05, GHS06, GHS08	GHS05, GHS06, GHS08
Signal word(s)	Danger	Danger
Hazard statements	H301 - Toxic if swallowed H311 - Toxic in contact with skin H331 - Toxic if inhaled H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage H317 - May cause an allergic skin reaction H335 - May cause respiratory irritation H341 - Suspected of causing genetic defects H350 - May cause cancer	H301 + H311 + H331 – Toxic if swallowed, in contact with skin or if inhaled H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H341 - Suspected of causing genetic defects H350 - May cause cancer

Precautionary statements*	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist/vapours. ~~P264 Wash hands thoroughly after handling.~~ P270 Do not eat, drink or smoke when using this product. ~~P271 Use only outdoors or in a well-ventilated area.~~ P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves (DIN EN 374)/protective clothing (DIN EN 14605)/safety goggles/ face-shield P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P302 + P352 IF ON SKIN: Wash with soap and water. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. ~~P308 + P313 IF exposed or concerned: Get medical advice/attention.~~ P310 Immediately call a POISON CENTER or doctor/physician. ~~P311 Call a POISON CENTER or doctor/physician.~~ ~~P312 Call a POISON CENTER or doctor/physician if you feel unwell.~~ P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. ~~P361 + P364 Take off immediately all contaminated clothing and wash it before reuse.~~ ~~P362 + P364 Take off contaminated clothing and wash it before reuse.~~ P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up P501 Dispose of contents and container in accordance with national regulations.	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist/vapours. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves (DIN EN 374)/protective clothing (DIN EN 14605)/safety goggles/ face shield P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P302 + P352 IF ON SKIN: Wash with soap and water. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P310 Immediately call a POISON CENTER or doctor. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up

		P501 Dispose of contents and container in accordance with national regulations.
Supplemental hazard statements	EUH 071 Corrosive to the respiratory tract[2].	
Notes	P271 can be excluded as based on the risk assessment, exposure is acceptable using the appropriate PPE. The other P-sentences that have been striked through are considered to be redundant due to the presence of other P-sentences.	

*****P-statements that are excluded based on the risk assessment or the intended use of the product[3], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] According to Regulation 1272/2008/EC, labelling as EUH071 "Corrosive to the respiratory tract" in addition to classification for inhalation toxicity is foreseen if the mechanism of toxicity is corrosivity. Considering that formaldehyde is a corrosive substance, additional labelling with EUH071 was regarded as appropriate.

[3] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

A letter of access to the active substance dossier of formaldehyde has been submitted. Please refer to Section 13 in the IUCLID file.

2.10 Data submitted in relation to product authorisation

All new studies are included in the reference list in annex 4.3 and are listed in IUCLID and summarised in the PAR and in the confidential annex.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	1 kg 2 kg 2.5 kg 3 kg	HDPE	screw cap, HDPE	Professional	yes
Can	5 kg 10 kg 20 kg 22 kg 25 kg	PE	screw cap, PE	Professional	yes
Drum	60 kg 100 kg 200 kg 220 kg	PE	screw cap, HDPE	Professional	yes
IBC	1000 kg 1025 kg	HDPE	screw cap, HDPE	Professional	yes

3.2 Physical, chemical, and technical properties

[Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation.]

[Note for the table: for storage stability test – long-term storage at ambient temperature, if no final report of the long-term shelf life study is available yet, an expected end date should be provided accompanied by proof that the study is running (e.g. protocol or, if available, interim data).]

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual assessment	37% formaldehyde (DES-F (BE-REG-00659) Batch: P2629735	Liquid	Shelf-life storage of DES-F(BE-REG-00659) over 24 months at 20°C Report: S22-109183 S. Tischer (2023)
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual assessment	37% formaldehyde (DES-F (BE-REG-00659) Batch: P2629735	Clear and colourless	Shelf-life storage of DES-F(BE-REG-00659) over 24 months at 20°C Report: S22-109183 S. Tischer (2023)
3.1.3.	Odour at 20 °C and 101.3 kPa	Waiver: Olfactory assessment is not possible, as the substance is classified as H331.			
3.2.	Acidity, alkalinity and pH value	pH: CIPAC MT 75.3, OECD 122	37% formaldehyde (DES-F (BE-REG-00659) Batch:	pH: 3.87 Acidity: 0.02% (w/w) calculated as H_2SO_4)	Shelf-life storage of DES-F(BE-REG-00659) over 24 months at

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Acidity: CIPAC MT 191, OECD 122</td><td>P2629735</td><td></td><td>20°C
Report: S22-109183
S. Tischer (2023)</td></tr>
<tr><td>3.3.</td><td>Relative density / bulk density</td><td>Ec method A.3, OECD 109</td><td>37% formaldehyde
Batch: 13-6-2021</td><td>Relative density at 20°C: 1.0975</td><td>Relative density of formaldehyde solution 37%
Report: S21-07208
S. Tischer (2021)</td></tr>
<tr><td>3.4.1.1.</td><td>Storage stability test – accelerated storage</td><td colspan="4">Waiver - At higher temperatures formic acid will be formed, which is undesirable, therefore it is not appropriate to perform accelerated storage stability tests at higher temperatures.

BE remark: "Do not store at temperatures above 30°C" must be added to the label</td></tr>
<tr><td>3.4.1.2.</td><td>Storage stability test – long-term storage at ambient temperature</td><td>CIPAC method MT 46.3 at 20 °C

Appearance
Mass change
Stability of the packaging

% AS:</td><td>37% formaldehyde (DES-F (BE-REG-00659)
Batch: P2629735</td><td>Storage in a black 1L PE-container with red protection ring screw shut tighly at 20°C during 12 months
<table>
<tr><th></th><th>Before</th><th>After 1 month</th><th>After 3 months</th><th>After 6 months</th><th>After 12 months</th></tr>
<tr><td>Appearance</td><td>A clear, colourless and non-viscous liquid</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight change</td><td>/</td><td>0.00%</td><td>0.00%</td><td>0.01%</td><td>0.02%</td></tr>
<tr><td>Packaging</td><td>The black 1L</td><td>No damag</td><td>No damag</td><td>No damag</td><td>No damag</td></tr>
</table></td><td>Shelf-life storage of DES-F(BE-REG-00659) over 24 months at 20°C
Report: S22-109183
S. Tischer (2023)</td></tr>
</table>

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>HPLC-DAD
% Methanol: GC-FID
% Formic acid: HPLC-DAD

pH (CIPAC MT 75.3)
Acidity (CIPAC MT 191)

Dilution stability:
CIPAC MT 41.1</td><td></td><td>
<table>
<tr><td></td><td>PE-container red protective ring screw cap shut tightly</td><td>e to the container shape or size was observed</td><td>e to the container shape or size was observed</td><td>e to the container shape or size was observed</td><td>e to the container shape or size was observed</td></tr>
<tr><td>% AS (% w/w)</td><td>37.6</td><td>37.7</td><td>39.0</td><td>36.8</td><td>35.8</td></tr>
<tr><td>% methanol (% w/w)</td><td>6.21</td><td>6.17</td><td>6.19</td><td>6.28</td><td>5.86</td></tr>
<tr><td>% Formic acid (% w/w)</td><td>0.00755</td><td>0.00743</td><td>0.01117</td><td>0.01081</td><td>0.0126</td></tr>
<tr><td>pH</td><td>3.87</td><td>3.91</td><td>3.86</td><td>3.87</td><td>3.83</td></tr>
<tr><td>Acidity (% w/w)</td><td>0.02</td><td>0.01</td><td>0.01</td><td>0.02</td><td>0.01</td></tr>
<tr><td>Dilution stability (16.2% v/v and 54% v/v of 37% formal dehyde) *</td><td>Homo-geneous, clear and colorless solution</td><td>Homo-geneous, clear and colorless solution</td><td>Homo-geneous, clear and colorless solution</td><td>Homo-geneous, clear and colorless solution</td><td>Homo-geneous, clear and colorless solution</td></tr>
</table>

*The dilution stability test was performed with the initial % of dilution.
The application rate was modified during the assessment. A new dilution stability test with the final % of dilution was</td><td></td></tr>
</table>

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				carried out (Please refer to the dilution stability section)	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waiver - The low temperature storage stability test does not need to be addressed as the product should not be stored ≤ 0°C. **BE remark**: "Protect from frost" must be added to the label			
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waiver - The biocidal product is packed in a non-transparent container, thus the impact of light on the product can be excluded. However, the mitigation measure "Protect from direct sunlight" will be added to the label. **BE remark**: "Protect from direct sunlight" must be added to the label			
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver - The effect of humidity can be waived as the product already contains water. The effect of temperature can be waived with the following label statement: 'Do not store at temperature above 30°C' (Please refer to the accelerated storage test)			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Waiver – Please refer to the long-term storage at ambient temperature test.			
3.5.1.	Wettability	Not applicable - The biocidal product is not a solid preparation to be dispersed in water.			
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Not applicable - The biocidal product is neither a suspension concentrate formulation nor a granular formulation.			
3.5.3.	Wet sieve analysis and dry sieve test	Wet sieve analysis: Not applicable - The biocidal product is neither a wettable powder nor a suspension concentrate. Dry sieve test: Not applicable - The biocidal product is neither a powder nor a granular formulation.			
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Not applicable - The biocidal product does not form or maintain as emulsion.			
3.5.5.	Disintegration time	Not applicable - The biocidal product is not a tablet.			
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	ISO 13320:2020	37% formaldehyde Batch nr. 0601156 MS Hatchfog Ultra	Dv(10) µm: 2.68 Dv(50) µm: 5.15 Dv(90) µm: 21.15 %V < 50µ (%): 98.85	Granulometric particle size analysis of from an aerosol fogger machine Report: N°9-806-2/22 F. Flecheux (2023)

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>3.5.7.</td><td>Persistent foaming (1% (v/v) and 99% (v/v) dilution of Formaldehyde solution 37% in water)</td><td>CIPAC MT 47.3</td><td>37% formaldehyde
Batch nr. P2629735</td><td>1% (v/v)<table><tr><td>Time</td><td>Volume (mL)</td></tr><tr><td>10 seconds</td><td>0</td></tr><tr><td>1 minute</td><td>0</td></tr><tr><td>3 minutes</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td></tr></table></td><td>Certificate of analysis N°Brenntag/25704 /Ch.8020/2022/A Ryckel, B., and Pigeon, O. (2022)</td></tr>
<tr><td></td><td></td><td></td><td>37% formaldehyde
Batch nr. NL03024383</td><td>99% (v/v)<table><tr><td>Time</td><td>Volume (mL)</td></tr><tr><td>10 seconds</td><td>5</td></tr><tr><td>1 minute</td><td>0</td></tr><tr><td>3 minutes</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td></tr></table></td><td>Certificate of analysis N°Brenntag/25775 /Ch.8076/2023/A Ryckel, B., and Pigeon, O. (2023)</td></tr>
<tr><td>3.5.8.</td><td>Flowability/pourability/dustability</td><td colspan="4">Flowability: Not applicable - The biocidal product is not a granular formulation.
Pourability: Not applicable - The biocidal product is not a suspension concentrate formulation.
Dustability: Not applicable - The biocidal product is not a dust formulation.</td></tr>
<tr><td>3.5.9.</td><td>Burning rate — smoke generators</td><td colspan="4">Not applicable - The biocidal product is not used as smoke generator.</td></tr>
<tr><td>3.5.10.</td><td>Burning completeness — smoke generators</td><td colspan="4">Not applicable - The biocidal product is not used as smoke generator.</td></tr>
<tr><td>3.5.11.</td><td>Composition of smoke — smoke generators</td><td colspan="4">Not applicable - The biocidal product is not used as smoke generator.</td></tr>
<tr><td>3.5.12.</td><td>Spraying pattern — aerosols / spray</td><td colspan="4">Not applicable -This end point is only required for aerosols.</td></tr>
<tr><td>3.6.1.</td><td>Physical compatibility</td><td colspan="4">Not applicable -The Product is not intended to be used in combination with other product.</td></tr>
</table>

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.6.2.	Chemical compatibility	Not applicable -The Product is not intended to be used in combination with other product.			
3.7.	Degree of dissolution and dilution stability (99% v/v dilution of formaldehyde solution 37% in water)	CIPAC MT 41.1	37% formaldehyde Batch nr. NL03024383	99% (v/v) After standing for 30 minutes: Homogeneous After standing for 24 hours: Homogeneous	Certificate of analysis N°Brenntag/25775 /Ch.8076/2023/A Ryckel, B., and Pigeon, O. (2023)
3.8.	Surface tension (at 20 °C and 99 % (v/v) dilution of Formaldehyde solution 37% in water)	In-house method (PA-U10-METTENS) similar to EU A5	37% formaldehyde Batch nr. NL03024383	At 20°C: 40 mN/m	Certificate of analysis N°Brenntag/25775 /Ch.8076/2023/A Ryckel, B., and Pigeon, O. (2023)
3.9.	Viscosity (all shear rated at 20 °C and 40 °C)	CIPAC MT192, OECD 114	37% formaldehyde Batch: 13-6-2021	The test item is considered to be a Newtonian liquid At 20°C: 2.79 mPa.s At 40°C: 1.74 mPa.s	Viscosity of Formaldehyde solution 37% Report: S21-07210 S. Tischer (2021)

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Formal-EA is a SL. With regard to product stability, no accelerated storage data and low temperature data are available, which is addressed by storage condition restrictions. Long term storage study at ambient temperature shows that FORMAL-EA is stable in HDPE packaging for 12 months. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. **Implications for labelling:** 'Protect from frost', "Protect from direct sunlight" and ' Do not store at temperatures above 30°C '

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.1.	Explosives	Waiver: The biocidal product does not contain functional groups associated with explosive properties. Moreover, based on the results of self-reactive properties, the decomposition energy is less than 500 J/g (-131 J/g) and the product is therefore not considered as explosive.			
4.2.	Flammable gases	Not applicable: The biocidal product is not a gas or a gas mixture.			
4.3.	Flammable aerosols	Not applicable: The biocidal product is not an aerosol			
4.4.	Oxidising gases	Not applicable: The biocidal product is not a gas or a gas mixture.			
4.5.	Gases under pressure	Not applicable: The biocidal product is not a gas or a gas mixture.			
4.6.	Flammable liquids	ISO 2719	37% formaldehyde (Sadeform 36+7) Batch: 400025026	The flash point is 73°C. **BE remark**: Not classified as flammable.	Sadeform 36+7: Vapour flammability, thermal stability and corrosion testing Report: S3016009439R2 /2021 S. Younis (2021)
4.7.	Flammable solids	Not applicable: The biocidal product is not solid.			
4.8.	Self-reactive substances and mixtures	Adiabatic Storage Test (UN Test H.2)	37% formaldehyde (Sadeform 36+7) Batch: 400025026	-SADT/SAPT > 75°C for a 50 kg package -Decomposition energy: -131 J/g < 300 J/g **BE remark:** Not classified as a self-reactive.	Sadeform 36+7: Vapour flammability, thermal stability and corrosion testing Report: S3016009439R2 /2021 S. Younis (2021)
4.9.	Pyrophoric liquids	Waiver: Based on experience, the product does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods			

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product / batch (AS% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td colspan="4">of time (days)).
Please refer to the long term storage test at ambient temperature.</td></tr>
<tr><td>4.10.</td><td>Pyrophoric solids</td><td colspan="4">Not applicable: The biocidal product is not solid.</td></tr>
<tr><td>4.11.</td><td>Self-heating substances and mixtures</td><td colspan="4">Waiver: The phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating.</td></tr>
<tr><td>4.12.</td><td>Substances and mixtures which in contact with water emit flammable gases</td><td colspan="4">Waiver: The biocidal product contains water. Therefore, an emission of flammable gases is not expected when the product comes in contact with water</td></tr>
<tr><td>4.13.</td><td>Oxidising liquids</td><td colspan="4">Waiver: The test does not need to be performed as the mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.</td></tr>
<tr><td>4.14.</td><td>Oxidising solids</td><td colspan="4">Not applicable: The biocidal product is not solid.</td></tr>
<tr><td>4.15.</td><td>Organic peroxides</td><td colspan="4">Waiver: The biocidal product does not contain substances which are organic peroxides, so the test does not need to be done.</td></tr>
<tr><td>4.16.</td><td>Corrosive to metals</td><td>UN test C.1</td><td>37% formaldehyde (Sadeform 36+7)
Batch: 400025026</td><td>Steel coupons (exposure time: 28 days)
<table><tr><th></th><th>Percentage mass loss (%)</th><th>Instrusion depth (µm)</th></tr><tr><td>Vapour space</td><td>0.0</td><td>none</td></tr><tr><td>Half submersed</td><td>2</td><td>163.3</td></tr><tr><td>Fully submersed</td><td>2.1</td><td>142</td></tr></table>Test item was replenished two times during the test.

Aluminium coupons (exposure time: 28 days)
<table><tr><th></th><th>Percentage mass loss (%)</th><th>Instrusion depth (µm)</th></tr><tr><td>Vapour space</td><td>0.0</td><td>none</td></tr><tr><td>Half submersed</td><td>0.77</td><td>239.7</td></tr><tr><td>Fully submersed</td><td>1.33</td><td>195.7</td></tr></table>Test item was replenished two times during the test.

BE remark: Not classified as corrosive to metals</td><td>Sadeform 36+7: Vapour flammability, thermal stability and corrosion testing
Report: S3016009439R2/2021
S. Younis (2021)</td></tr>
</table>

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	/	37% formaldehyde	The auto-ignition temperature is supported by the literature search: - The handbook data (CRC, 2010)[1], Knovel (2012)[2], RömppChemie (2015)[3], the auto-ignition temperature is 424°C. - Gestis (2015)[4] and Ullmanns (2005)[5] report an auto-ignition temperature of 430°C. - The Merck index (2013)[6], reports an auto-ignition temperature of 300°C. [1]Lide, D.R. (2010) CRC Handbook of Chemistry and Physics, 90th Edition. CRC Press/Taylor and Francis, Boca Raton, FL. [2]Wypych G. (2012) Knovel Solvents: A Properties Database - A comprehensive collection of property information for over 1600 different solvents. ChemTec Publishing Toronto - New York Copyright © 2008 [3]Römpp Chemie Lexikon (2015). Formaldehyd. Georg Thieme Verlag KG Rüdigerstraße 14 70469 Stuttgart [4]GESTIS - Substance database (2015). Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) [5]O'Neil, M.J. (2013). The Merck Index, 15th edition, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A., licensed to The Royal Society of Chemistry for use in the U.S.A. and Canada. [6]Reuss G., Disteldorf W., Gamer A.O., Hilt A. (2005). Formaldehyde. Ullmanns Encyclopedia of Industrial Chemistry; Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim A worst case auto-ignition temperature of 300°C can be used.	
4.17.2.	Relative self-ignition temperature for solids	Not applicable: The biocidal product is not solid.			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.17.3.	Dust explosion hazard	Not applicable: The biocidal product is not solid.			

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards

3.4 Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues
Principle of the method for determination of the active substance formaldehyde: HPLC-DAD determination of Formaldehyde at 210 nm after dissolution of the test item in ultrapure water with 0.1% phosphoric acid and derivatisation with derivatisation reagent (ammonium acetate, acetic acid and acetyl acetone in ultrapure water) to diacetyldihydrolutidine (DDL). The HPLC-mode was isocratic with a flow-rate of 1 ml/min and an injection volume of 10 µl. The eluent was water with 0.1 % of phosphoric acid (1000/1 (v/v)). Principle of the method for determination of the relevant impurity methanol: GC-FID determination of Methanol after dissolution of the test item in internal standard solution (739 mg/L ethanol in ultrapure water) and adding of saturated sodium chlorite solution. Principle of the method for determination of the relevant impurity formic acid: The relevant impurity formic acid is analysed by High Performance Liquid Chromatographic. 1 g sample is taken and dissolved in about 80 ml of ultrapure water with 0.1% phosphoric acid in a 100 ml volumetric flask. The solution is sonicated and filled up to the mark with ultrapure water with 0.1% phosphoric acid. The sample solution is diluted ½ with ultrapure water with 0.1% phosphoric acid. Analysis is done by HPLC-DAD at 210 nm with a C18 column and water with 0.1% phosphoric acid as an eluent, using isocratic elution. The method validations are performed starting from a 30% formaldehyde solution. This however does not affect the result as both a 30% and 37% solution will be diluted to the same level to determine the validation parameters.

Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of	Range	Mean	RSD	Concentr	Number		

				measurements				ation tested	of replicates		
Active substance	Concentration range: 0.500 mg/L – 10.0 mg/L (= 8.33% – 167% referred to a nominal test item concentration of 600 mg/ 100 ml dilution factor 1000) Number of samples: 6 correlation coefficient (r^2): 1	The analysis of ultrapure water with derivatisation reagent (0.5 mL ultra water filled up to 5 mL with derivatisation reagent) showed that the background noise contributes to an extent less than 3 % of the total peak area of formaldehyde measured in the samples. Chromatogram is provided.	Low (34.5 mg/l from test item + 20.2 mg /l added) High (34.5 mg/l from test item + 60.4 mg/l added)	5 5	96.5-104 96.2-98.2	99.5 97.1	3 0.8	Mean concentration: 29% w/w of formaldehyde RSD: 1.03% The Horwitz ratio was calculated to be 0.64, which is acceptable since the ratio is ≤1.	5	/	Development and Validation of an analytical method for the content determination of formaldehyde in formaldehyde solution 30% Report: S21-00515 S. Tischer (2022)
Relevant	Concentr	GC-FID	Low	5	97.7-	99.2	1.4	Mean	5	2.503 mg/L	Developme

impurity (methanol)	ation range: 100.1 mg/L – 2503 mg/L (= 1% – 25.03 % referred to a nominal test item concentration of 500 mg/ 50 ml) Number of samples: 7 correlation coefficient (r^2): 0.9996	analysis of internal standard solution showed no significant interference (< 3 %) with the signal of Methanol, so that relevant interference with the analytes can be excluded. Chromatogram is provided.	(5.918 -6.148 mg from test item + 2.503 mg added) High (5.935 -5.974 mg from test item + 8.761 mg added)	5	101 92.9-93.3	93.1	0.2	concentration: 5.62% w/w of methanol RSD:1.8 % The Horwitz ratio was calculated to be 0.87, which is acceptable since the ratio is ≤1		recovery (corresponding to 2.50% w/w)	nt and Validation of an analytical method for the content determination of methanol in formaldehyde solution 30% Report: S21-00516 S. Tischer (2022)
Relevant Impurity (formic acid)	Concentration range: 0.263 mg/L – 21.0 mg/L (=0.00526 % – 0.420 % referred to a	The analysis of the solvent (ultrapure water with 0.1% phosphoric acid) shows that the background noise contributes	Low (0.198 mg/l from test item + 0.510 mg/l added) High	5 5	87.6-106.9 102.2-104.5	98.5 103.2	8.0 0.9	Mean concentration: 0.0441 % w/w of formic acid RSD:8.0 %	5	0.510 mg/Lrecovery (corresponding to 0.0102% w/w)	Development and Validation of an analytical method for the content determination of formic acid in formaldehyde solution

	nominal test item concentration of 100 mg/ 100 ml) Number of samples: 7 correlation coefficient (r^2): 0.9999	to an extent less than 3 % of the total peak of formic acid measured in the samples. Chromatogram is provided.	(0.198 mg/l from test item + 5.10 mg/l added)					The Horwitz ratio was calculated to be 1.51, which is acceptable because of the low amount of spiked reference item.			30% Report: S21-00517 S. Tischer (2022)

Table 3.7 Analytical methods for soil

Analytical methods for soil	
Reference is made to the active substance dossier of formaldehyde.	Assessment report formaldehyde, 2019

Table 3.8 Analytical methods for air

Analytical methods for air	
Reference is made to the active substance dossier of formaldehyde. Analysis of airborne formaldehyde is determined using RP-HPLC-UV, RP18 column. The limit of quantification (LOQ) is 0,03 µg/m3 air.	Assessment report formaldehyde, 2019

Table 3.9 Analytical methods for water

Analytical methods for water	
Reference is made to the active substance dossier of formaldehyde. Analysis of formaldehyde residues in water are determined using GC-ECD, DB-5 and AT-1701 column. The limit of quantification (LOQ) is 0,08 µg/L for drinking water and 5 µg/L for surface water.	Assessment report formaldehyde, 2019

Table 3.10 Analytical methods for animal and human body fluids and tissues

Analytical methods for animal and human body fluids and tissues	
Monitoring is not meaningful since formaldehyde is permanently present in humans.	Assessment report formaldehyde, 2019

Table 3.11 Analytical methods for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring of active substances and residues in food and feeding stuff	
As no MRL were fixed, no analytical method for the determination of active substance in in food/feed of plant and animal origin is required.	Assessment report formaldehyde, 2019

Table 3.12 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods for the determination of formaldehyde, methanol and formic acid (reference: Tischer et al 2022 (study reports S21-00515, S21-00516 and S21-03517)) in the biocidal product are available. Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of formaldehyde in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required. - As no MRL was fixed, no analytical method for the determination of active substance in food/feed of plant and animal origin is required.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected

Main group 01: DISINFECTANTS

Product type:

- PT3 (*Veterinary Hygiene*)

The product ***FORMAL-EA*** is a soluble concentrate (to be diluted with tap water) and contains 37% formaldehyde (CAS N°50-00-0) as active substance.

The product ***FORMAL-EA*** is intended to be used indoor by professional users for automated airborne room disinfection (via *Cold Ultrasonic Fogging*) for:

- **Use #1**: Disinfection of hatching-eggs*, at +20°C in a 49 m^3 fumigation sluice

* NOTE: Eggs are disinfected twice. The first disinfection is performed just after arrival at the hatchery in the fumigation sluice before incubation and the second disinfection occurs in the hatchers. Eggs are daily delivered from farms, transferred to trays on a setter trolley and then disinfected in a fumigation sluice. In this use, disinfection of the sluice only is claimed.

After leaving the sluice, the eggs are transferred to setters where they are incubated for 18 days.

This procedure is fully automated. Once the effective concentration of 5g formaldehyde/m^3 is achieved in the room, these conditions are maintained for at least 60 min prior to starting the ventilation. During this period, the eggs are in continuous contact with the disinfectant, as air circulation as well as the saturation level is maintained. Mechanical rotation of eggs is not applied, because the complete surface of each egg – regardless of the location of the tray / trolley - is covered by the humid air (very thin layer of condensate, but no droplets, at the eggshell).

- **Use #2**: Disinfection of empty/closed animal housing (volume > 4 m^3), at +20°C

Target organisms include bacteria (mycobacteria & spore-forming bacteria excluded), fungi, yeasts and viruses.

The "organisms to be protected" are first animals and second humans as animal consumers.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

"Formaldehyde is effective against all types of cells, including microorganisms. Cells are highly permeable to formaldehyde.
As a potent electrophile, formaldehyde rapidly react with cellular biological nucleophiles constituents to inhibit growth via damages of protein/peptide/DNA-RNA purine bases. Formaldehyde is a well-known cross-linking agent that can inactivate, stabilize, or immobilize proteins. Formaldehyde reacts with amino acids via the free thiol -SH and amine -NH2 groups of proteins (Chen NH & al. – 2016 – "Formaldehyde Stress Responses in Bacterial Pathogens" Front. Microbiol. 7:257; Hoffman EA & al. – 2015 – "Formaldehyde Crosslinking: A Tool for the Study of Chromatin Complexes" Journal of Biological Chemistry 44:26404; Kamps JJAG & al. – 2019 – "How formaldehyde reacts with amino acids" Commun. Chem 2:126; Metz B & al. – 2004 – "Identification of formaldehyde-induced modifications in proteins: reactions with model peptides". J Biol Chem. 279(8):6235). Reaction with free thiol -SH generate thiazolidine adducts (for example, cysteine reacts most efficiently). Reaction with amine -NH2 create imine or Schiff-base adducts (via an N-methylol intermediate) which react afterwards with other amines forming irreversible stable cross-link methylene bridges."

3.5.3 Efficacy data

In order to support the claims, the ECHA guidance vol II Parts B+C from Nov. 2022 has been followed. According to this new version, only Phase 2/Step2 tests performed according to the EN 17272 standard should be performed and submitted for review. Phase 2/Step1 suspension tests were submitted anyway. Listed for information only in the table below, these suspension tests were not taken into account for determining the global efficacy since such suspension tests are not required anymore in the new version of the guidance.
Standardized simulated-use fogging tests performed according to the EN 17272 standard (with an adapted protocol at +20°C) were submitted and performed using the *MS Hatchfog Ultra* device, in a volume of 74 m^3 with an application rate of 5g formaldehyde/m^3 and a contact of 60 or 120 min respectively for use#1 and use #2.

To determine the efficacious concentration of formaldehyde for animal house disinfection, a simulated use test is used. Based on the outcome of a CG informal e-consultation from

September 2021, it was proposed to perform a simulated use test according to the unmodified EN 17272 to achieve a comparable and harmonised evaluation. The test should be performed in a room of 30-150m^3, test labs that were contacted and were able to perform the EN 17272, do not have rooms available with a volume of 150m^3. In general, the room volumes at the test labs are between 60-80m^3. Due to the room size, the device required for stable disinfection could not be used as it is designed to treat large volumes and thus the MS Hatchfog Ultra was also used in the EN 17272
The temperature of the simulated use test (+20°C) deviates from the proposed temperature (+10°C). A higher temperature was selected as disinfection of animal housing is done only in closed stables which are heated before disinfection.

About the test temperature, the APP have contacted several labs and they all indicated that they are not able to perform the EN 17272 test at +10°C. Therefore, the APP proposes to perform the tests at +20°C. The APP also clarify that +20°C does correspond with the practical situation. The stable should be heated before use and this restriction will be added to the SPC.

For Use 1, there is a deviation from the proposed temperature (+30°C) as in this use, only disinfection in the disinfection sluice is claimed. This sluice is not heated and thus is similar to room temperature. Therefore, testing is performed at +18-20°C, which can be considered to be worst case compared to testing at +30°C. When comparing the EN 1656 at +18°C with the EN 1656 at +10°C, the formaldehyde concentration required is lower when tested at 18°C compared to +10°C (although contact time at +10°C is longer). The simulated use tests have been performed at +/-20°C, as the temperature in the room cannot be strictly controlled during fogging.

Characteristics of the *MS Hatchfog Ultra* device used to perform the EN 17272 tests) :
- Equipment name and model: *MS Hatchfog Ultra*
- Diffusion principles: 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 %)

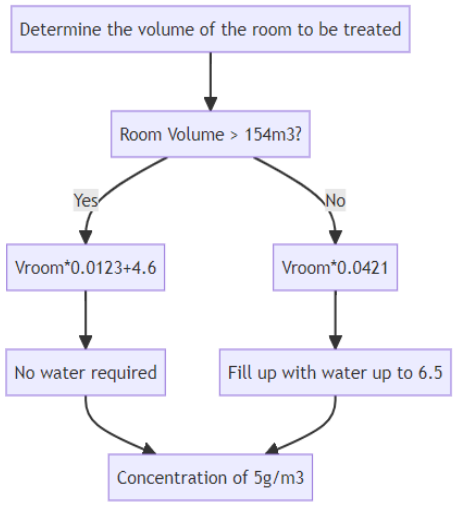
~~- Particle size distribution: population centered Dv(50) (µm): 5.15 µm; mean diameter D[4][3] (µm): 8.94 µm; particle population under the threshold of 50 µm: 98.85 %~~

- Description of the ambient conditions: the stable should be at 20°C and have a relative humidity of 55% to start the disinfection.
- The distribution test showed that the fog reached the outer corners.

The fogging process (for uses #1 & #2) when using the *MS Hatchfog Ultra* device is described as follows by the Applicant:

1) **Preparation and dilution phase**:

The *MS Hatchfog Ultra* device needs at least 6.5 L of liquid in the tank to start the fogging process.
The device automatically stops fogging when the volume in the tank reaches 4.6 L.
Based on these specifications, the volume of FORMAL-EA to be used for a specific volume, can be then calculated as indicated below:



For rooms ≥ 154 m³, the volume of Formal-EA to be added to the tank should be calculated as follows:
$VOLUME_{FORMAL\text{-}EA}$ (L)= Room volume (m^3)/density (1097,5g/L)*13.52g FORMAL-EA/m^3+4.6L FORMAL-EA
⇔ **$VOLUME_{FORMAL\text{-}EA}$ (L) = Room volume (m^3)*0.0123 (L/m^3) + 4.6 L**
In this case, as the amount of product is more than 6.5 L (the minimum amount of liquid for MS HATCHFOG ULTRA to start fogging), no dilution step is required, and the product is

used pure (100%).

For rooms ≤ 154 m³, the volume of Formal-EA to be added to the tank should be calculated as follows:

$VOLUME_{FORMAL\text{-}EA}$ (L) = Room volume (m^3)/density (1097,5g/L)*13.52g FORMAL-EA/m^3*3,42

⇔ $VOLUME_{FORMAL\text{-}EA}$ (L)= Room volume (m^3)*0.0421(L/m^3)

The amount of FORMAL-EA needed is less than 6.5 L. As only 1.9 L of solution in the tank is fogged, the factor of 3.42 is included in the formula which is the ratio of 6.5L/1.9L. In this case, as the amount of product is less than 6.5 L (the minimum amount of liquid for MS HATCHFOG ULTRA to start fogging), 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%.

For a 74 m^3 room (room volume used for the EN 17272 studies):

a) From the calculation using the second formula presented just above for rooms ≤ 154 m^3, we need 3.1154 L of *FORMAL-EA*

b) This solution will be added to the tank and filled up to 6.5 L with water to be able to start the device, otherwise it will not start !

c) 3.1154 L of *FORMAL-EA* (containing 37% formaldehyde) in a final volume of 6.5 L

⇔ **17.7338 % v/v dilution of *FORMAL-EA*** ⇔ 6.5615 % v/v formaldehyde

d) Since the *MS Hatchfog Ultra* device needs at least 6.5 L of liquid in the tank to start the fogging process and automatically stops fogging when the volume in the tank reaches 4.6 L, only 1.9 L of 17.7338 % dilution of *FORMAL-EA* will be fogged in 74 m^3.

⇔ 25,6757 mL of 17.7338 % dilution of *FORMAL-EA*/m^3 fogged

⇔ 4.5533 mL formaldehyde/m^3

⇔ 4.9972 g formaldehyde/m^3 (with $density_{formaldehyde}$ = 1,0975 g/mL) ≈ **5 g formaldehyde/m^3**

⇔ 12.32 mL *FORMAL-EA* /m^3

2) **Conditioning phase**:

The *MS Hatchfog Ultra* device will release formaldehyde fog at a speed of respectively 0,475l/min. Depending on the volume, the conditioning phase will be longer or shorter. MS Hatchfog Ultra will stop fogging when the tank contains 4.6L of liquid.

3) **Disinfection phase**:

Use #1: The treated room will be closed, and ventilation shut down for 60min.

Use #2: The treated room will be closed, and ventilation shut down for 120min.

4) **Terminal phase**:

Use #1: The room will be ventilated after 60min at a rate of at least 2000 m^3/h. After

20 min of ventilating, the operator is allowed to re-enter the room

Use #2: The room will be ventilated after 120min. After 2-4 days of ventilating, the operator is allowed to re-enter the room.

Table 3.13 Efficacy data

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr>
<td>PT3
- #Use 1: Disinfection of hatching eggs (in disinfection sluice) by fogging</td>
<td>37% formaldehyde (Ref. SN 33113 & SN 33113-a) as single dilution in water – To be stored at RT in darkness.</td>
<td>Bactericidal activity
Staphylococcus aureus
Enterococcus hirae
Pseudomonas aeruginosa
Proteus hauseri</td>
<td>EN 1656 (2019)
Quantitative P2S1 suspension test

Temperature: +18°C ± 1°C
Contact time: 60 min
Concentrations tested: from 0.25% to 4%
I.S.: 3 g BSA/L (clean)</td>
<td>
<table>
<tr><th colspan="6">Log Reduction
(Pass criteria: ≥ 5 Log reduction)</th></tr>
<tr><td></td><td>4%</td><td>3%</td><td>2.5%</td><td>2%</td><td>1%</td></tr>
<tr><td>S. aureus*</td><td colspan="4">> 5.04</td><td><3.97</td></tr>
<tr><td colspan="6">* The test with S. aureus was performed (with the batch SN 33113) first as a sort of screening, as this was the most resistant organism. After obtaining a pass concentration with this organism, the test was conducted for the other organisms with a different batch i.e. SN 33113-a.</td></tr>
<tr><td></td><td>2%</td><td>1%</td><td>0.75%</td><td>0.5%</td><td>0.25%</td></tr>
<tr><td>E. hirae</td><td>5.01</td><td colspan="4">< 4.12</td></tr>
<tr><td>P. aeruginosa</td><td colspan="4">> 5.05</td><td>4.66</td></tr>
<tr><td>P. hauseri</td><td colspan="4">> 5.06</td><td>4.54</td></tr>
</table>
BACTERICIDAL ACTIVITY
at 2% (⇔ 0.74 % formaldehyde)
in 60 min
at +18°C
under clean conditions
</td>
<td>Werner, S. and Naujox, K., 2021a – (Study N° 2021-2900)</td>
<td>#6.7.1
For information</td>
</tr>
<tr>
<td></td>
<td>37% formaldehyde (Ref. SN 33113-a) as single dilution in water – To be stored at RT in darkness.</td>
<td>Yeasticidal activity
Candida albicans</td>
<td>EN 1657 (2016)
Quantitative P2S1 suspension test

Temperature: +18°C ± 1°C
Contact time: 60 min
Concentrations tested: 0.1; 0.5 & 1%
I.S.: 3 g BSA/L (clean)</td>
<td>
<table>
<tr><th colspan="4">Log Red4ction
(Pass criteria: ≥ 4 Log reduction)</th></tr>
<tr><td></td><td>1%</td><td>0.5%</td><td>0.1%</td></tr>
<tr><td>C. albicans</td><td colspan="2">> 4.15</td><td>< 3.08</td></tr>
</table>
YEASTICIDAL ACTIVITY
at 0.5% (⇔ 0.185 % formaldehyde)
in 60 min
at +18°C
under clean conditions
</td>
<td>Werner, S. and Naujox, K., 2021 (Study N° 2021-3721)</td>
<td>#6.7.2
For information</td>
</tr>
</table>

