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 APPLICATIONS

(submitted by the evaluating Competent Authority)

SPEED EASY CLEAN

Product type 2

Nonanoic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-KH057823-35

Evaluating Competent Authority: FR

Date: December 2023

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1. CONCLUSION

The biocidal product, SPEED EASY CLEAN, is based on 4.46 % of nonanoic acid and is a product type 2 used for curative treatment on hard surfaces by spaying with hand pressure sprayer. The product is used outdoor by non-professional users.

Conclusions of the assessments of each section are given below:

Conclusion of Physico chemical properties and analytical methods

The physical, chemical and technical properties of the biocidal product SPEED EASY CLEAN are acceptable for the RTU formulation.

The accelerated storage data for 8 weeks at 40°C show that the product is stable at temperature below 40°C. The mitigation measure do not store above 40°C is added to SPC. The shelf life stability studies (25°C, 24 months) show that the product is stable in different packaging during 18 months.
Particle size distribution of droplets of spray were not submitted. However, as inhalation exposure is not a concern for human health, this property was waived for this product. For completion of the dossier, particle size distribution of droplets before and after storage are required in post authorisation within 2 years.

The formulation is not classified for physical hazards.

Conclusion of Efficacy

French competent authorities (FR CA) assessed that the ready to use product SPEED EASY CLEAN has shown a sufficient efficacy by spraying at an application rate of 50 mL/m^2 against:

- green algae (*Chlorophyta spp.)* on porous and non-porous surfaces (one product application)
- red algae (*Rhodophyta spp.*) on porous surfaces only (two product applications, 2 weeks spaced)
- lichen on porous surfaces only (two product applications, 2 weeks spaced)

However, the efficacy of the product is not demonstrated against yeast and fungi based on the efficacy data provided. The efficacy is also not demonstrated against red algae with only one application or on non-porous surface.

Conclusion of risk characterisation for human health

No unacceptable risk is observed for non-professional users.

Conclusion of risk for consumers via residues in food

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

Conclusion of risk characterisation for environment

The risk assessment has been conducted for the active substance and the substance of concern CMIT-MIT (for surface water in case of direct emissions only). Acceptable risks are reached for the environment for the claimed use considering the following risk mitigations measures:

- The area adjacent to the treated surface shall be protected by an impermeable cover (width of 1 m minimum) during application of the product.
- Do not apply the product in case rain is expected within 24 hrs.
- Do not rinse treated surfaces with water after application.
- Areas covered by plants, which may have been exposed unintentionally shall be watered extensively in order to avoid any damage to plants.
- Do not apply the product when there is wind, in order to avoid transfer to other areas by drift.

2. ASSESSMENT REPORT

2.1. Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
SPEED EASY CLEAN	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Evergreen Garden Care France SAS
	Address	4 Allée des Séquoias 69760 Limonest France
Authorisation number	**FR-2023-0069**	
Date of the authorisation	**06/12/2023**	
Expiry date of the authorisation	**05/12/2033**	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Evergreen Garden Care France SAS
Address of manufacturer	4 Allée des Séquoias 69760 Limonest France
Location of manufacturing sites	Usine de Fourneau 27580 Bourth France

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Nonanoic acid, Pelargonic acid
Name of manufacturer	Nantong Shenyu Green Medicine CO, Ltd
Address of manufacturer	D-E Block, 9th floor, 251, Ledu Road, songiiang District 201600 Shanghai China
Location of manufacturing sites	Yangkou Chemical Industry Zoon, Rudong County, Jiangsu Province 201600 Shanghai China

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Nonanoic acid (Pelargonic acid)
IUPAC or EC name	Nonanoic acid
EC number	203-931-2
CAS number	112-05-0
Index number in Annex VI of CLP	607-197-00-8
Minimum purity / content	896 g/kg
Structural formula	$CH_3(CH_2)_6CH_2COOH$

2.1.2.2 Candidate(s) for substitution

Nonanoic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[1]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%) w/w**
Pelargonic Acid **Technical (purity 96.2%**)	**Nonanoic Acid**	**Active substance**	**112-05-0**	**203-931-2**	4.46% w/w **44.6 g/L**
Pelargonic Acid **pure**	**Nonanoic Acid**	**Active substance**	**112-05-0**	**203-931-2**	4.3% w/w **43 g/L**
CMIT-MIT	Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one	Non-active substance[2]	55965-84-9		0.00125**% w/w**

2.1.2.4 Information on technical equivalence

The used source of active substance is not a reference source. The source used has been declared technically equivalent. The ECHA Case Number for the decision of the technical equivalence of the source is BC-FX019950-15.

2.1.2.5 Information on the substance(s) of concern

CMIT-MIT has been identified as substance of concern in the SPEED EASY CLEAN product (see Confidential PAR for further details).

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product

The biocidal product contains the active substance "Pelargonic acid", which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. None of the co-formulants are identified as endocrine disruptors.
Please refer to confidential annex for further details.