	37% formaldehyde (Ref. SN 33113-a) as single dilution in water – To be stored at RT in darkness.	**Fungicidal activity** *Aspergillus brasiliensis*	**EN 1657 (2016)** **Quantitative P2S1 suspension test** Temperature: +18°C ± 1°C Contact time: 60 min Concentrations tested: 0.25 => 6% I.S.: 3 g BSA/L (clean)	**Log Red4ction** (Pass criteria: ≥ 4 Log reduction) 2.5% => 6% | 0.5% => 2% | 1% *A. brasiliensis*: > 4.41 | > 4.36 | 3.75 **FUNGICIDAL ACTIVITY** at 0.5% (⇔ 0.185 % formaldehyde) in 60 min at +18°C under clean conditions	Werner, S. and Naujox, K., 2021c (Study N° 2021-2901)	#6.7.3 **For information**
	37% formaldehyde (Ref. SN 33113-a) as single dilution in water – To be stored at RT in darkness.	**Virucidal activity** ECBO virus	**EN 14675 (2015)** **Quantitative P2S1 suspension test** Temperature: +18°C ± 1°C Contact time: 60 min Concentrations tested: 0.25 => 2% I.S.: 3 g BSA/L (clean)	**Log Reduction** (Pass criteria: ≥ 4 Log reduction) 2% | 1% | 0.75% | 0.5% | 0.25% ECBO: No* | No* | No* | Yes** | No* ** due to the cytotoxicity of the product the ≥ 4lg reduction could not be demonstrated using the endpoint titration method.* ***The ≥ 4lg reduction could be demonstrated using the LVP-method* **NO conclusion since report not clear at all i.e. Log reductions not clearly (without ambiguity) reported.**	Werner, S. and Schmit, N., 2021 (Study N° 2021-3498)	#6.7.4 **Rejected**
	37% formaldehyde (Ref. 56017) as single dilution in water – To be stored at RT in darkness.	**Bactericidal activity** *Staphylococcus aureus* *Enterococcus hirae* *Proteus hauseri* *Pseudomonas aeruginosa* **Fungicidal/yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis* **Virucidal activity** ECBO virus Porcine parvovirus	**EN 17272 (2020)** **Quantitative P2S2 Surface Test (room disinfection by fogging)** **- Emission device**: MS Hatchfog Ultra (MS Schippers) - Cold Ultrasonic fogging **- Particle size distribution:** Population centered Dv(50) (µm): 5.15 µm; mean diameter D[4][3] (µm): 8.94 µm; particle population under the threshold of 50 µm: 98.85 % **- Diffusion time:** 0.475 L/min **- Concentrations tested**: 17.7% ⇔ 5g formaldehyde/m³ ⇔ **12.32 mL FORMAL-EA/m³** - **Dosage**: 25.68 mL/m³ **- Room volume**: 74 m³ **- Test Carrier:** poplar wood	**Log Reduction** (Pass criteria: ≥ 5 Log reduction) *P. aeruginosa*: 6.29 *S. aureus*: 7.03 *E. hirae*: 7.16 *P. hauseri*: 6.17 **Log Reduction** (Pass criteria: ≥ 4 Log reduction) *C. albicans*: 5.88 *A. brasiliensis*: 6.03 **Log Reduction** (Pass criteria: ≥ 4 Log reduction) ECBO virus: > 6.40 Porcine parvovirus: > 5.49 **BACTERICIDAL, FUNGICIDAL/YEASTICIDAL & VIRUCIDAL ACTIVITY** With 5g formaldehyde/m³	Torrellas, M. and Esteban, E., 2023a – Study No. D/22/B0*700* Torrellas, M. and Esteban, E., 2023b – Study No. D/22/B0701 Fernandez, M. and Esteban, E., 2023a – Study No. D/22V0324-2	#6.7.5.1 / 6.7.5.2/ 6.7.5.3 **R.I. 1 Key Study**

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>
- Layout of the carriers:
Position inside the chamber: vertical
Distance to the device: 3.9 m

- Temperature & Relative humidity:
<table>
<tr><th></th><th>Bacteria</th><th>Fungi/Yeasts</th><th>Virus</th></tr>
<tr><td>T°C before</td><td colspan="2">20.3</td><td>20.1-20.3</td></tr>
<tr><td>T°C after</td><td colspan="2">20.2</td><td>20.2-20.5</td></tr>
<tr><td>RH before</td><td colspan="2">55</td><td>55</td></tr>
<tr><td>RH after</td><td colspan="2">68</td><td>66-67</td></tr>
</table>
- Contact time:
• Time of releasing the product by dispersion: 5 min
• Time of contact after dispersion of the product: 60 min

- Interference substances: 3 g BSA/L (clean)
For sensitive organisms (Pseudomonas aeruginosa, Proteus hauseri, Candida albicans): 1/20 skimmed milk (100 g/L) was added to 3 g/L BSA.
</td>
<td>
in 60 min
at +18°C
under clean conditions

+ The disinfection process with the product, tested under the same conditions described for the efficacy test, shows a 7.03 log reduction (B + F/Y) & a 7.07 log reduction (V) against Staphylococcus aureus, therefore it shows a good distribution when studying the efficacy against Staphylococcus aureus CECT 239 (= ATCC 6538) in all the test carriers, when the activity is evaluated according to the EN 17272: 2020 Standard under the conditions of the BPR: 2022 Guidance.

Since the dossier was submitted in 2021, the EFF guidance from 2018 is of application. In this version, about disinfection of hatching-eggs, there is no requirement about P2S2 tests. Then, from the beginning, the APP made the decision to design the tests using poplar wood as representative type of surface for egg disinfection.
On the other hand, in the guidance version from August 2023, it's now mentioned that "for P2S2 test the EN test for porous surfaces should be used for bacteria" and that "sterile eggshells may be used in P2S2 tests, as an alternative porous surface for disinfection of hatching-eggs".
About the efficacy test performed, we could agree that poplar wood is not the best representative type of surface for egg disinfection, but it's worst-case since porosity of eggs is in between.
we consider poplar wood as porous surface & worst-case since porosity of eggs is in between. Use of porous surface does be set against this potential overestimation.
Furthermore, about the results, the min Log reduction achieved for bacteria is 6.17 (with Log 5 reduction as pass criteria), for fungi/yeasts is 5.88 (with Log 4 reduction as pass criteria) and for porcine parvovirus is 5.49 (with Log 4 reduction as pass criteria). The margin of safety is high enough to consider the treatment as efficacious. At the renewal of the product, the APP must follow the guidance in-force and update the dossier with a SU test on porous surface in presence of eggshells or a field test in order to
</td>
<td></td>
<td></td>
</tr>
</table>

				confirm that the application rate validated is sufficient for this use.		

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr><td>PT3
- #Use 2: Disinfection of animal housing by fogging</td><td>30% formaldehyde as single dilution in water</td><td>Bactericidal activity
Staphylococcus aureus
Enterococcus hirae
Proteus hauseri
Pseudomonas aeruginosa</td><td>EN 1656 (2019)
Quantitative P2S1 suspension test

Temperature: +10°C ± 1°C
Contact time: 120 min
Concentrations tested: 0.75 => 3%
I.S.: 3 g BSA/L (clean)</td><td>Log Reduction
(Pass criteria: ≥ 5 Log reduction)
<table><tr><th></th><th>3%</th><th>2%</th><th>1.5%</th><th>1%</th><th>0.75%</th></tr><tr><td>S. aureus</td><td colspan="2">> 5.07</td><td colspan="3"><2.0</td></tr><tr><td>E. hirae</td><td>> 5.2</td><td colspan="2"><2.15</td><td colspan="2"><2.07</td></tr><tr><td>P. aeruginosa</td><td colspan="3">> 5.05</td><td>-</td><td>-</td></tr><tr><td>P. hauseri</td><td colspan="3">> 5.25</td><td>-</td><td>-</td></tr></table>
BACTERICIDAL ACTIVITY
at 3% (⇔ 0.9 % formaldehyde)
in 120 min
at +10°C
under clean conditions</td><td>Werner, S. and Naujox, K., 2021 (Study N° 2021-1358)</td><td>#6.7.6
For information</td></tr>
<tr><td></td><td>30% formaldehyde as single dilution in water</td><td>Yeasticidal activity
Candida albicans</td><td>EN 1657 (2016)
Quantitative P2S1 suspension test

Temperature: +10°C ± 1°C
Contact time: 120 min
Concentrations tested: 0.1 => 3%
I.S.: 3 g BSA/L (clean)</td><td>Log Reduction
(Pass criteria: ≥ 4 Log reduction)
<table><tr><th></th><th>3% / 2%/ 1,5%</th><th>1% / 0,75%</th><th>0,1%*</th></tr><tr><td>C. albicans</td><td>>4.14</td><td>>4.46</td><td><3.01</td></tr></table>* DES-F (37% formaldehyde stabilized with 7 % Methanol)

YEASTICIDAL ACTIVITY
at 0.75% (⇔ 0.225 % formaldehyde)
in 120 min
at +10°C
under clean conditions</td><td>Werner, S. and Naujox, K., 2021 (Study N° 2021-2044 and 2022-2171)</td><td>#6.7.7
For information</td></tr>
<tr><td></td><td>37% formaldehyde (Ref. SN 33113-a) as single dilution in water – To be stored at RT in darkness.</td><td>Fungicidal activity
Aspergillus brasiliensis</td><td>EN 1657 (2016)
Quantitative P2S1 suspension test

Temperature: +10°C ± 1°C
Contact time: 120 min
Concentrations tested: 0.01 => 2%
I.S.: 3 g BSA/L (clean)</td><td><table><tr><th></th><th colspan="5">Log Reduction
(Pass criteria: ≥ 4 Log reduction)</th></tr><tr><th></th><th>2%</th><th>1%</th><th>0,5%</th><th>0.1%</th><th>0.01%</th></tr><tr><td>A. brasiliensis</td><td colspan="3">> 4.37</td><td colspan="2">< 3.30</td></tr></table>
FUNGICIDAL ACTIVITY
at 0.5% (⇔ 0.185 % formaldehyde)</td><td>Werner, S. and Naujox, K., 2021 (Study N° 2021-3724)</td><td>#6.7.8
For information</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td>in 120 min
at +18°C
under clean conditions</td><td></td><td></td></tr>
<tr><td></td><td>37% formaldehyde (Ref. SN 33113-a) as single dilution in water – To be stored at RT in darkness.</td><td>Virucidal activity
ECBO virus</td><td>EN 14675 (2015)
Quantitative P2S1 suspension test

<u>Temperature:</u> +18°C ± 1°C
<u>Contact time</u>: 60 min
<u>Concentrations tested</u>: 0.25 => 2%
<u>I.S.</u>: 3 g BSA/L (clean)</td><td><table><tr><th colspan="4">Log Reduction
(Pass criteria: ≥ 4 Log reduction)</th></tr><tr><td></td><td>1.25%</td><td>1%</td><td>0.75%</td></tr><tr><td>ECBO</td><td colspan="2">Yes*</td><td>No</td></tr></table>* The ≥ 4lg reduction could be demonstrated using the LVP-method

NO conclusion since report not clear at all i.e. Log reductions not clearly (without ambiguity) reported.</td><td>Werner, S. and Schmit, N., 2022 (Study No. 2021-2869)</td><td>#6.7.9
Rejected</td></tr>
<tr><td></td><td>37% formaldehyde (Ref. 56017) as single dilution in water – To be stored at RT in darkness.</td><td>Bactericidal activity
Staphylococcus aureus
Enterococcus hirae
Proteus hauseri
Pseudomonas aeruginosa

Fungicidal/yeasticidal activity
Candida albicans
Aspergillus brasiliensis

Virucidal activity
ECBO virus
Porcine parvovirus</td><td>EN 17272 (2020)
Quantitative P2S2 Surface Test (room disinfection by fogging)

- Emission device: MS Hatchfog Ultra (MS Schippers) - Cold Ultrasonic fogging

- Particle size distribution: Population centered Dv(50) (µm): 5.15 µm; mean diameter D[4][3] (µm): 8.94 µm; particle population under the threshold of 50 µm: 98.85 %
- Diffusion time: 0.475 L/min
- Concentrations tested: 17.7%
⇔ 5g formaldehyde/m³
⇔ 12.32 mL FORMAL-EA/m³

- Dosage: 25.68 mL/m³
- Room volume: 74 m³
- Test Carrier: stainless steel

- Layout of the carriers:
Position inside the chamber: vertical
Distance to the device: 3.9 m

- Temperature & Relative humidity:<table><tr><td></td><td>Bacteria</td><td>Fungi/Yeasts</td><td>Virus</td></tr><tr><td>T°C before</td><td>20.0</td><td>20.0</td><td>20.0-20.3</td></tr></table></td><td><table><tr><th colspan="2">Log Reduction
(Pass criteria: ≥ 5 Log reduction)</th></tr><tr><td>P. aeruginosa</td><td>6.27</td></tr><tr><td>S. aureus</td><td>7.07</td></tr><tr><td>E. hirae</td><td>6.96</td></tr><tr><td>P. hauseri</td><td>6.23</td></tr></table><table><tr><th colspan="2">Log Reduction
(Pass criteria: ≥ 4 Log reduction)</th></tr><tr><td>C. albicans</td><td>5.92</td></tr><tr><td>A. brasiliensis</td><td>5.96</td></tr></table><table><tr><th colspan="2">Log Reduction
(Pass criteria: ≥ 4 Log reduction)</th></tr><tr><td>ECBO virus</td><td>> 6.20</td></tr><tr><td>Porcine parvovirus</td><td>> 5.24</td></tr></table>BACTERICIDAL, FUNGICIDAL/YEASTICIDAL & VIRUCIDAL ACTIVITY
With 5g formaldehyde/m³
in 120 min
at +18°C
under clean conditions

+ The disinfection process with the product, tested</td><td>Torrellas, M. and Esteban, E., 2023c – Study No. D/22/B0698

Torrellas, M. and Esteban, E., 2023d – Study No. D/22/B0699

Fernandez, M. and Esteban, E., 2023b – Study No. D/22V0322-2</td><td>#6.7.10.1 / 6.7.10.2/ 6.7.10.3
R.I. 1
Key Study</td></tr>
</table>

			<table><tr><td>T°C after</td><td>20.1</td><td>20.1</td><td>20.1-20.2</td></tr><tr><td>RH before</td><td>55</td><td>55</td><td>55</td></tr><tr><td>RH after</td><td>64</td><td>64</td><td>64-66</td></tr></table> **- Contact time:** • Time of releasing the product by dispersion: 5 min • Time of contact after dispersion of the product: 120 min **- Interference substances:** 3 g BSA/L (clean) For sensitive organisms (*Pseudomonas aeruginosa*, *Proteus hauseri*, *Candida albicans*): 1/20 skimmed milk (100 g/L) was added to 3 g/L BSA.	under the same conditions described for the efficacy test, shows a 7.07 log reduction (B + F/Y) & a 7.05 log reduction (V) against Staphylococcus aureus, therefore it shows a good distribution when studying the efficacy against *Staphylococcus aureus* CECT 239 (= ATCC 6538) in all the test carriers, when the activity is evaluated according to the EN 17272: 2020 Standard under the conditions of the BPR: 2022 Guidance. *Due to the size of the device, efficacy testing was not possible according to the EN 17272 in a test laboratory. Based on the EN 17272, we observed that 5g/m3 is effective. This concentration can be generated with this device, but to show that this device will distribute FORMAL-EA throughout the stable, a distribution test was performed in a stable. Based on this test, it was confirmed that the device was able to produce a fog that reached all corners of the stable.*		

3.5.4 Efficacy assessment

The product ***FORMAL-EA*** is intended to be used indoor by professional users for automated airborne room disinfection via *Cold Ultrasonic Fogging* for:

1) **Use #1**: Disinfection of hatching-eggs, at +20°C in the disinfection sluice only
2) **Use #2**: Disinfection of empty/closed animal housing, at +20°C

To support the claims, the ECHA guidance vol II Parts B+C from Nov. 2022 has been followed. According to this new version, only Phase 2/Step2 tests performed according to the EN 17272 standard should be performed and then were submitted for review.
Based on the data provided, activity of the product *FORMAL-EA* is demonstrated against bacteria (mycobacteria & spore-forming bacteria excluded), fungi, yeasts and viruses with 5g formaldehyde/m^3 (⇔ 12.32 mL FORMAL-EA/m^3) for applications via Cold Ultrasonic Fogging (particle population under the threshold of 50 µm: 98.85 %) in a 74 m^3 room at +20°C and 50-75% RH, under clean conditions:

- **With a contact time of one hour (Use #1)**
- **With a contact time of two hours (Use #2), on hard/porous and non-porous surfaces**

Since the EN 17272 tests were performed in a 74 m^3 room (volume between 30 and 150 m^3), the efficacy of the product is proven for large enclosures > 4 m^3.

3.5.5 Conclusion on efficacy

Activity of the product ***FORMAL-EA*** is demonstrated against bacteria (mycobacteria & spore-forming bacteria excluded), fungi, yeasts and viruses with 5g formaldehyde/m^3 for applications via Cold Ultrasonic Fogging (particle population under the threshold of 50 µm: 98.85 %) in > 4 m^3 rooms at +20°C and 50-75% RH, under clean conditions:
- Use #1 - Airborne disinfection of hatching eggs in the disinfection sluice**:** one hour contact time.
- Use #2 - Airborne disinfection of hard/porous and non-porous surfaces in animal housing: two hours contact time.

The efficacy of the product ***FORMAL-EA*** for both applications has been demonstrated.
Both simulated-use tests performed at 5g formaldehyde/m^3 (⇔ 12.32 mL FORMAL-EA/m^3) have shown the required log reduction for all claimed target organism, therefore this concentration is used in the risk assessments.

3.5.6 Occurrence of resistance and resistance management

According to the BPC opinion, as formaldehyde is not specific for one cellular target, the development of resistance is unlikely if sufficiently high formaldehyde concentrations are guaranteed that exceed the capacity of the innate detoxification systems.

3.5.7 Known limitations

There are no known limitations to the product.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

Not applicable - product is not intended to be authorised for use with other biocidal product(s).

3.6 Risk assessment for human health

The product consists of 100% premix of the active substance. This premix contains 37% formaldehyde solution and < 7% methanol.According to the Assessment Report (2019) and the BPC opinion on the application for approval of the active substance formaldehyde for PT3 "The active substance is a formaldehyde solution in water (25-55.5% formaldehyde, <7% methanol as stabilizer). So this product falls within the limits set up in the Assessment report and the BPC opinion and the classification proposed in this document is applicable to the product.

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the current harmonised classification of the a.s. formaldehyde (6th ATP). However, there is a new RAC opinion from 2022 (CLH-O-0000007130-88-01/F) which would have an impact on the acute toxicity endpoints and would lead to a different classification and labelling of the product (new: Acute Tox. 4, H302, Acute Tox. 2, H330, acute dermal toxicity no longer required) when the new ATP with classification from the RAC Opinion is released.

3.6.2 Skin corrosion and irritation

Table 3-14 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin corrosion cat 1B
Justification for the value/conclusion	Formaldehyde concentration more than 25% is classified as a skin corrosive. The product contains 37% formaldehyde and is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used.
Classification of the product according to CLP	Skin corr. 1B - H314: Causes severe skin burns and eye damage

Table 3-15 Data waiving

Data waiving	
Information requirement	IUCLID: 8.1.1 – Skin corrosion and irritation
Justification	According to the guidance on information requirements (Volume III Part A, May 2018), testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.3 Eye irritation

Table 3-16 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye Damaging cat 1
Justification for the value/conclusion	Formaldehyde concentration more than 25% is classified as eye damaging. The product contains 37% formaldehyde.
Classification of the product according to CLP	Where a chemical is classified as skin corrosion Sub-Category 1A, 1B, 1C or Category 1, labelling for serious eye damage/eye irritation can be omitted as this information is already included in the hazard statement for skin corrosion Category 1 (H314). *However a classification as* Eye Dam. 1; H318 is still required.

Table 3-17 Data waiving

Data waiving	
Information requirement	IUCLID: 8.1.2 – Eye irritation
Justification	According to the guidance on information requirements (Volume III Part A, May 2018), testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.4 Respiratory tract irritation

Table 3-18 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The specific concentration limit of formaldehyde is 5 % for the classification as STOT SE 3. The product contains formaldehyde (H335) > 5% therefore H335 is required for the mixture and triggers classification as STOT SE 3 (respiratory tract irritation).
Classification of the product according to CLP	*A classification as* STOT SE 3; H335 is still required. However the hazard statement H335 may be omitted for the labelling if a corrosivity pictogram (GHS05) is assigned. Additional Hazard statement of EUH071 (Corrosive to the respiratory tract) will be included in the labelling.

Table 3-19 Data waiving

Data waiving	
Information requirement	/
Justification	Respiratory irritation is currently not included in the testing strategies. In addition, according to the guidance on information requirements (Volume III Part A,May 2018), testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the

	rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.5 Skin sensitization

Table 3-20 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin Sens. 1
Justification for the value/conclusion	The product is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used.
Classification of the product according to CLP	Skin Sens. 1 - H317: May cause an allergic skin reaction

Table 3-21 Data waiving

Data waiving	
Information requirement	IUCLID 8.3.1 – Skin sensitisation
Justification	According to the guidance on information requirements (Volume III Part A,May 2018), testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.6 Respiratory sensitization

Table 3-22 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No classification
Justification for the value/conclusion	The product is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used and no classification is needed for respiratory sensitisation.
Classification of the product according to CLP	No classification

Table 3-23 Data waiving

Data waiving	
Information	IUCLID 8.3.2 – Respiratory sensitisation

requirement	
Justification	According to the guidance on information requirements (Volume III Part A, May 2018), testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.7 Acute oral toxicity

Table 3-24 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Acute tox. 3
Justification for the selected value	The product is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used.
Classification of the product according to CLP	Acute tox. 3 - H301: Toxic if swallowed.

Table 3-25 Data waiving

Data waiving	
Information requirement	IUCLID 8.5.1 – Acute oral toxicity
Justification	According to the guidance on information requirements (Volume III Part A,May 2018), testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.8 Acute inhalation toxicity

Table 3-26 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Acute tox. 3
Justification for the selected value	The product is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used.
Classification of the product according to CLP	Acute tox. 3 - H331: Toxic if inhaled

Table 3-27 Data waiving

Data waiving	
Information requirement	IUCLID: 8.5.2 – Acute inhalation toxicity
Justification	According to the guidance on information requirements (Volume III Part A,May 2018), testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.9 Acute dermal toxicity

Table 3-28 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Acute tox. 3
Justification for the selected value	The product is the same as the product evaluated in connection with the approval for listing of the active substance; therefore, the classification of the active substance provided in the Assessment Report (2019) is used.
Classification of the product according to CLP	Acute tox. 3 - H311: Toxic in contact with skin

Table 3-29 Data waiving

Data waiving	
Information requirement	IUCLID: 8.5.3 – Acute dermal toxicity
Justification	According to the guidance on information requirements (Volume III Part A,May 2018), testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active ingredient and there are no co-formulants present. The product is the same as the product evaluated in connection with the approval for listing of the active substance. Testing is therefore scientifically unjustified.

3.6.10 Information on dermal absorption

Table 3-30 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Formaldehyde
Value(s)	100%

Justification for the selected value(s)	Formaldehyde concentrations more than 25% are classified as skin corrosive. According to the Technical Agreements on Biocide – TOX 21 (Aug 2021), a default dermal absorption of 100 % should be used for corrosive substances.

Table 3-31 Data waiving

Data waiving	
Information requirement	IUCLID: 8.6 – Dermal absorption
Justification	For corrosive substances a default of 100% should be used. The product is classified as corrosive and therefore a dermal absorption of 100% is used for the mixtures according to the TAB.

3.6.11 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as there are no additional co-formulants added to the active substance.

3.6.12 Other

3.6.13 Food and feeding stuffs studies

Not relevant

3.6.14 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant

3.6.15 Other test(s) related to the exposure to humans

Not relevant

3.6.16 Available toxicological data relating to endocrine disruption

No toxicological data related to endocrine disruption are available.

3.6.17 Exposure assessment and risk characterisation for human health

3.6.18 Introductory remarks

The human health risk assessment has been performed for the following uses:

Use 1: Disinfection of eggs (disinfection sluice) by fogging. Eggs are disinfected twice, one time after arrival in the fumigation sluice and one time in the hatchery. In this use, disinfection of the sluice is claimed only. An example of a disinfection sluice is presented in Figure 1. Eggs are daily delivered from farms, transferred to trays on a setter trolley and then disinfected in a fumigation sluice. The fumigation sluice has an average volume of 49m^3 (Emission Scenario Document for PT3, JRC 2011). After leaving the sluice, the eggs are transferred to setters where they are incubated for 18 days.

The fogging device is in the room and the fogging process is started using a time delay to make sure the operator can leave the room. The whole disinfection process (from start to finish) is automated so safety of personnel can be guaranteed. During the fogging the disinfection sluice can be completely sealed for fumigation. After fumigation (during the prescribed contact time), the door of the disinfection sluice remains closed, but the ventilation is put to a maximum to remove the formaldehyde from the room. Based on technical data[4] from ventilators used in disinfection sluices, the ventilation rates are high >2000m^3/h. After ventilation, the disinfection sluice is opened, and the device is not removed from the room.
The exposure assessment is calculated using an in-use concentration of 5 g formaldehyde/m^3.

Figure 1: Example of a disinfection sluice

Use 2: Disinfection of animal housing by fogging. All animals are removed from the stable before disinfection. The stables are thoroughly cleaned before disinfection. For this use, a fogging device is loaded with a disinfectant outdoors, placed in the unit and the fogging process is started using a time delay to make sure the operator can leave the room. The whole disinfection process (from start to finish) is automated so safety of personnel can be guaranteed. During the fogging the stables should be completely sealed for fumigation. After fumigation (during the prescribed contact time), the door of the stable remains closed, but the ventilation is put to a maximum to remove the formaldehyde from the room. Default ventilation rates are used per animal category (Table 53 HH BPR guidance). After ventilation, the stable is opened, and the device is removed from the room (the device is not cleaned

4

Ventilation2.pdf

after application). The exposure assessment is calculated using an in-use concentration of 5g formaldehyde/m^3.

Relevant guidance documents consulted for human health risk assessment

1. Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C)
2. HeadHoc recommendation 6, Methods and models to assess exposure to biocidal products in different product types
3. HeadHoc recommendation 14, Default human factor values for use in exposure assessments for biocidal products
4. ConsExpo factsheets
5. Technical notes for Guidance

Relevant exposure models or exposure studies used for human health risk assessment

1- ConsExpo
2- ART model
3- TNsG model

Strategy for human health risk assessment

Formaldehyde is of high chemical reactivity, causing local irritation or corrosion at exposed epithelia. There is also convincing evidence for skin sensitisation by the a.s. Formation of DNA-protein links is thought to lead to clastogenic effects. At concentrations causing cytotoxicity in the respiratory tract with induction of regenerative cell proliferation, formation of nasopharyngeal cancer has been established in rats.

In the table below, an overview is presented of the human health risk assessment strategy.

Use	Task	Proposed models/approach
1.	Mixing and loading	Dermal (Systemic): Not required for corrosive substances, covered by the qualitative risk assessment. Dermal (local): As there is no AEC dermal, the local dermal risk assessment is done qualitatively. Inhalation (systemic and local): Consexpo
	Application	Dermal: exposure is not expected Inhalation: exposure is not expected
	Post-Application	Dermal and inhalation: No exposure is expected because the machine is not removed nor cleaned after the application.
	Secondary exposure	Secondary exposure can be excluded due to the fast evaporation (Assessment report formaldehyde (2019)), but a re-entry time should be defined as RMM. Dietary risk assessment not considered for this application as no animals are present.
	Animal health	The viability of embryos was checked
2.	Mixing and loading	Dermal (Systemic): Not required for corrosive substances, covered by the qualitative risk assessment Dermal (local): As there is no AEC dermal, the local dermal risk assessment is done qualitatively. Inhalation: ART model
	Application	Dermal: exposure is not expected Inhalation: exposure is not expected
	Post-Application	Dermal (systemic): Not required for corrosive substances, covered by the qualitative risk assessment Dermal (local): The local exposure was assessed qualitatively. Inhalation: exposure is not expected

	Secondary exposure	Secondary exposure can be excluded due to the fast evaporation (Assessment report formaldehyde (2019)), but a re-entry time should be defined as RMM. Dietary risk assessment not considered for this application as no animals are present.
	Animal health	Not considered for this application.

Considerations on volatility of the active substance(s) and substance(s) of concern
The vapor pressure of formaldehyde is 187 Pa at 25°C, it is considered a volatile substance. Therefore, the exposure to vapour has been also considered for inhalation exposure.

Strategy for livestock exposure and/or dietary risk assessment
Dietary risk assessment has been assessed for use 1 – disinfection of eggs (disinfection sluice) by fogging.
Strategy for the assessment of substance(s) of concern
There is no substance of concern in the product.

Strategy for disinfectant by-products assessment
Not relevant.

3.6.19 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3-32 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	NO	NO	NO	NO	YES
Dermal	YES	NO	NO	NO	NO
Inhalation	YES	NO	NO	YES	NO

3.6.20 List of exposure scenarios

Table 3-33 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group** (e.g. professionals, non-professionals, professional bystanders, non-professional bystanders/general public)
Primary exposure		
1	***Disinfection of eggs (disinfection sluice) by fogging***	
1.1	Mixing and loading: MS Hatchfog Ultra: Indoor diluting concentrated product to the required level based on the room size and added manually into the tank of the fogging device.	Professional
2	***Disinfection of animal housing by fogging***	
2.1	Mixing and loading: MS Hatchfog Ultra: Outdoor diluting concentrated product to the required level based on the room size and added manually into the tank of the fogging device. MS Fogger B: Outdoor pouring concentrated product into the tank of the fogging device.	Professional
2.2	Post-application: removal and cleaning of the equipment	Professional
Combined primary exposure		
2	***Disinfection of animal housing by fogging***	
2.1 + 2.2	Mixing and loading and post-application	Professional
Secondary exposure		
4.1	Inhalation exposure of bystander/professional entering the treated area after disinfection of eggs (disinfection sluice) by fogging	Professional
4.2	Inhalation exposure of bystander/professional entering the treated area disinfection of animal housing by	Professional

Summary table: exposure scenarios		
	fogging.	

3.6.21 Reference values to be used in risk characterisation

Table 3-34 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Rat, overall (28-d, 90-d, 2-yr)	15 mg/kg bw/d	100	Oral absorption of 100% is used	0.15 mg/kg bw/d
AELmedium-term			100	Oral absorption of 100% is used	0.15 mg/kg bw/d
AELlong-term			100	Oral absorption of 100% is used	0.15 mg/kg bw/d
AECdermal	-	-	-	n.r.	-
AEC acute inhalation	Human, eye irritation (subjective)	0.36 µg/L	3	n.r.	0.12 µg/L air
AEC medium-term inhalation	Human, overall ocular/respiratory irritation	0.12 µg/L	1	n.r.	0.12 µg/L air
AEC long-term inhalation	Rat, Monkey, 6-mo	1.2 µg/L	10	n.r.	0.12 µg/L air
ARfD	-	-	-	-	-
ADI	-	-	-	-	-
Orientating reference value for animal health	Rat, overall (28-d, 90-d, 2-yr)	15 mg/kg bw/d	5		3 mg/kg bw/d

3.6.22 Specific reference value for groundwater

Not applicable, because no reference value for groundwater was established. Thus, the European standard value 0.1 µg/l for the maximum admissible concentration of pesticide in drinking water (Council Directive 98/83/EC) applies.

3.6.23 Professional users (including industrial users and trained professional users)

The Technical Agreements for Biocides (TAB, 9 November 2018) and WG-III-2016 states that systemic dermal and oral route is not necessary for exposure to corrosive concentrations as exposure will be negligible as appropriate PPE and RMM will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. However, systemic inhalation should be calculated if inhalation exposure is possible.
Below, only the scenarios where possible exposure can occur are listed.
In the description of the exposure scenario's for the professional user the packaging size of 20kg is used as the smallest packaging size of the 37% formaldehyde solution. This is based on the feedback from the users. Apparently the smaller packages are not relevant for the professional user, so the 20kg packaging can be considered worst case.

Scenario 1.1: Mixing and loading – Disinfection of eggs (disinfection sluice) by fogging – Use 1

Description and input parameters

Table 3-35 Description and input parameters

Description of Scenario 1.1
The disinfection in the hatchery takes place in the fumigation sluice and not in the hatchers. The fumigation sluice has a volume of 49 m^3 and is disinfected on average 7 times per day; therefore, a total volume of 343 m^3 must be disinfected. According to the efficacy results, a concentration of 5 g/m^3 formaldehyde is used for the disinfection of the sluice. Based on the above, 1715 g formaldehyde is needed to disinfect the fumigation sluice 7 times per day. The smallest packaging size of the 37% formaldehyde solution is 20 kg, which contains 7400 g formaldehyde. Thus, one bottle of 20kg formaldehyde is sufficient for 7 applications in one day. Therefore, a frequency of 1 mixing and loading phase is used to calculate the exposure. The concentrated product is loaded into the fogging device. For rooms <154m^3 water needs to be added, for rooms > 154m^3 pure product is poured into the device. To calculate the systemic and local inhalation exposure, the exposure to vapour model in ConsExpo 1.1.1 is used as formaldehyde is a volatile substance with a vapour pressure of 187 Pa. The following parameters have been used to assess the inhalation exposure.

Input parameters for Scenario 1.1			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Absorption values (or equivalent):	100%	Default value
	Body weight:	60 kg	HEAdhoc recommendation 14
	Molecular weight of Active Substance	30.0258 g/mol	CAR
	Kow (10 log)	0.35	CAR
	Concentration of active substance	100%	Product information
	Volume of the fumigation sluice	49 m^3	ESD PT3 default value
	Number of fumigation sluices	1	ESD PT3 default value
	Number of disinfection events	7/day	ESD PT3 default value
	Total volume to be disinfected	343 m^3	Calculated
	Dosage	5 g/m^3	Product-specific data
	Product amount: 20kg packaging	20000 g	Product information
	Frequency	1/day	With a frequency of 1 time per day for mixing and loading, the fumigation sluice can be disinfected 7 times per day.
	Exposure duration	10 min	HEAdhoc Recommendation 6, No. 9
	Molecular weight matrix	47.62 g/mol	Product information
	Density of product:	1.0975 g/ml	Product information
	Room volume	2 m^3	expert judgment based on commenting from DE
	Ventilation rate	0.6/h	Consexpo default value
	Inhalation rate	1.25 m^3/h	HEAdhoc recommendation 14
	Vapour pressure	187 Pa	CAR

	Application temperature	20ºC	ConsExpo default value
	Mass transfer coefficient	10m/hr	Consexpo Cleaning Products Fact Sheet
	Release area mode	Constant	ConsExpo default value
	Release area	20 cm^2	ConsExpo default value
	Emission duration	10 min	HEAdhoc Recommendation 6, No. 9
Tier 2 (Mask)	Protection Factor	20	-

Scenario 2.1: Mixing and loading – disinfection of animal housing by fogging – Use 2

Description and input parameters

Table 3-36 Description and input parameters

Description of Scenario 2.1
The concentrated product is loaded into the fogging device. For rooms <154m^3 water needs to be added, for rooms > 154m^3 pure product is poured into the device. Loading takes place outdoor. The frequency is determined as follows: as a worst case, the largest housing volume of the animal group – turkey with a volume of 12500 m3 is used. According to the efficacy results, a concentration of 5 g/m^3 formaldehyde is used for the disinfection of animal housing. To disinfect this volume, 62500 g formaldehyde is needed. Therefore, 9 bottles of 20kg (containing 7400 g formaldehyde) should be used to disinfect the turkey stable. For all other animal groups, less bottles are required. Therefore, using a frequency of 9 times covers all other animal housing. As the mixing and loading is done outdoors, the ART model is used to assess the inhalation exposure. The following parameters have been used to assess the inhalation exposure.

Input parameters for Scenario 2.1			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Product Type	Liquids	Product information
	Process Temperature	Room temperature (15-25 °C)	
	Exposure duration	10 min	HEAdhoc Recommendation 6, No. 9
	Vapour Pressure	187 Pa	CAR
	Liquid Mole Fraction	1	See appendix 4.1.1 See comment in parameters for scenario 1.1
	Activity Coefficient	1	Default ART
	Is the primary emission source located in the breathing zone of the worker	yes	Worst case
	Activity Class	Transfer of liquid products	Product information
	Activity Subclass	Falling liquids	Worst case
	Which of the situations below does best represent your activity?	1-10 l/minute	Filling of bottles
	Animal housing volume	12500 m^3	"Emission Scenario Document for Insecticides for Stables and Manure Storage Systems", Table 5.2 on page 37
	Quantity of formaldehyde applied per cubic meter	5 g/m^3	Product-specific data
	Amount of FA needed	62500 g	Calculated
	Formaldehyde amount: 20kg *37%	7400 g	Product information
	Frequency	9 /day	Product specific data – 9 bottles – worst case
	What is the level of containment of the process?	Handling that reduces contact between product and adjacent air	Expert judgement based on DE comment

	Is the transfer of liquid performed by splash or submerged loading?	Splash loading	Worst case
	General Control Measures	No localised controls	Worst case
	Is the process fully enclosed and is the integrity of that enclosure regularly monitored?	No	Worst case
	Are demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)?	No	Worst case
	Are general housekeeping practices in place?	No	Worst case
	Is the work performed indoors, outdoors or in a spray room or downward laminar flow booth?	Outdoors	CAR
	Is the source located close to buildings?	Yes	Worst case
	Are secondary sources present in the workroom in addition to the source in the breathing zone of the worker?	No	The only formaldehyde source is the bottle of formaldehyde during mixing and loading
	Inhalation rate	1.25 m^3/hr	HEAdhoc recommendation 14
	body weight	60 kg	HEAdhoc recommendation 14
	Calculated exposure by ART (90^{th} percentile)	4.3 mg/m^3	ART output
	Confidence Interval	1.9 mg/m3–10 mg/m3	ART output
Tier 2 (Mask)	Protection Factor	40	

Scenario 2.2: Post application – disinfection of animal housing by fogging

Description and input parameters

Table 3-37 Description and input parameters

Description of Scenario 2.2
As a post-application step, the equipment is removed from the stable (2-4) days after the application). As a waiting period will be installed before a person can enter the stable again, no significant inhalation exposure is expected. Dermal exposure is also not expected, as according to the CAR 100% of formaldehyde is released to the air after fogging[5].

[5] Evaporation of formaldehyde after wet or room disinfection in animal housings, expert statement, unpublished

Outcome of systemic exposure and risk characterisation

Table 3-38 Summary table: estimated systemic exposure and risk characterisation for professional users

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.15 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario 1.1	1/no PPE	-	-	6.4E-3	6.4E-3	4.27	Yes
Scenario 2.1	1/no PPE	-	-	1.34E-1	1.34E-1	89.3	Yes

Combined scenarios

Outcome of combined systemic exposure and risk characterisation

Not relevant

Outcome of (semi-)quantitative local exposure and risk characterisation

Table 3-39 Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³]**	**Estimated exposure / AEC (%)** AECinhalation = 0.12 mg/m³	**Acceptable (yes/no)**
Scenario 1.1	1/no PPE	-	1.9	1.9	1583	No
	2/Mask factor 20	-	0.095	0.095	79.2	Yes
Scenario 2.1	1/no PPE	-	4.3	4.3	3583	No
	2/Mask factor 40	-	0.108	0.108	90	Yes

Outcome of qualitative local risk assessment

For the dermal route no AEC is available, so no quantitative local risk assessment is performed. As the concentrated product is corrosive, sensitizing and mutagenic, a qualitative local risk assessment is performed for:

- The mixing and loading phase of all uses
- The post application phase of use 2 – disinfection of animal housing.