2.1.2.7 Type of formulation

AL any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the products according to the Regulation (EC) 1272/2008

1 Please delete as appropriate.

2 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

Classification	
Hazard category	None
Hazard statement	None
Labelling	
Signal words	None
Hazard statements	None
Precautionary statements	
Note	EUH208: Contains reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3- one (C(M)IT/MIT). May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Hard surface algaecide

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Green algae (*Chlorophyta spp.)* Red algae (*Rhodophyta spp*) Lichen
Field of use	Outdoor – curative treatment Use on hard surface (multiple types i.e. wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc.) except the roof.
Application method(s)	Spraying - Ready to use product
Application rate(s) and frequency	Application rate: 100% - 50 mL/m^2 - For green algae: one application of the product on the surface (porous and non-porous surfaces) - For red algae and lichen: two applications of the product (2 weeks spaced) on the surface (porous surfaces only) Two applications per year at a maximum
Category(ies) of users	Non-professional
Pack sizes and packaging material	Opus trigger: 0.5-2 L HDPE, f*-HDPE Pump and wand 2.5-5L HDPE, , f-HDPE Refill cap and handle 2.5-5L HDPE, f-HDPE Trigger spray 0.5-2 L HDPE, f-HDPE Refill cap 3-5L HDPE, f-HDPE screw cap + manual sprayer and automatic sprayer + clip: 3,5-5L HDPE, f-HDPE Only trigger spray systems assessed in this dossier are usable for this product.

	*fluorinated HDPE

2.1.4.2 Use-specific instructions for use

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2.1.4.3 Use-specific risk mitigation measures

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use. Do not treat in rainy weather or on frozen surfaces. Do not clean the surface after treatment. Allow the product to take effect for at least several days after application of the product on the surfaces as well as between two applications on the surfaces. Inform the registration holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

The area adjacent to the treated surface shall be protected by an impermeable cover (width of 1 m minimum) during application of the product. Do not apply the product in case rain is expected within 24 hrs. Do not rinse treated surfaces with water after application. Areas covered by plants, which may have been exposed unintentionally shall be watered extensively in order to avoid any damage to plants. Do not apply the product when there is wind, in order to avoid transfer to other areas by drift.

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

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

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

Keep out of reach of children and non-target animals/pets
Do not store at a temperature above 40°C.
Shelf life : 18 months
Store away from light

2.1.6 Other information

The presence of 1,2-benzisothiazol-3(2H)-one (BIT), skin sensitizer which could induce an allergic reaction, must be mentioned on the label.

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure (s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Opus trigger	0.5-2L	HDPE, f-HDPE*,	PP	Non Professional	Yes
Pump and wand	2.5-5L	HDPE, f-HDPE*	PP	Non Professional	Yes
HDPE + refill, cap and handle	2.5 - 5 L	HDPE, f-HDPE*	HDPE	Non Professional	Yes

HDPE + trigger	0,5-2 L	HDPE, f-HDPE*	PP	Non Professional	Yes
HDPE Refill + cap	3 - 5 L	HDPE, f-HDPE*	HDPE	Non Professional	Yes

* Fluorinated HDPE

The technical details of sprays were included in the IUCLID dossier. Only these spray devices are usable for this product.

The 1 litre pack has an integrated trigger. Model: SP05 CR2 ERGO/FOAMER
The 3 litre has a hose end trigger (nested trigger): supplier : calmar materiel number 745903
The 5 litre use a battery operated trigger HDPE only. Supplier wanda; materiel number PS1441
The hose end trigger (nested) is also compatible with the 5 litre pack.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A list of studies performed on products is provided in the PAR in Annex 1.

2.1.8.2 Access to documentation

A letter of access to the data of the CAR of nonanoïc acid (PT2) has been submitted by Belchim (owners of studies on nonanoïc acid for PT 2) and allows EVERGREEN GARDEN CARE FRANCE SAS to refer to active substance data.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Hard surface cleaner

Product Type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Use on hard surface multiple types i. e. wood, plastic, fabric (as in patio furniture), bricks. paving. cement, concrete etc.
Target organism (including development stage)	alga-Algae-Adults Lichen-Lichens-Adults mould-Mould fungi-Adults yeast-Yeasts-Adults
Field of use	Outdoor Hard surface multiple types i.e. wood, plastic, fabric as in patio furniture, bricks, paving, cement, concrete etc.
Application method(s)	Method: Manual application Detailed description: Spray without dilution – Ready-to-use product.
Application rate(s) and frequency	Application Rate: 50mL/m² Dilution (%): - The treatment can be repeated after 2-4 weeks in case of persistent deposit. Maximum Number of applications per year :2
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	Opus trigger: 0.5-2 L HDPE, f-HDPE Pump and wand 2.5-5L HDPE, , f-HDPE Refill cap and handle 2.5-5L HDPE, f-HDPE Trigger spray 0.5-2 L HDPE, f-HDPE Refill cap 3-5L HDPE, f-HDPE screw cap + manual sprayer and automatic sprayer + clip: 3,5-5L HDPE, f-HDPE