To assess the dermal local, a qualitative risk assessment according to the Guidance document Volume III Part B section 4.3.2 is performed. Assuming PPE and good hygiene practice the dermal exposure can be avoided and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.

Table 3-40 Outcome of qualitative local risk assessment

Hazard				**Exposure information**					**Risk**	
Hazard	**Effect**	**Additional**	**P**	**Tasks,**	**Potential**	**Frequenc**	**Potentia**	**Relevant**	**Conclusion**	**Uncertaintie**

category	**s in terms of C&L**	**relevant hazard information**	**T**	**uses, processes**	**exposure route**	**y and duration of potential exposure**	**l degree of exposure**	**RMMs & PPE**	**on risk**	**s attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
Very high	Skin Sens. 1, H 317 Skin Corr. 1B H 314 Eye Dam. 1, H318 STOT SE 3, H335	Concentration : 37% Classification limit: Skin Sens. 1, H 317 (C≥0.2%) Skin corr. 1B, H314 (C≥25%) STOT SE 3, H335 (C≥5%) Skin Irrit. 2, H 315 (5%≤C≤25%) Eye Irrit. 2, H319 (5%≤C≤25%))	3	Manual mixing and loading (Scenario 1.1, 2.1)	Skin Eye (splashes, hand to eye transfer) Respiratory tract	Max. 10 times per day/few minutes	Not relevant	**RMM:** - Containment as appropriate. - Minimisation of manual phases. - Avoidance of contact with contaminated tools and objects - Minimise number of staff exposed. - Management/ supervision in place to check that the RMMs in place are being used correctly and followed. - Training for staff on good practice. - Good standard of personal hygiene. **PPE, RPE:**	**Acceptable:** + low likelihood of exposure + high degree of operational and organisational RMM in use + professionals using appropriate PPE	 ↑ Adherence to instructions for use my vary

								- Substance/task appropriate gloves and coverall. - Substance/task appropriate respirator; - Eye protection/face shield		
Very high	Skin Sens. 1, H 317 Skin Corr. 1B H 314 Eye Dam. 1, H318 STOT SE 3, H335	Concentration : 37% Classification limit: Skin Sens. 1, H 317 (C≥0.2%) Skin corr. 1B, H314 (C≥25%) STOT SE 3, H335 (C≥5%) Skin Irrit. 2, H 315 (5%≤C≤25%) Eye Irrit. 2, H319 (5%≤C≤25%))	3	Exposure during the removal of the fogging equipment (scenario 2.2)	Skin (touching surfaces with potential formaldehyde deposited), inhalation (residues of formaldehyde vapours)	1 time per day/few minutes	Not relevant	**RMM:** - Minimise number of staff exposed. - Management/ supervision in place to check that the RMMs in place are being used correctly and followed. - Training for staff on good practice. - Good standard of personal hygiene. **PPE, RPE:** - Substance/task appropriate gloves and coverall. - Substance/tas	**Acceptable:** + low likelihood of exposure (the operator will not be exposed to a 37% formaldehyde concentration, they could be exposed to deposited formaldehyde after fogging which is almost negligible) + high degree of operational and organisational RMM in use + professionals using	↑ Adherence to instructions for use my vary

								k appropriate respirator. - Eye protection/face shield.	appropriate PPE	

Conclusion

The proposed use of formaldehyde for the disinfection of eggs (disinfection sluice) by fogging and disinfection of animal housing by fogging does not present health risks to professional users due to inhalation and dermal exposure if the appropriate PPE and RPE are worn.

- Use 1: gloves, coverall and respiratory protection (APF 20) + eye protection/face shield during mixing and loading
- Use 2: gloves, coverall and respiratory protection (APF 40) + eye protection/face shield during mixing and loading and removal and cleaning of equipment

3.6.24 Non-professional users

Non-professional use of formaldehyde is excluded. Therefore, non-professional primary exposure is not assessed.

3.6.25 Secondary exposure to professional bystanders and non-professional bystanders/general public

Secondary inhalation and dermal exposure of professional bystander is not expected since the access to treated areas is restricted. Secondary exposure of the general public is prevented by implementing a waiting period after which re-entry is safe again.

Scenario 4.1: Secondary exposure – re-entry after Disinfection of eggs (disinfection sluice) by fogging – Use 1

Description and input parameters

Table 3-41 Description and input parameters

Description of Scenario 4.1
Worst case, it is assumed that a bystander can enter the treated room after application. The professional worker might not be wearing PPE and thus the exposure assessment is performed without PPE. The worker is then exposed to volatilised formaldehyde. As the exposure concentration (i.e. the applied dosage) is above the acceptable limit, a restriction to re-enter the building can be implemented. The time to safeguard re-entry is calculated using Consexpo: - After fogging, the concentration of formaldehyde in the fumigation sluice is 5 g/m^3 which is higher than the acceptable exposure limit of 0.12 mg/m^3. Therefore, a re-entry time should be determined for the bystander to enter the treated room safely (with or without PPE). - To model the air concentration in the treated room and to determine the re-entry time, the Consexpo model Exposure to vapour – instantaneous release was selected. - To determine the time where the acceptable exposure limit is reached, the air concentration was modelled in the fumigation sluice.

Input parameters for Scenario 4.1			
Dermal exposure			
Exposure is negligible as entry to the treated area is restricted. After a contact time of 1h and a defined waiting period, any deposited formaldehyde will be evaporated from the surface.			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Model	Exposure to vapour	Expert judgment
	Model of release	Instantaneous release	Expert judgment
	Air concentration	5 g/m^3	air concentration of formaldehyde after fogging application
	Remaining fraction of product	100%	Worst case
	Room volume	49 m^3	Volume of fumigation sluice
	Formaldehyde amount	245 g	air concentration of formaldehyde after fogging (mg/m3) × room volume (m3)
	Ventilation rate	41 hr^{-1}	RMM added to the use instructions*
	Acceptable concentration	0.12 mg/m^3	CAR
	Inhalation rate	1.25 m^3/hr	HEAdhoc recommendation 14
	Body weight	60 kg	HEAdhoc recommendation 14

* The room volume of 49 m³ is ventilated at a ventilation rate of > 2000m³/h. The instructions of use and the RMM mentions the rate of >2000 m³/h.
This means the air in the room is refreshed at a rate of 2000/49 = 40.8 times each hour. Rounded up this gives 41 hr-1.

Based on Figure a re-entry time of 0.27 hours was determined. The air concentration of formaldehyde after 0.27 hours waiting time is 0.078 mg/m3 which is lower than the acceptable exposure concentration (0.12 mg/m3). Therefore, the general public is allowed to re-enter the treated room 20 minutes after the proposed contact time.

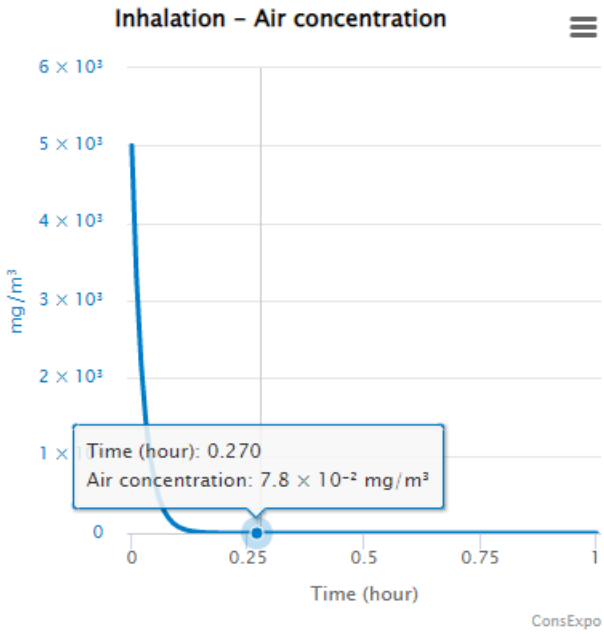


Figure 2: Concentration of formaldehyde after the waiting period (Consexpo output)

Systemic exposure calculation:
The air concentration of formaldehyde is 0.078 mg/m3 or lower at the proposed re-entry time.
Based on this the max systemic exposure during a time period of 8h/day for a person weighing 60 kg and an inhalation rate of 1.25m³/h was calculated :

(0.078 mg/m³ * 1.25 m³/h*8h)/ 60kg = 0.013 mg/kg bw/day

Scenario 4.2: Secondary exposure – re-entry after disinfection of animal housing by fogging – Use 2

Description and input parameters

Table 3-42 Description and input parameters

Description of Scenario 4.2
Worst case, it is assumed that a bystander/professional can enter the treated room after application. The bystander might not be wearing PPE and thus the exposure assessment is performed without PPE. The worker is then exposed to volatilised formaldehyde. As the exposure concentration (i.e. the applied dosage) is above the acceptable limit, a restriction to re-enter the treated room can be implemented. The time to safeguard re-entry is calculated using Consexpo - After fogging application, the concentration of formaldehyde in the air is 5 g/m^3 which is higher than the acceptable exposure limit of 0.12 mg/m^3. Therefore, a re-entry time should be determined for the bystander to enter the treated room safely without PPE. - To model the air concentration in the treated room and to determine the re-entry time, the Consexpo model Exposure to vapour – instantaneous release was selected. - To determine the time where the acceptable exposure limit is reached, the air concentration was modelled in a representative stable (590 m^3) with the lowest ventilation rate (0.9/h).

Input parameters for Scenario 4.2			
Dermal exposure			
Exposure is negligible as entry to the treated area is restricted. After a contact time of 2h and a defined waiting period, any deposited formaldehyde will be evaporated from the surface.			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Model	Exposure to vapour	Expert judgment
	Model of release	Instantaneous release	Expert judgment
	Air concentration	5 g/m^3	air concentration of formaldehyde after fogging application
	Remaining fraction of product	100%	Worst case
	Formaldehyde amount	2950 g	air concentration of formaldehyde after fogging (g/m3) × room volume (m3)
	Room volume	590 m^3	Representative stable - Veal calves (i1=3)) – See Table 4.1
	Ventilation rate	0.9/hr	Lowest ventilation rate - (Dairy cows (i1=1)) – See Table 4.1
	AEC	0.12 g/m^3	CAR
	Inhalation rate	1.25 m^3/hr	HEAdhoc recommendation 14
	Body weight	60 kg	HEAdhoc recommendation 14

Based on Figure , a re-entry time of 12 hours was determined. The air concentration of formaldehyde after 12 hours waiting time is 0.1 mg/m^3 which is lower than the acceptable exposure concentration (0.12 mg/m3). Therefore, the general public is allowed to re-enter the treated room 12 hours after the proposed contact time.

After discussion with the applicant it was decided to increase the re-entry time, since in practice, the stables are also closed for 2-4 days after the fogging application. However, the re-entry to 12 hours would be sufficient based on the exposure calculations.

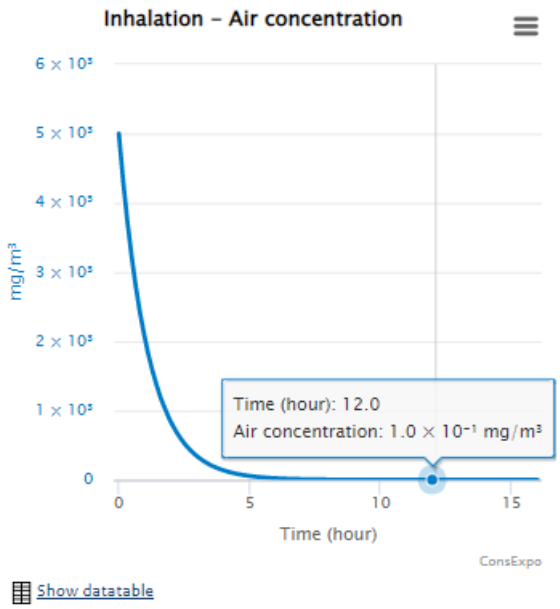


Figure 3: Concentration of formaldehyde after the waiting period (Consexpo output)

Systemic exposure calculation:
The air concentration of formaldehyde is 0.1 mg/m3 or lower at the proposed re-entry time.
Based on this the max systemic exposure during a time period of 8h/day for a person weighing 60 kg and an inhalation rate of 1.25m³/h was calculated :

(0.1 mg/m³ * 1.25 m³/h*8h)/ 60kg = 0.017 mg/kg bw/day

Outcome of systemic exposure and risk characterisation

Table 3-43 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.15 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario 4.1	1/no PPE	-	-	0.013	0.013	8.67	Yes
Scenario 4.2	1/no PPE	-	-	0.017	0.017	11.33	Yes

Combined scenarios

Not applicable

Outcome of (semi-)quantitative local exposure and risk characterisation

Table 3-44 Summary table: estimated local exposure and risk characterisation for professional bystanders and non-

professional bystanders/general public

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [%]**	**Estimated total exposure [mg/m³ or %]**	**Estimated exposure / AEC (%)** $AEC_{inhalation}$ = 0.12 mg/m³	**Acceptable (yes/no)**
Scenario 4.1	1/no PPE	-	0.078	0.078	65	Yes
Scenario 4.2	1/no PPE	-	0.1	0.1	83.33	Yes

Outcome of qualitative local risk assessment

Not applicable

Conclusion

The proposed use of formaldehyde for disinfection of disinfection sluices in egg hatcheries (use 1) and disinfection of animal housing by fogging (use 2) does not present health risks to the general public due to inhalation if the appropriate re-entry time of the treated room is considered.

- Use 1: a re-entry time of 20 minutes after treatment
- Use 2: a re-entry time of 12 hours after treatment (based on the re-entry time calculated using ConsExpo, the air concentration is 0.1 mg/m3 after 12 hours of ventilation time corresponding to 99.998% evaporation of formaldehyde. However, it is proposed to extend the waiting time to 2 – 4 days.)

should be respected.

3.6.26 Monitoring data

No monitoring data have been submitted

3.6.27 Dietary risk assessment

3.6.28 Information of non-biocidal use of the active substance and residue definitions

Table 3-45 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses					
	Sector of use	**Residue definition**	**Sample matrix**	**Reference regulation**	**Reference**
1.	Feed additives	300 - 1000 mg/kg feed	Feed	NA	EFSA Journal 2014; 12(2): 3550

3.6.29 Estimating livestock exposure to active substances used in biocidal products and Worst-Case Consumer Exposure (WCCE)

List of scenarios

Table 3-46 Summary table of main representative exposure scenarios

Summary table of main representative exposure scenarios			
Scenario number	Type of use	Description of scenario	Subject of exposure
DRA-1	Professional use in egg hatcheries	Dietary exposure of general public (WCCE) through the consumption of poultry hatched from treated eggs – Use 1	food
DRA-2	Professional use for animal housing disinfection	Animal exposure assessment and dietary exposure of general public (WCCE) – Use 2	food

DRA-1: Dietary exposure of general public (WCCE) through the consumption of poultry hatched from treated eggs

In the active substance assessment report, a dietary risk assessment is not performed. It could however be possible that formaldehyde penetrates through the shell and remains in

poultry that will later be slaughtered for its meat. The intake of possible formaldehyde contaminated meat is assessed using data available in public literature.
In a study performed by Williams and Siegel (1969), they have used 565 mg formaldehyde per m^3 and found that the concentration of formaldehyde in the albumen of eggs after fumigation was low (0.08-0.16 mg/kg). After hatching, poultry which is raised in intensive rearing conditions is ready for slaughter in 8-12 weeks.
Based on information from the formaldehyde assessment report, formaldehyde is to a large extent exhaled as CO_2 or excreted with urine or, to a minor extent, with faeces (after 12 hours, 40% exhaled, 10% urine, 1% faeces in rats, after 96 hours, 10% residue in the whole body). This indicates that formaldehyde residues are dissipated relatively fast, which means that after 8-12 weeks, the formaldehyde residues will be negligible.
In addition, EFSA (2014)[6] reported that the absolute values for formaldehyde concentrations found in milk or meat are generally not higher than 0.3 mg/kg. Thus, the values found by Williams and Siegel (1969) are below this value. EFSA assessed formaldehyde as feed additive, intended for all animal species at concentrations between 200 and 1000 mg active substance/kg complete feed and concluded that formaldehyde as a feed additive would not increase consumer exposure and consequently would not pose an additional risk for the consumer. In the body, free and reversibly bound formaldehyde, when ingested, is readily absorbed in the gastrointestinal tract, and joins the pool of endogenous formaldehyde (WHO, 2005). Although the dosage applied for the disinfection of hatching eggs is 5000mg formaldehyde/m^3 compared to 565 mg/m^3, an increase of the residues found in the albumen with a factor 1000 (80-160mg/kg) is still below the concentration formaldehyde in feed additives.

Regarding the disinfection of eggs hatcheries, based on a literature search and an EFSA publication we can expect that the levels found in the albumen of the egg will be low and the residues remaining in the chicks would not exceed the acceptable levels of formaldehyde ingestion by humans, particularly if we take into account that the level of endogenous formaldehyde is more important than the exogenous intake of formaldehyde. Furthermore, formaldehyde is known to show high reactivity with proteins so a negligible residue level can be expected.

DRA-2: Animal exposure assessment and dietary exposure of general public (WCCE)

Deriving an ADI was considered not necessary in the formaldehyde assessment report, based on EFSA (2014)[7] which compares the endogenous formaldehyde turnover with the exogenous contribution from food sources. It was concluded that the relative contribution of exogenous formaldehyde was negligible compared to the formaldehyde turnover and the background levels of formaldehyde from food sources.

Furthermore it can be expected that the relative exposure of livestock, following animal housing disinfection, will be negligeable because of its high reactivity and volatility of active substance. Therefore, we do not expect any risk for the consumers.

[6] Scientific Opinion on the safety and efficacy of formaldehyde for all animal species based on a dossier submitted by Adiveter S.L.1 , EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), EFSA Journal 2014;12(2):3562
[7] European Food Safety Authority. "Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources." *EFSA Journal* 12.2 (2014): 3550.

3.6.30 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

Not applicable.

3.6.31 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

The product is not intended to be used by non-professional.

3.6.32 Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities
0.01 mg/kg (LOQ)	According to Art 18(1)(b) Reg (EC) No. 396/2005.	-
No MRL required	According to Reg. (EU) 37/2010	-

3.6.33 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The product contains just one active substance and there is no substance of concern in the product.

3.6.34

3.6.35 Overall conclusion on risk assessment for human health

Table 3-47 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1	Disinfection of eggs (disinfection sluice) by fogging	**Acceptable** when using mask (APF 20), coverall, eye protection/face shield and gloves	- 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 during mixing and loadingof the product is mandatory.Use of respiratory protective

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
			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 (>2000m^3/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 2000m^3/h is used for 20 minutes or until the formaldehyde is below the AEC of 0,12mg/m .
2	Disinfection of animal housing by fogging	**Acceptable** when using mask (APF 40), coverall, eye protection/face shield and gloves	- 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 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 removal and cleaning of equipment. - The use of eye protection during during mixing and loading and removal and cleaning of equipmentof the product is mandatory.Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during mixing and loading and 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/m^3. - Mixing and loading should be done outdoor - Apply only in stables which are sealed and heated. - After application: keep the stable closed

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
			and heated during 2-4 days while ventilating stable

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

Not relevant.

3.7.2 Risk for livestock animals

Based on the data requirements laid down in the Biocidal Products Regulation (BPR), the safety of non-target animals after application of biocidal products has to be addressed as well. The livestock could be exposed taking into account that the biocidal product is intended to be used to treat animal housing however livestock should not be present during the application phase, nor should it re-enter after calculated time of ventilation. Although we can assume that the inhalation risk is low, a conservative risk assessment regarding local exposure to derive relevant re-entry time has been performed:

- Dermal exposure: Not relevant because the animals are not present during treatment and taking into account the hight volatility of active substance (Pa) and the high reactivity with proteins, we can expect that the residue of formaldehyde should be negligeable.
- Oral exposure: Not relevant because the animals are not present during treatment and taking into account the hight volatility of active substance (Pa) and the high reactivity with proteins, we can expect that the residue of formaldehyde should be negligeable.
- .
- Inhalation: Exposure to the air concentration of formaldehyde using the 'exposure to vapour' model in ConsExpo 1.1.1

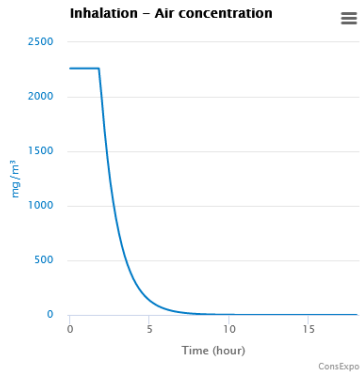
Representative animal housing volumes have been considered:

- Dairy cattle
- Calf
- Fattening pig
- (Broiler) Chicken
- Rabbit

As chronic uses as a worst-case and the NOAEC (0.36 µg/L or 360 µg/m³) value for a chronic exposure has been taken into account to make risk assessment.

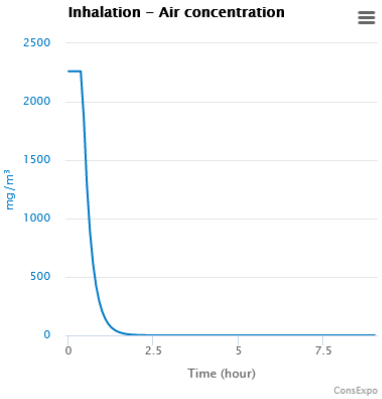
Input parameters for animal health risk assessment			
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Model	Exposure to vapour	Expert judgment
	Mode of release	Instantaneous release	Expert judgement
	Animal housing volume	9630 m^3 (dairy cattle)	Guidance on the BPR: Volume III Human Health
		590 m^3 (calf)	
		2110 m^3 (Fattening pig)	
		600 m^3 (parent chickens, free range grating floor)	
		0.072 m^3 (Rabbit)	
	Ventilation rate housing	0.9 /h (Dairy cattle)	Guidance on the BPR: Volume III Human Health
		4.1/h (Calf)	
		1.9/h (Fattening pig)	
		4.3/h (Chicken)	
		5.2/h (rabbit)	
	Application rate	13.52 g/m^3	Product specific
	Formaldehyde concentration	40 g/l	Product specific
	Total amount of formaldehyde in air	5 g/m^3	Product specific
	Daily application	1 /day	Product-specific data
	Application Time	120 min	Product specific
	Air concentration at time of passing (Peak concentration (TWA 15 min)) mg/m^3	2300 mg/m^3	ConsExpo output

Dairy cattle:



At 11.7 h the level of formaldehyde present in the air (0.35 mg/m³) is lower than the NOAEC value (0.36 mg/m³).

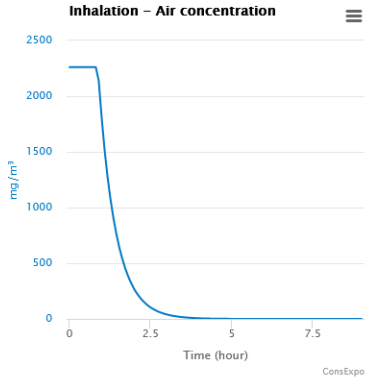
Calf:



Show datatable

At 11.7 h the level of formaldehyde present in the air (0.31 mg/m³) is lower than the NOAEC value (0.36 mg/m³).

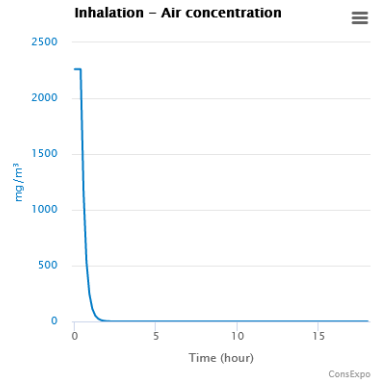
Fattening pig:



Show datatable

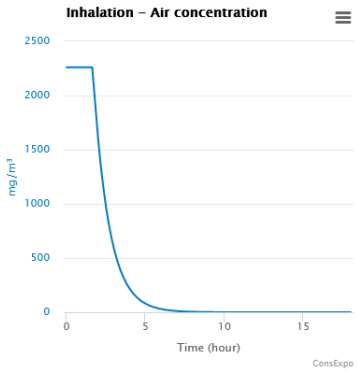
At 5.49 h the level of formaldehyde present in the air (0.35 mg/m³) is lower than the NOAEC value (0.36 mg/m³).

(Broiler) Chicken:



At 2.53 h the level of formaldehyde present in the air (0.23 mg/m³) is lower than the NOAEC value (0.36 mg/m³).

Rabbit:



At 10.44 h the level of formaldehyde present in the air (0.29 mg/m³) is lower than the NOAEC value (0.36 mg/m³).

To conclude: According to the animal health risk assessment the re-entry time claimed will be set after **12h**.
But according to the proposed RMM provided by the applicant the re-entry is advisable after 2-4 days for humans and animals.

3.8 Risk assessment for the environment

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.2 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

No new endpoint studies have been submitted since the approval of the active substance. The risk assessment is entirely based on the list of endpoints as published in the assessment report (Assessment report for formaldehyde, PT3, November 2019) for which Germany was the rapporteur member state. The assessment report is available on the ECHA website.

Formaldehyde is highly volatile and it is readily biodegradable fulfilling the 10d-window

criterion. The active substance is not hydrolysable in water but is susceptible to direct photolysis in air. Formaldehyde will not be transported in the atmosphere due to its short half-life in air. In soil, formaldehyde will only weakly be absorbed to sediment or soil and thus a high mobility in these compartments is assumed. Finally, formaldehyde is not expected to accumulate in the environment.

The endpoints applied in the environmental risk assessment are summarised in the tables below.

Table 3-48 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment			
	Value	**Unit**	**Remarks**
Fate and behaviour in the environment			
Molecular weight	30.0258	g/mol	Assessment report formaldehyde (2019)
Melting point	-15	°C	Assessment report formaldehyde (2019)
Vapour pressure (at 25°C)	187	Pa	Assessment report formaldehyde (2019)
Water solubility (at 20°C)	1000000	mg/l	Considered as completely soluble (Assessment report formaldehyde (2019))
Log Octanol/water partition coefficient (K_{ow})	0.35	Log 10	Assessment report formaldehyde (2019)
Organic carbon/water partition coefficient (K_{oc})	15.90	L/kg	Assessment report formaldehyde (2019)
Henry's Law Constant (at 25 °C)	0.034	$Pa/m^3/mol$	Assessment report formaldehyde (2019)
Characterisation of biodegradability	Readily biodegradable	-	Assessment report formaldehyde (2019)
Rate constant for STP	1	h^{-1}	No experimental value is available. Default endpoint for readily biodegradable was used
Transformation fraction and maximum radioactivity	-	%	Not applicable
DT_{50} for biodegradation in surface water	-	d or hr (at 12ºC)	Not available
Transformation fraction and maximum radioactivity	-	%	Not applicable
DT_{50} for hydrolysis in surface water	-	d or hr (at 12ºC /pH)	Not hydrolysable

DT_{50} for degradation in soil	30	d (at 12ºC)	No experimental value is available. Default endpoint for readily biodegradable was used
Transformation fraction and maximum radioactivity	-	%	Not applicable
DT_{50} for degradation in air	1.97	d	Assessment report formaldehyde (2019)
DT_{50} for degradation in the sewer system	-	d or hr (at 12ºC)	No experimental data is available. Degradation in the sewer was therefore not considered.
DT_{50} for degradation in manure	-	d or hr (at 12ºC)	No experimental data is available. Degradation in manure was therefore not considered.
Predicted no effect concentrations (PNEC)			
Sewage treatment plant	0.2	mg/L	Based on a EC50 for activated sludge and an assessment factor of 100.
Surface water	0.0104	mg/L	Based on long-term study on the reproduction of Daphnia magna and an assessment factor of 100.
Marine water	-	mg/L	No studies with marine organisms are available.
Sediment	-	mg/kg wwt	Formaldehyde is not expected to adsorb onto the sediment (Koc = 15.9 L/kg) and no tests with sediment-dwelling organisms have been provided by the applicants. Therefore, the risk characterisation for the sediment compartment is already covered by the risk characterisation for surface water**.**
Marine sediment	-	mg/kg wwt	No studies with marine organisms are available.
Soil	0.00416	mg/kg wwt	In the absence of valid experimental data with terrestrial organisms, the PNECsoil was derived from the PNECwater using the equilibrium partitioning method according to the TGD.
Bird	-		No endpoint is available
Mammals	-		No endpoint is available

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remark**
Air	7.81×10^{-2}	Simple Treat 4.1
Water	8.01	
Sludge	0.149	
Degraded in STP	91.83	

No PNECs are available for sediment and were therefore derived from the PNEC for surface water. Considering that both the predicted environmental concentration (PEC) in sediment and the PNEC for this compartment are calculated by equilibrium partitioning and because of the active substance's hydrophobicity no additional assessment factors are required, the risk ratios (PEC: PNEC) in sediment are always equal to those for water. The risk evaluation for sediments is therefore covered by the risk ratios for surface water. No PECs and

PEC:PNEC ratios were consequently calculated for sediment.

No PNECs are available for the marine ecosystem. Because an additional dilution factor of ten is applied to both PEC and PNEC, the risk ratios for the marine compartment are always equal to those for freshwater and freshwater sediment. Considering that the risk assessment for marine water is covered by the assessment for fresh water, PECs and PEC:PNECs ratios were not calculated for the marine ecosystem.

No PNECs are available for soil and were therefore derived from the PNEC for surface water.

3.8.3 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substance and available information for the non-active substance.

3.8.4 Substances of concern

No substances of concern regarding the environment were identified as apart from the active substance, the biocidal product contains no co-formulants. Consequently, only the active substance was addressed in the environmental risk assessment.

3.8.5 Screening for endocrine disruption relating to non-target organisms

There are no additional co-formulants in the product, thus an assessment of endocrine-disrupting properties of non-active substances is not relevant.

3.8.6 Emission estimation

3.8.7 General information

Predicted Environmental Concentrations (PECs) were calculated according to the Emission Scenario Documents scenario documents (ESDs, release to the environment) for product type 3: veterinary hygiene biocidal product, the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment), the Technical Agreement on Biocides (TAB) and the model SimpleTreat (concentrations for micro-organisms in the sewage treatment plant (STP) the STP's effluent) by using the default values for parameters, unless otherwise noted. Distribution in the STP has been calculated using SimpleTreat version 4.1 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance with the TAB. Distribution in the STP and the environment is calculated based on the physical-chemical properties as listed in section 3.2.

Release of active substance(s) during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substance is added are disposed as solid waste and usually incinerated.

Emission to groundwater was modelled using the latest version of FOCUS PEARL (version 4.4.4) based on the substance's physical-chemical parameters. Details on the assessment are presented in section 3.8.3 of the PAR.

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product

for the different applications. Compartments highlighted in bold are directly exposed.

Emission was calculated for each intended use based on the highest efficacious concentration, i.e. in-use concentration as specified in the SPC.

The risk assessment approach is summarised below.

Table 3-49 Environmental risk assessment

Environmental risk assessment					
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance(s)**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
1	Disinfection of eggs (disinfection sluice) by fogging	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal product (2011)	5 g/m^3	-	**STP** **Air** Freshwater Soil Groundwater
2	Disinfection of animal housing by fogging		5 g/m^3	-	**Air** Soil Groundwater

3.8.8

3.8.9 Emission estimation for the scenario(s)

Scenario 1- Disinfection of eggs (disinfection sluice) by fogging

Table 3-50 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Disinfection of eggs (disinfection sluice) by fogging			
Quantity of active substance applied per cubic meter	5	g/m^3	Product-specific data
Disinfected area	Fumigation sluice	-	Set value
Volume of the fumigation sluice	49	m³	Default value
Number of disinfection sluices	1	-	Default value
Number of disinfection events	7	/d	Default value
Fraction to air	98%	-	CAR formaldehyde
Fraction to STP	2%	-	CAR formaldehyde

Calculations for Scenario 1 - Disinfection of eggs (disinfection sluice) by fogging

The environmental risk assessment has only been assessed for the disinfection of eggs in the disinfection sluice. According to the applicant, disinfection in the hatcher is mainly done by heating paraformaldehyde in a pan. This application is considered fumigation, but falls

outside the scope of this dossier according to the applicant.

The application for the product in this dossier is done by fogging. However, given the high volatility of formaldehyde, and the relatively high temperature and ventilation rate in the hatcheries, it is expected that the majority of the substance will be emitted to air. This is in line with the approach used for disinfection of animal housing (Scenario 2, see below), and with the approach of the human health risk assessment.

Therefore, a fraction released to air of 98% will be used, similar to the approach in the formaldehyde CAR (Doc IIB, Table 8-11). The terrestrial compartment will indirectly be contaminated via deposition.

The remaining fraction (2%) of the product will be emitted to the sewage treatment plant (STP). The aquatic and terrestrial compartments may also be indirectly contaminated via STP effluents or sewage sludge application respectively. To simulate the behaviour of formaldehyde in the STP, SimpleTreat 4.1 was used.

For the emission to air and subsequent deposition, a soil depth of 5 cm was taken into account. This deviation from the standard depth of 20 cm was proposed by the applicant, and accepted as a worst-case approach because deposition can possibly take place on grassland.

For the emission to STP and subsequent application of STP sludge to agricultural soil, the standard depth of 20 cm was kept.

Table 3-51 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	3.43×10^{-2}	
Air	1.68	

Scenario 2 - disinfection of animal housing by fogging

Table 3-52 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: disinfection of animal housing by fogging			
Application rate of active substance	5	g a.s./m^3	Product-specific data
Fraction to air	100%	-	CAR formaldehyde PT3
Highest volume	12500	m^3	ESD PT18 - Turkeys in free range with litter floor (cat 16); ENV TAB 54

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: disinfection of animal housing by fogging			
Highest application frequency	13	d/year	ESD PT3 - Ducks in free range with litter floor (cat 17)

Calculations for Scenario 2 - disinfection of animal housing by fogging

The environmental risk assessment has been assessed for the use 'disinfection of animal housing by fogging'. The calculations have been performed using a 5 g/m^3 dosage of formaldehyde. Before disinfection, all manure is removed from the stable after which the stable is thoroughly cleaned. After cleaning, the stable is disinfected. As disinfection is performed using fogging, the volume formaldehyde is low and will evaporate quickly at higher temperatures which are implemented before fogging.

Based on the re-entry time calculated using ConsExpo, the air concentration is 0.1 mg/m^3 after 12 hours of ventilation time corresponding to 99.998% evaporation of formaldehyde. Moreover, in practice stables are heated and the stables are closed for 2-4 days. It should be noted that the aqueous layer of formaldehyde formed on the surfaces will be very small and evaporation is assumed to be complete in 2 days in a heated stable.

According to the CAR, the aerosol droplets will completely evaporate, at least during the incubation and drying period. It is therefore assumed that 100% formaldehyde is released to the air after fogging. Thus, releases to manure/slurry and/or waste water are not expected. It is assumed that 100% of the amount formaldehyde which is fogged and released to the air is deposited from the atmosphere to the soil compartment.

The environmental risk assessment has been performed with the worst-case assumptions resulting in the highest emission of formaldehyde to the environment. These assumptions are the largest housing volume and the highest application frequency. The largest volume corresponds to the animal housing of turkeys with 12500 m^3 and the highest application frequency is for ducks with 13 applications per year. Therefore, disinfection of turkey housing, 13 times per year results in the highest emission of formaldehyde to air. The amount of formaldehyde released to the air following the disinfection of turkey housing is 812.5kg/year, corresponding to 62.5 kg/day. This emission in not continuous and is expected to occur only 13 days in a year. The emission of 62.5 kg/day is used to calculate the annual average concentration in air, deposition flux and consequently the concentration in soil (PEC soil) and the concentration in the groundwater (PEC groundwater). The calculations have been provided in Annex 4.1.3.

As the risk assessment has been performed with the worst-case assumption and as the housing volume of all animal categories are smaller than 12500 m^3, the application frequency of 13 times per year can be proposed for all animal categories.

For the emission to air and subsequent deposition, a soil depth of 5 cm was taken into account. This deviation from the standard depth of 20 cm was proposed by the applicant, and accepted as a worst-case approach because deposition can possibly take place on grassland.

Table 3-53 Resulting local emission to relevant environmental compartments when

released to the air

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$)**	**Remarks**
Air	812.5 kg/year 62.5 kg/d	The highest emission (highest volume of turkey housing and the highest frequency of duck housing) will be used to calculate the exposure to the different environmental compartments.

3.8.10 Exposure calculation and risk characterisation

Table 3-54 Summary table of PNEC, PEC and PEC:PNEC values

Summary table of PNEC, PEC and PEC:PNEC values	
	Formaldehyde
PNEC values	
PNECstp(mg/L)	2.00E-1
PNECwater (mg/L)	1.04E-2
PNECsoil (mg/kg wwt)	4.16E-3
SCENARIO 1 – Disinfection of eggs (disinfection sluice) by fogging – emission via STP and air	
PEC values	
PECair (mg/m3)	4.67E-4
PECstp(mg/L)	1.37E-3
PECwater (mg/L)	1.37E-4
PECsoil (mg/kg wwt)	2.19E-4
PECgw(μg/L)	**0.449**
PEC/PNEC values	
PEC/PNECstp	6.73E-3
PEC/PNECwater	1.32E-2
PEC/PNECsoil	5.28E-2
SCENARIO 2 – Disinfection of animal housing by fogging – aerial deposition	
PEC values	
PECair (mg/m3)	6.19E-4
PECsoil (mg/kg wwt)	2.22E-4
PECgw(μg/L)	**0.558**
PEC/PNEC values	

PEC/PNECsoil	5.36E-2

Atmosphere

Conclusion: Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimise the risk for stratospheric ozone depletion. There are no indications that the active substance contributes to depletion of the ozone layer as the compounds are not listed as 'controlled substances' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. The half-life of 1.97 day is below the trigger of 2 days, which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.

Sewage treatment plant (STP)

Conclusion:
- Use 1: For the emission pathway via STP and air, PEC/PNECstp value is lower than 1. Therefore, risk to the STP is considered acceptable.
- Use 2: STP is not exposed via aerial deposition. Therefore, risk to the STP is considered acceptable.

Aquatic compartment

The marine environment is not included in the summary table under section 3.8.3 considering that the risk assessment for freshwater covers that of the marine environment.

Conclusion:
- Use 1: PEC/PNECwater value is lower than 1. Therefore, risk to the aquatic compartment is considered acceptable.
- Use 2: Surface water is not exposed via aerial deposition. Therefore, risk to the aquatic compartment is considered acceptable.

Terrestrial compartment

Conclusion:
- Use 1: For the emission pathway via STP and air, PEC/PNECsoil value is lower than 1. Therefore, risk to the terrestrial compartment is considered acceptable.

- Use 2: For the emission pathway via aerial deposition, PEC/PNECsoil value is lower than 1. Therefore, risk to the terrestrial compartment is considered acceptable.

Groundwater

Conclusion:
- Use 1: For the emission pathway via STP and air, the groundwater concentration exceeds the limit of 0.1µg/l

- Use 2: For the emission pathway via aerial deposition, the groundwater concentration exceeds the limit of 0.1µg/l

FOCUS PEARL calculations – Use 1/2

Tier 2 calculations were performed for groundwater concentrations with FOCUS PEARL (version 4.4.4).

According to the calculated PEC values above, scenario 2 is considered as the worst-case regarding groundwater concentrations. For this use, only aerial deposition is considered as as a relevant emission pathway.

Similar to the approach in the formaldehyde CAR for PT3, the average deposition flux (in mg/(m².d) was converted to an annual application rate in kg/ha.

The required organic matter-water partitioning coefficient (K_{om}) was derived by K_{oc}/1.724. The Freundlich constant (1/n) was set equal to 0.9, as a screening test is not considered feasible, and it was expected that further sorption study would not improve the information on the distribution behaviour of formaldehyde. The same approach was used in the active substance CAR, where the Freundlich exponent was also set to 0.9.

The tables with input parameters and output from FOCUS PEARL are included in Appendix 4.1.3.

Conclusion: Groundwater concentrations calculated with FOCUS PEARL are < 0.1µg/l for all 9 FOCUS scenarios.

3.8.11 Primary and secondary poisoning

3.8.12 Primary poisoning

The product is applied as a disinfectant indoors. Considering that non-target organisms do not normally reside indoors, primary poisoning is unlikely. The risks related to primary poisoning are therefore acceptable.

3.8.13 Secondary poisoning

As the log K_{ow} for formaldehyde is <3 and the active substances are not highly adsorptive (K_{oc} <20000 L/kg in sediment), bioconcentration is not expected according to the trigger values presented in the guidance. Experimentally derived bioconcentration factors (BCFs) demonstrated that the active substance does not fulfil the criteria for bioaccumulation (BCF <2000). The risk for bioconcentration in the proposed use is therefore considered not relevant. The standards for bioconcentration are met and no further assessment of secondary poisoning is deemed necessary.

Considering that the active substance has neither a non-systemic mode of action nor does it accumulate in plants, exposure to bees via contaminated pollen is negligible. It cannot be conclusively expected that the product is harmful to bees and other pollinators.

3.8.14 Mixture toxicity

Not relevant for this product as the product contains only one active substance and no substance of concern.

3.8.15 Aggregated exposure (combined for relevant emission sources)

The use of formaldehyde as a biocide is significantly smaller (<10%) of the total tonnage of

formaldehyde for other applications, see the following figure[8], provided by the applicant.

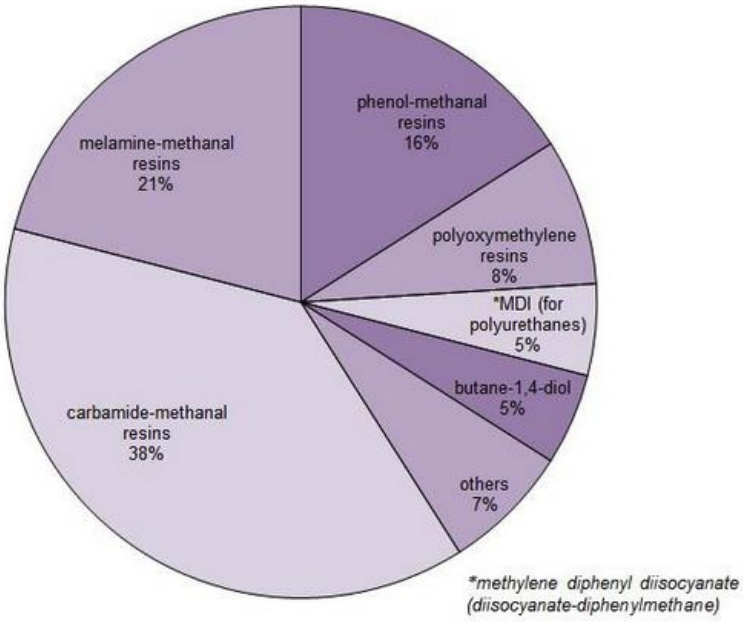


Figure 1 Uses of methanal.

Aggregated exposure is therefore not relevant.

3.8.16 Overall conclusion on the risk assessment for the environment

Table 3-55 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1	Disinfection of eggs (disinfection sluice) by fogging	Acceptable	/
2	Disinfection of animal housing by fogging	Acceptable	-Apply only in stables which are sealed and heated -After application: keep the stable closed and heated during 2-4 days while ventilating

[8] https://www.essentialchemicalindustry.org/chemicals/methanal.html

3.9 Assessment of a combination of biocidal products

The product is not intended to be used in combination with other biocidal product.

3.10 Comparative assessment

3.10.1 3.10.1 Screening phase

According to the most recent scientific information available on the active substance in the biocidal product, Formaldehyde shall be considered as a candidate for substitution using the criteria in Article 10(1) of the regulation(EU) No 528/2012 (hereafter "the BPR"). Formaldehyde is considered as meeting the exclusion criteria according to Article 5(1) of the BPR. This conclusion is based on the Assessment Report for Formaldehyde from 9/08/2023 which states that formaldehyde meets at least one of the exclusion criteria listed in Article 5(1)(a), classified as Carcinogenicity: Category 1B.

According to the Article 23(1) of the BPR, Member States are required to perform a comparative assessment for biocidal products containing an active substance that is a candidate for substitution. The Belgian CA has used conducted this comparative assessment in accordance with the EU guidance: Technical Note for Guidance "CA-march14-Doc.5.4-Final".

3.10.23.10.2 Information on the active substance and the biocidal product (family)

Mode of action of the active substance

Formaldehyde interacts with protein, DNA and RNA in vitro. The interaction with protein results from a combination with the primary amide and the amino groups. It reacts with carboxyl, sulfhydryl and hydroxyl groups. Furthermore, formaldehyde reacts with nucleic acid (e.g. DNA of bacteriophages or viruses) . It inhibits viral DNA synthesis by forming DNA cross-links (e.g. in SV40) and can modify viral proteins (e.g. HBsAg and HBcAg of HBV) . It penetrates bacterial spores and fungal conidia, acts sporostatic and inhibits germination.) According to the harmonised classification and labelling (ATP06) approved by the European Union, this substance is toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is toxic if inhaled, may cause cancer, is suspected of causing genetic defects and may cause an allergic skin reaction.

Use of the product
USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

Product Type :	PT3
Description of the use(s) :	Airborne disinfection of hatching eggs (in disinfection sluice)
Target organism(s) :	Bacteria Yeasts Fungi Viruses
Field(s) of use :	INDOOR

Application method(s) :	Cold Ultrasonic Fogging
Application rate(s) and frequency :	5g formaldehyde/m3
Category(ies) of user(s) :	Professional

USE 2 – Airborne disinfection of animal housing

Product Type :	PT3
Description of the use(s) :	Airborne disinfection of animal housing
Target organism(s) :	Bacteria Yeasts Fungi Viruses
Field(s) of use :	INDOOR
Application method(s) :	Cold Ultrasonic Fogging
Application rate(s) and frequency :	5g formaldehyde/m3
Category(ies) of user(s) :	Professional

3.10.33.10.3 Mapping of existing alternatives to the relevant BP

3.10.43.10.3.1 Identified eligible alternative biocidal products

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

1 similar products to FORMAL-EA are currently authorised on the Belgian market

Product name	Active substance	Target organism	Validity
WESSOCLEAN GOLD LINE	Peracetic acid	YEAST BACTERIA	Valid from 3/08/2023 to 3/08/2033

USE 2 – Airborne disinfection of animal housing

16 similar products to FORMAL-EA are currently authorized on the Belgian market

Description of the use(s) :	Airborne disinfection of animal housing

Target organism(s) :	Bacteria Yeasts Fungi Viruses
Field(s) of use :	INDOOR
Application method(s) :	Cold Ultrasonic Fogging

Product name	Active substance	Target organism	Description of use	User
Intra Hydrocare	hydrogen peroxide	Biofilm Bacteria Fungi Yeast	Surfaces disinfection by manual spraying in livestock buildings	Professional
INDAL PAA 5	peracetic acid	Spores Bacteria Mycobacteria Biofilm Fungi Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional
OXYGRIFFE	peracetic acid	Spores Bacteria Mycobacteria Algae Fungi Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional
DETERQUAT CIP OXY 5	peracetic acid	Spores Bacteria Mycobacteria Biofilm Fungi Yeast Virus Algea	Surfaces disinfection by manual spraying in livestock buildings	Professional
DETERQUAT OXYPRO FOAM AAG	peracetic acid	Bacteria Mycobacteria Biofilm Fungi Yeast Virus	Surfaces disinfection by manual spraying (foam) in livestock buildings	Professional
Oxypur CS	peracetic acid	Spores Bacteria Yeast Virus	Surfaces disinfection by manual spraying or automatic (spraying, dipping) in livestock buildings	Professional
SOPUROXID 15	peracetic acid	Spores Bacteria Yeast Virus	Surfaces disinfection by manual spraying or automatic (spraying, dipping) in livestock buildings	Professional
ACIDOFOAM	peracetic	Spores	Surfaces disinfection by manual	Professional

CF	acid	Bacteria Yeast Virus	spraying or automatic (spraying, dipping) in livestock buildings	
SOPUROXID 3.2	peracetic acid	Spores Bacteria Yeast	Surfaces disinfection by nebulization in livestock buildings	Professional
SOPUROXID 5C (	peracetic acid	Spores Bacteria Yeast Virus	Surfaces disinfection by manual spraying or automatic (spraying, dipping) in livestock buildings	Professional
SOPUROXID 5 (	peracetic acid	Bacteria Yeast Virus Spores	Surfaces disinfection by manual spraying or automatic (spraying, dipping) in livestock buildings	Professional
IODOL 100	Iodine	Bacteria	Surfaces disinfection by manual spraying in livestock buildings	Professional
IODOSAN 15	Iodine	Bacteria Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional
IODOSAN 30 Plus	Iodine	Bacteria Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional
IODOSAN 18	Iodine	Bacteria Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional
IODOSAN 30	Iodine	Bacteria Yeast Virus	Surfaces disinfection by manual spraying in livestock buildings	Professional

3.10.53.10.3.2 Identified eligible non-chemical alternatives

There is no non-chemical alternatives for both of use.

3.10.63.10.4 Screening phase

3.10.6.1.1 3.10.4.1 Chemical diversity assessment

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

Active substance name	Mode of action	Resistance reported ?
Peracetic acid	When peracetic acid is dissolved in water, it disintegrates hydrogen peroxide and acetic acide. The microbicidal action of hydrogen peroxide is based on its oxidizing power which irreversibly destroys the active systems of the cells of microorganisms. Used	no

	alone or with chlorine or formaldehyde, in liquid or gaseous form (peracetic acid vapour), it kills most free micro-organisms by releasing oxygen with the production of hypochlorite or hydroxyl radicals. Under normal conditions, this product degrades into non-toxic by-products (acetic acid, oxygen and water). According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance causes severe skin burns and eye damage, is very toxic to aquatic life, is a flammable liquid and vapour, is harmful if swallowed, is harmful in contact with skin, is harmful if inhaled and if heated may cause a fire.	

Conclusion

Chemical diversity adequate to minimize the occurrence of resistance ? No

Does the product/family subject to comparative assessment contain an active substance meeting the exclusion criteria ? Yes

Next step : TIER I-B

USE 2 – Airborne disinfection of animal housing

Active substance name	Mode of action	Resistance reported ?
Peracetic acid	See USE 1 bellow	no
Hydrogen peroxide	The microbicidal action of hydrogen peroxide is based on its oxidizing power which irreversibly destroys the active systems of the cells of microorganisms. Peroxide-based products are also suitable for cold, low-concentration disinfection. According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance causes severe skin burns and eye damage,	no

	may cause fire or explosion (strong oxidiser), is harmful if swallowed and is harmful if inhaled. The disinfection mechanism of hydrogen peroxide is based on the release of free oxygen radicals (H2O2 → H2O + O2). Free oxygen radicals oxidize organic material and only water and oxidation products remain. Free radicals have both oxidising and disinfecting abilities thereby leading to their disinfection potential. Hydrogen peroxide e.g. oxidizes proteins through oxidation. The efficiency of hydrogen peroxide depends on several factors, such as pH, catalysers, temperature, peroxide concentration, and reaction time.	
Iodine	The iodine is capable of penetrating the wall of micro-organisms, and, in its free form, of acting on their cytoplasmic proteins. Its bactericidal activity is then rapid. Iodine will thus irreversibly destroy microorganisms by oxidizing their structural proteins and enzymes. According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is very toxic to aquatic life, is harmful in contact with skin and is harmful if inhaled.	no

Conclusion (Follow the chart in section 7.1 of the CA doc)
Chemical diversity adequate to minimize the occurrence of resistance ? No
Does the product/family subject to comparative assessment contain an active substance meeting the exclusion criteria ? Yes
Next step : TIER I-B

3.10.6.1.2 3.10.4.2. TIER I : comparison to eligible alternative BPs

3.10.6.1.2.1.1 TIER I-A :

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

Not relevant

USE 2 – Airborne disinfection of animal housing

Not relevant

3.10.6.1.2.1.2 TIER I-B :

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

The chemical diversity is not met for use 1. There is only one other product authorized for this use and the active substance has also several classifications same as formaldehyde.

Conclusion
Is the overall risk of the alternative authorized BP significantly lower for human health, animal health and the environment ? No
Does the alternative authorized BP present other significant economic or practical disadvantage ? No
Next step : END of comparative assessment

USE 2 – Airborne disinfection of animal housing

There are 3 other substances actives which are used for PT3 surfaces disinfection in livestock buildings products.

For Iodine, the active substance does not meet the exclusion criteria neither the substitution criteria.
For Peracetic acid, the active substance does not meet the exclusion criteria neither the substitution criteria.
For Hydrogen peroxide, the active substance does not meet the exclusion criteria neither the substitution criteria.

All of the products authorized are also for professional users. The ways of applying the product are also more diversified (Surfaces disinfection by manual spraying or automatic (spraying, dipping) and nebulization, which has a mode of operating similar to fogging).
The conclusion of the comparison between the uses and the substance active of the products is that the chemical diversity is reached without the evaluated product and with less hazardous substances. The target organisms are mostly similar to the target organisms of Formal-EA.

Conclusion
Is the overall risk of the alternative authorized BP significantly lower for human health, animal health and the environment ? Yes
Does the alternative authorized BP present other significant economic or practical disadvantage ? No
Next step : END of comparative assessment

3.10.6.1.3 3.10.4.3. TIER II : comparison to eligible non-chemical alternatives

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

No non-chemical alternatives, not relevant

USE 2 – Airborne disinfection of animal housing

No non-chemical alternatives, not relevant

3.10.73.10.5. Overall conclusion

USE 1 - Airborne disinfection of hatching eggs (in disinfection sluice)

As the chemical diversity criteria is not met (only one product authorized in Belgium for this use), the product can be authorized for a period not exceeding 5 years in accordance with article 23(6) of the BPR.

USE 2 – Airborne disinfection of animal housing

As the chemical diversity criteria is not met (only one product authorized in Belgium for this use), the product can be authorized for a period not exceeding 5 years in accordance with article 23(6) of the BPR.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Molecular weight matrix

The molecular weight of the matrix (or: mol weight matrix) is the weighted average of the matrix, which contains the chemical of interest. If the product is a mixture of compounds in the evaporation model the parameter 'mol weight matrix' has to be specified.
The mol weight matrix is determined from the molecular weights and concentrations of the product ingredients as: Mw / fraction solvents

Molecular weight matrix calculations (Based on p. 59 Consexpo disinfectant fact sheet)		
Pure product		
Mw formaldehyde	30	g/mol
Fraction formaldehyde	37	%
Fraction solvents	63	%
Molecular weight matrix	**47.62**	g/mol

Liquid mole fraction calculation
For the ART model, the liquid mole fraction of the active substance should be provided. Below the mole fraction has been calculated.

Molar ratio calculations				
Pure product				
Component	**g/100g**	**MW (g/mol)**	**mol/100g**	**Mole fraction**
Formaldehyde	37.00	30.03	1.23	0.27
Water	56.01	18.02	3.11	0.68
Methanol	6.99	32.04	0.22	0.05
Sum	100.00		4.56	1.00

Animal housing characteristics

Table 4-1: Defaults for animal housing (Table 53 HH BPR guidance)

Parameter	**Floor area**	**Wall and floor area**	**Housing volume**	**Wall and floor area/housing volume**	**Ventilation rate**	**Height (housing volume/floor area)**
Unit	m²	m²	m³	-	1/h	m
Dairy cows (1)	1170	1670	9630	0,17	0,9	8,23
Beef cattle (2)	370	1000	3063	0,33	2,0	8,28
Veal calves (3)	160	330	590	0,56	4,1	3,69

Sows, in individual pens (4)	560	910	1960	0,46	3,5	3,50
Sows in groups (5)	710	1160	2480	0,47	2,8	3,49
Fattening pigs (6)	600	970	2110	0,46	1,9	3,52
Laying hens in battery cages without treatment (7)	750	1100	2810	0,39	5,2	3,75
Laing hens in battery cages with aeration (belt drying) (8)	750	1100	2810	0,39	5,2	3,75
Laying hens in batters cages with forced drying (deep pit, high rise) (9)	750	1100	2810	0,39	5,2	3,75
Laying hens in compact battery cages (10)	750	1100	2810	0,39	5,2	3,75
Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	1430	2030	5360	0,38	1,3	3,75
Broilers in free range with litter floor (12)	1110	1600	4170	0,38	4,3	3,76
Laying hens in free range with grating floor (aviary system) (13)	1270	1822	4780	0,38	2,9	3,76
Parent broilers in free range with grating floor (14)	390	600	1458	0,41	4,3	3,74
Parent broilers in rearing with grating floor (15)	500	750	1880	0,40	4,3	3,76
Turkeys in free range with litter floor (16)	3330	4650	12500	0,37		3,75
Geese in free range with litter floor (18)	2500	3500	9380	0,37		3,75
Ducks in free range with litter floor (17)	2000	2820	7500	0,38		3,75

Scenario 1.1: Mixing and loading – Disinfection of eggs (disinfection sluice) by fogging

Inhalation

Mean event concentration	1.9 mg/m³
Peak concentration (TWA 15 min)	1.9 mg/m³
Mean concentration on day of exposure	1.3×10^{-2}mg/m³
Year average concentration	1.3×10^{-2}mg/m³
External event dose	6.4×10^{-3}mg/kg bw
External dose on day of exposure	6.4×10^{-3}mg/kg bw
Internal event dose	6.4×10^{-3}mg/kg bw
Internal dose on day of exposure	6.4×10^{-3}mg/kg bw/day
Internal year average dose	6.4×10^{-3}mg/kg bw/day

Integrated

Internal event dose	6.4×10^{-3}mg/kg bw
Internal dose on day of exposure	6.4×10^{-3}mg/kg bw/day
Internal year average dose	6.4×10^{-3}mg/kg bw/day

Scenario 2.1: Mixing and loading – disinfection of animal housing by fogging

Systemic inhalation exposure: Calculated exposure by ART*frequency*inhalation rate*exposure duration/60/body weight

Calculated local inhalation by ART: 4.3 mg/m³
Systemic inhalation exposure: 0.134 mg/kg bw/day

ART report Formal-EA.xls

Full ART report :

ART REPORT – Formal-EA

mixing and loading-disinfection of animal housing by fogging- last version applicant

Chemical details	
Chemical	formaldehyde
CAS No.	50-00-0

Scenario details	
Number of activities	1
Total duration (mins)	10
Nonexposure period (mins)	0

Details for Activity mixing and loading

Duration (mins): 10

Emission sources: Near field ✓

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	187 Pa
Liquid mole fraction	1
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 1 - 10 l/minute
Containment level	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	No
Dispersion	
Work area	Outdoors
Source located close to buildings?	Yes

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 4.3 mg/m³.

The inter-quartile confidence interval is 1.9 mg/m³ to 10 mg/m³.

Scenario 4.1 : Secondary exposure – re-entry after Disinfection of eggs (disinfection sluice) by fogging
and
4.2


Formal EA - Re-entry time.ce

The export (CE files) from Consexpo for scenario 4.1 and 4.2. :

Systemic inhalation exposure:
exposure by Consexpo air concentration modelling *inhalation rate*exposure duration/60kg body weight

4.1.2 Dietary assessment and animal health

The dietary risk assessment has been performed qualitatively.
Calculations performed for the animal health risk assessment are presented in the PAR.

4.1.3 Environment

Aerial deposition following disinfection of animal housing by fogging

a. Annual average predicted environmental concentration in air

The annual average predicted environmental concentration of formaldehyde (PECair) in air during emission episode is calculated using equations 43, 44 and 45 in Guidance on BPR: Vol IV Environment Parts B+C. The following parameters have been used.

Parameter	Value	Unit	Remark
$Elocal_{air}$	62.5	Kg/d	The highest emission (highest volume of turkey housing and the highest frequency of duck housing) after disinfection
$Cstd_{air}$	2.78E-4	mg/m^3	concentration in air at source strength of 1 kg/d
$T_{emission}$	13	/year	ESD PT3 for ducks

$Clocal_{air}$ = Elocalair*Cstdair
$Clocal_{air}$ = 1.74E-2 mg/m3

$Clocal_{air,ann}$ (PEC) = Clocalair*Temission/365
$Clocal_{air,ann}$ (PEC) = 6.19E-4 mg/m3

b. Annual average total deposition flux

The annual average total deposition flux ($DEP_{total,\ ann}$) is calculated using equations 46 and 47in Guidance on BPR: Vol IV Environment Parts B+C. The following parameters have been used.

Parameter	Value	Unit	Remark
CONjunge and SURFaer	1.00E-04	Pa	Product of the constant of Junge equation and surface area of aerosol particles
Vp	187	Pa	Vapour pressure (25°C)

Fassaer	5.35E-7	-	fraction of the substance bound to aerosol
DEPstd, aer	1.00E-02	mg . m^{-2} . d^{-1}	standard deposition flux of aerosol-bound compounds at a source strength of 1 kg.d^{-1}
DEPstd, gas	4.00E-04	mg . m^{-2} . d^{-1}	deposition flux of gaseous compounds as a function of Henry's law constant, at a source strength of 1 kg.d^{-1}
T emission	13	d/year	ESD PT3 for ducks

DEPtotal= Elocalair*(Fassaer*DEPstdaer+(1-Fassaer)*DEPstdgas)DEPtotal = 2.5E-2 mg . m-2 . d -1

DEPtotal,ann = DEPtotal*Temission/365
DEPtotal,ann = 8.90E-4 mg . m^{-2} . d^{-1}

c. Calculation of PEClocal for the soil compartment

The predicted environmental concentration of formaldehyde (PECsoil) in soil during emission episode is calculated using equations 58 and 59 in Guidance on BPR: Vol IV Environment Parts B+C. The following parameters have been used.

Parameter	Value	Unit	Remark
DEPtotalann	8.90E-4	mg . m^{-2} . d^{-1}	annual average total deposition flux
DEPTHsoil	0.05	m	mixing depth of soil for grassland
RHOsoil	1700	Kg/m3	bulk density of wet soil
K	4.72E-2	/d	first order rate constant for removal from top soil

Dair (aerial deposition flux) = DEPtotalann/Depthsoil*RHOsoil
Dair = 1.05E-5 mg/kg/d

Cdepsoil (PECsoil) = Dair/k – (Dair/k)*Exp(-365*10*k)
Cdepsoil (PECsoil) = 2.22E-4 mg/kg wwt

d. Calculation of PEClocal for the groundwater

The predicted environmental concentration of formaldehyde (PECgw) in groundwater during emission episode is calculated using equations 70in Guidance on BPR: Vol IV Environment Parts B+C. The following parameters have been used.

Parameter	Value	Unit	Remark
PEClocalsoil	2.22E-4	Mg/kg wwt	predicted environmental conc. in soil
Ksoil-water	0.677	m3/m3	soil-water partition coefficient
RHOsoil	1700	Kg/m3	bulk density of wet soil

PECgw = PECsoil*RHOsoil/Ksoil-water
PECgw = 0.558 µg/l

Input parameters and output from SimpleTreat 4.1

SimpleTreat 4 Export file

Calculation mode:	**SimpleTreat 4**
Version:	**4.1.0**
Date:	Monday, February 5, 2024

Input

Substance	**User value**	Default value	Unit
Chemical class	**Neutral**		-
Molecular weight	**30,0258**		g/mole
Octanol-water partition coefficient (Kow)	**2,24**		-
Aparent Kow at actual pH (Dow)			-
Vapour pressure	**187**		Pa
Vapour pressure used (temp. corrected)	**9,286387E+01**		Pa
Temperature for determining vapour pressure	**298,15**	293,15	Kelvin
Solubility (S)	**1000000**		mg/l
Solubility used (temp. corrected)	**8,693628E+05**		mg/l
Temperature for determining solubility	**298,15**	293,15	Kelvin
pKa			-
Henry coefficient (H)	**0,034**	3,207305E-03	Pam3/mole
Henry coefficient used (temp. corrected - only for user value)	**0,01942151256**		Pam3/mole
Temperature for determining Henry coefficient (only for user value)	**298,15**	2,931500E+02	Kelvin
Organic carbon partition coefficient (Koc)	**15,9**	2,419362E+00	l/kg
Partition coefficient in raw sewage (Kps)		4,770000E+00	l/kg
Partition coefficient in activated sludge (Kpas)		5,883000E+00	l/kg
Mode of operation			
Facility type	**Municipal**	Municipal	-
Operation mode	**Primary solids removal**	Primary solids removal	-
Sewage flow (Q)	**0,2**	0,2	m3/d PE
Mass of sewage solids (SO)	**0,09**	0,09	kg/d PE
Mass of O2 binding material in sewage (BOD)	**60**	60	g O2/d PE
Fraction of BOD in sewage solids (FB)	**0,5417**	0,5417	-
Fraction of sewage solids removed by primary sedimentation (FS)	**0,67**	0,67	-
Sludge loading rate (ksir)	**0,1**	0,1	-
pH	**7**	7	-
Surface or bubble aeration	**surface**	surface	-
Model parameters			
Surplus sludge	**0,02117469086**		$kg_{dwt}PE^{-1}\ d^{-1}$
Biodegradation			
Biodegradation method selected	**OECD 301 series, 310, 302 series**		-
Biodegradation constant	**1**		hr-1
Biodegradation constant used (temp. corrected)			hr-1
Temperature for determining biodegradation constant			Kelvin
Biodegradation applies to	**Aqueous phase**		-
Emission scenario			
Temperature environment	**288,15**	288,15	Kelvin
Wind speed	**3**	3	m/s
Number of inhabitants	**10000**	10000	Person
Emission rate chemical	**1**	1	kg/d

Output

Elimination percentages	Value	Unit
Elimination in the primary settler		
Volatilization	0,00	%
Via primary sludge	0,14	%
Total	0,00	%
Elimination in the aerator		
Stripping	0,00	%
Biodegradation	91,83	%
Total	0,00	%
Elimination in the solids liquid separator		
Volatilization	0,00	%
Via surplus sludge	0,01	%
Total	0,00	%
Total elimination from waste water	**91,99**	%
Total emission via effluent	**8,01**	%
Balance	**0,00**	%
Concentrations		
Air	1,31E-09	g/m3
Combined sludge	1,82E+00	mg/kg
Primary sludge	2,38E+00	mg/kg
Surplus sludge	2,37E-01	mg/kg
Raw sewage	5,00E-01	mg/l
Dissolved	4,99E-01	mg/l
Associated	1,07E-03	mg/l
Settled sewage	4,99E-01	mg/l
Dissolved	4,99E-01	mg/l
Associated	3,53E-04	mg/l
Mixed liquor	4,10E-02	mg/l
Dissolved	4,00E-02	mg/l
Associated	9,46E-04	mg/l
Effluent	4,00E-02	mg/l
Dissolved	4,00E-02	mg/l
Associated	7,10E-06	mg/l
In solids effluent	2,37E-01	mg/kg

Tables with input parameters and output from FOCUS PEARL for groundwater

Table 4-2 Summary of PECgw simulations with FOCUS PEARL [vs 4.4.4]

Summary of PEC_{gw} simulations with FOCUS PEARL [vs 4.4.4]	
Input parameters related to active substance	
Molecular weight (g/mol)	30.0258
Henry's Law constant at 25°C ($Pa.m^3.mol^{-1}$)	0.034
Vapour pressure at 25°C (Pa)	187
Water solubility at 25°C (mg/L)	165000*
Log_{10} Octanol/water partition coefficient (-)	0.35
Organic carbon/water partition coefficient (L/kg)	15.9
Organic matter/water partition coefficient Kom (L/kg)	9.223
DT_{50} in soil at 12°C (d)	30
Coefficient for uptake by plant (-)	0
1/n	0.9
Input parameters related to scenario 2	
DEPtotal,ann ($mg.m^{-2}.d^{-1}$)	8.90E-4
Yearly application rate of formaldehyde App rate (kg/ha)	3.25E-3**

* In a similar approach as in the formaldehyde CAR, water solubility was recalculated to reflect the correct Henry's Law constant (which is not available as input parameter) (WS = VP x MW / H)

** Yearly application rate calculated similar as in formaldehyde CAR: App rate = DEPtotal,ann x 365d x 0.01

Table 4-3 PECgroundwater - Output (FOCUS PEARL V. 4.4.4) in µg/L

$PEC_{groundwater}$ - Output (FOCUS PEARL V. 4.4.4) in µg/L			
Scenario 2 – Aerial deposition			
Location	Grassland (crop)	Arable land (crop)	
Chateaudun	0.005426	0.004370	
Hamburg	0.030714	0.034928	
Jokioinen	0.021127	-	
Kremsmunster	0.008813	0.009458	
Okehampton	0.033562	0.035131	
Piacenza	0.022754	0.025554	
Porto	0.042193	0.041920	
Sevilla	0.016193	0.020876	
Thiva	0.004802	0.004674	

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the active substance is available.

There are no substances of concern.

4.3 List of studies for the biocidal product

[List the studies by Reference No (Annex III requirement)/IUCLID Section Number and within a section alphabetically by author.]

Table 4-4 List of studies for the biocidal product

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/ IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/ No)**	**Data Protection Claimed (Yes/ No)**
Singh, S. Gledhill, I. & Simmons, C.	2021	4.6, 4.8, 4.16	Vapour Flammability, Thermal Stability and Corrosion Testing	Vapour Flammability, Thermal Stability and Corrosion Testing Report No: S3016009439R2/2021	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Tischer, S.	2021a	3.3	Relative Density of Formaldehyde solution 37%	Relative Density of Formaldehyde solution 37% Study No: S21-07208	Test Report	Formaldehyde Biocidal Product Consortium Uebergdreef 49 9160 Lokeren	Yes	Yes
Tischer, S.	2022a	3.4	Shel-life storage stability of formaldehyde 37%	Shel-life storage stability of formaldehyde 37% Study No: S21-09141	Test Report	Formaldehyde Biocidal Product Consortium Uebergdreef 49 9160 Lokeren	Yes	Yes
Ryckel, B., & Pigeon, O.	2022	3.5	Persistent foaming of Formaldehyde solution 37%	Persistent foaming of Formaldehyde solution 37% Study No: 25704	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes

Ryckel, B., & Pigeon, O.	2023	3.5	Persistent foaming of Formaldehyde solution 37%	Persistent foaming of Formaldehyde solution 37% Study No: 25755	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Mathieu, JB., & Flecheux, F., 2023	2023	3.5	Particle size distribution of formaldehyde 37% using MS Hatchfog Ultra	Particle size distribution of formaldehyde 37% using MS Hatchfog Ultra Study No: 9-806-2/22	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Ryckel, B., & Pigeon, O.	2023	3.7	Dilution stability of formaldehyde solution 37%	Dilution stability of formaldehyde solution 37% Study No: 25755	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Ryckel, B., & Pigeon, O.	2023	3.8	Surface Tension of Formaldehyde solution 37%	Surface Tension of Formaldehyde solution 37% Study No: 25755	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Tischer, S.	2021b	3.9	Viscosity of Formaldehyde solution 37%	Viscosity of Formaldehyde solution 37% Study No: S21-07210	Test Report	Formaldehyde Biocidal Product Consortium Uebergdreef 49 9160 Lokeren	Yes	Yes
Tischer, S.	2022b	5	Formaldehyde - Methods of detection and identification	Development and Validation of an Analytical Method for the Content Determination of Formaldehyde in Formaldehyde solution 30% Study No: S21-00515	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	Yes	Yes
Tischer, S.	2022c	5	Methanol - Methods of detection and identification	Development and Validation of an Analytical Method for the Content Determination of Methanol	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	Yes	Yes

				in Formaldehyde solution 30% Study No: S21-00516				
Tischer, S.	2022d	5	Formic acid - Methods of detection and identification	Development and Validation of an Analytical Method for the Content Determination of Formic acid in Formaldehyde solution 30% Study No: S21-03517	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	Yes	Yes
Werner, S. & Naujox, K.	2021a	6.7	6.7.1. Use 1 - Efficacy data - Bactericidal activity - P2S1 - EN 1656	Test Report EN 1656, Quantitative suspension test – bactericidal activity (phase 2, step 1), Report No: 2021-2900, 2021-3558	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Hildebrandt, C.	2023a	6.7	6.7.1. Use 1 - Efficacy data - Bactericidal activity - P2S1 - EN 1656	Justification on exact log reduction applicable to all tests	Expert statement	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Naujox, K.	2021b	6.7	6.7.2. Use 1 - Efficacy data - Yeasticidal activity - P2S1 - EN 1657	Test Report EN 1657, Quantitative suspension test – yeasticidal activity (phase 2, step 1), Report No: 2021-3721	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Naujox, K.	2021c	6.7	6.7.3. Use 1 - Efficacy data - fungicidal activity - P2S1 - EN 1657	Test Report EN 1657, Quantitative suspension test – fungicidal activity (phase 2, step 1), Report No: 2021-2901, 2021-3539	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes

Werner, S. & Naujox, K.	2023	6.7	6.7.4. Use 1 - Efficacy data - Virucidal activity - P2S1 - EN 14675	Test Report EN 14675, Quantitative suspension test – virucidal activity (phase 2, step 1), Report No: 2021-3498	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Torrellas, M. & Esteban, E.,	2023a	6.7	6.7.5.1. Use 1 - Efficacy data - Bactericidal activity - P2S2 - EN 17272	Test Report EN 17272 - bactericidal activity of the product 37% Formaldehyde, Report No: D/22/B0700	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Torrellas, M. & Esteban, E.	2023b	6.7	6.7.5.2. Use 1 - Efficacy data – Yeasticidal and fungicidal activity - P2S2 - EN 17272	Test Report EN 17272 - Yeasticidal/fungicidal activity of the product 37% Formaldehyde, Report No: D/22/B0701	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Fernande z, M. & Esteban, E.,	2023a	6.7	6.7.5.3. Use 1 - Efficacy data - Virucidal activity - P2S2 - EN 17272	Test Report EN 17272 - virucidal activity of the product 37% Formaldehyde, Report No: D/22V0324-2	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Werner, S. & Naujox, K.	2021d	6.7	6.7.6. Use 2 - Efficacy data - Bactericidal activity - P2S1 - EN 1656	Test Report EN 1656, Quantitative suspension test – bactericidal activity (phase 2, step 1), Report No: 2021-1358	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Naujox, K.	2022	6.7	6.7.7. Use 2 - Efficacy data - Yeasticidal activity - P2S1 - EN 1657	Test Report EN 1657, Quantitative suspension test – yeasticidal activity (phase 2, step 1), Report No: 2021-2044 and 2022-2177	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes

Werner, S. & Naujox, K.	2021e	6.7	6.7.8. Use 2 - Efficacy data - Fungicidal activity - P2S1 - EN 1657	Test Report EN 1657, Quantitative suspension test – fungicidal activity (phase 2, step 1), Report No: 2021-3724	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Schmidt, N.	2023	6.7	6.7.9. Use 2 - Efficacy data - Virucidal activity - P2S1 - EN 14675	Test Report EN 14675, Quantitative suspension test – virucidal activity (phase 2, step 1), Report No: 2023-2869	Test Report	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Werner, S. & Hildebrandt, C.	2023	6.7	Added to 6.7.9	Justification for contact time	Expert statement	Elements Advisory Uebergdreef 49 9160 Lokeren Belgium	No	Yes
Torrellas, M. & Esteban, E.,	2023c	6.7	6.7.10.1. Use 2 - Efficacy data - Bactericidal activity - P2S2 - EN 17272	Test Report EN 17272 - bactericidal activity of the product 37% Formaldehyde, Report No: D/22/B0698	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Torrellas, M. & Esteban, E.	2023d	6.7	6.7.10.2. Use 2 - Efficacy data – Yeasticidal and fungicidal activity - P2S2 - EN 17272	Test Report EN 17272 - Yeasticidal/fungicidal activity of the product 37% Formaldehyde, Report No: D/22/B0699	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes
Fernandez, M. & Esteban, E.,	2023b	6.7	6.7.10.3. Use 2 - Efficacy data - Virucidal activity - P2S2 - EN 17272	Test Report EN 17272 - virucidal activity of the product 37% Formaldehyde, Report No: D/22V0322-2	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes

Meulenbroeks, R.	2023	6.7	Added to 6.7.10.1/6.7.10.2/6.7.10.3	Distribution test	Test Report	Elements Advisory Antwerpsesteenweg 39/101b 9000 Gent, Belgium	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

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Pees, M., Motola, G., Brüggemann-Schwarze, S., Bachmeier, J., Hafez, H. M., & Tebrün, W. (2023). Impact on Hatchability and Broiler Performance after Use of Hydrogen Peroxide Nebulization versus Formaldehyde Fumigation as Pre-Incubation Hatching Egg Disinfectants in Field Trial. Poultry, 2(1), 1-11.

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4.4.2 Guidance documents

- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2022
- Technical Agreement on Biocides (TAB), Analytical Methods and Physicochemical Properties, February 2022
- Guidance on the BPR: Volume II Efficacy (Parts B+C), 2022
- Technical Agreement on Biocides (TAB), Efficacy, July 2020
- Guidance on the BPR: Volume III Human Health - Information requirements, 2022
- Guidance on the BPR: Volume III Human Health - Assessment & Evaluation (Parts B+C), December 2017
- HeadHoc recommendation 6, Methods and models to assess exposure to biocidal products in different product types
- HeadHoc recommendation 14, Default human factor values for use in exposure assessments for biocidal products
- Technical Agreement on Biocides (TAB), Human Health (TOX), August 2021

- ConsExpo factsheets
- Technical notes for Guidance
- Guidance on dermal absorption. EFSA Journal 2017;15(6):4873 [60 pp.]. doi: 10.2903/j.efsa.2017.4873
- Guidance on the BPR: Volume IV Environment - Health - Assessment & Evaluation (Parts B+C), October 2017
- Emission Scenario Documents scenario documents (ESDs, release to the environment) for product type 3: veterinary hygiene biocidal product, 201
- Technical Agreement on Biocides (TAB), Environment, October 2022

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of of 22 May 2012 concerning the making available on the market and use of biocidal products
- Regulation (EU) No 1272/2008 of the European Parliament and of the Council of of 16 December 2008 on classification, labelling and packaging of substances and mixtures

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.