2.2.2 Physical, chemical and technical properties

The range of values in different tests is due to the different tests performed in different packaging. 5 packaging were tested.
Concentration of use: RTU product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
Physical state at 20 °C and 101.3 kPa	CEMAS SOP CEM-3249	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Liquid	Benitez, 2017a	acceptable
Colour at 20 °C and 101.3 kPa	CEMAS SOP CEM-3249		Mobile, opaque, white formulation. Some black material observed at the bottom of some packaging initially Explanation by industry on presence of black matter: Tested material was performed on a pilot scale production. The bottles were filled by hand. This could have contaminated the bottles. On the PPP market, a similar product is available (the only difference is the source of the active substance). This observations have not been previously reported in PPP products.		acceptable
Odour at 20 °C and 101.3 kPa			Faint smell that could not be identified		acceptable
Acidity / alkalinity	CIPAC MT 75.3	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	pH: 3.79 – 3.92 neat	Benitez, 2017a	acceptable
	CIPAC MT 191	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w)	1.33 – 1.40 % w/w as H_2SO_4	Benitez, 2017a	acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
		Formulation Lot No. CH13092016			
Relative density / bulk density	OECD 109, EEC A3	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	D_4^{20} - 0.9997	Benitez, 2017a	acceptable
Storage stability test – accelerated storage	CIPAC MT 46 Analytical method used: CAM-0199/001 (cf part 2.4)	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Packaging tested after **8 weeks at 40°C,** Fluorinated HDPE 500 mL PET : 1L HDPE : 1L HDPE : 3L HDPE : 5L 2 bottles of each type were stored for each time point. 2 bottles of each type were pulled from storage at each time point for testing. So the tests at different time points were performed on different bottles of the same type. That could explain the variation in content observed in the study. See Table 2.2.2-1	**Benitez, 2017a**	Biocidal product is stable after 8 weeks at 40°C Mitigation measure: do not store above 40°C has been added to SPC. PET packaging are not claimed but reported in the PAR for transparency reason and possible future minor change dossier.
Storage stability test – long term storage at ambient temperature	Analytical method used: CAM-0199/001 (cf part 2.4)	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016 Packaging tested**,** Fluorinated HDPE PET (spray tested : «SP05 » sprayer, single mode of spray)	2 bottles of each type were stored for each time point. 2 bottles of each type were pulled from storage at each time point for testing. So the tests at different time points were performed on different bottles of the same type. That	**(Seward, 2020) CEMS - 7887**	Slight panelling was observed but not considered as an issue as packaging integrity is not modified Biocidal product is stable : 24 months in fluorinated HDPE packaging (-9.4%) 24 months in PET packaging (-5.5%)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
		HDPE /1L (spray tested : «SP05 » sprayer, single mode of spray) HDPE /3L(Spray tested : Nested Sprayer, 2 modes of spray : narrow and wide) HDPE /5L (Spray tested : Wanda Sprayer, 3 modes of spray: narrow, medium and wide)	could explain the variation in content observed in the study. See **Table 2.2.2-2 Ambient storage stability, 24 months at 25°C, 500mL Fluorinated HDPE, (Seward, 2020)** **Table 2.2.2-3 Ambient storage stability, 24 months at 25°C, 1L PET (not claimed), (Seward, 2020)** **Table 2.2.2-4 Ambient storage stability, 24 months at 25°C, HDPE /1L, (Seward, 2020)** **Table 2.2.2-5 Ambient storage stability, 24 months at 25°C, HDPE /3L, (Seward 2020)** **Table 2.2.2-6 Ambient storage stability, 24 months at 25°C, HDPE /5L, (Seward, 2020)**		24 months in 3L HDPE packaging (-8.3%) 24 months in 5 L HDPE packaging (-9.6%) The test performed on the HDPE 1L shows a loss of active substance higher than 10% (-13%) after 24 months and a loss of 9.2% after 18 months. eCA considers the shelf life study and degradation observed are unclear and no acceptable justification was provided. Based on these data, the shelf life of the product is set at 18 months. PET packaging are not claimed but reported in the PAR for transparency reason and possible future minor change dossier.
	CAM-229-001	Pelargonic acid RTU EW S19690 R586.009 Pelargonic acid: 4.3 % w/w Packaging tested**,** Fluorinated HDPE HDPE /1L HDPE /3L HDPE /5L	In this study, samples tested in seaward 2020 study above were tested again with a new analytical method. Results with the old method Method CAM-0199-001 and new method CAM-0229-001 were compared	E. Seward 2020 CEMS-9141	This study use an analytical method that include a hydrolysis step. This hydrolysis step could quantify both active substance and esterified active substance. The method is not considered selective and thus data generated cannot be used to set shelf life of the product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
			Data with method CAM-0199-001 are derived from study seaward 2020 above, while the second one include an hydrolysis step within the analysis process with KOH at the start of analysis. Test items have been analyses with both methods and results are reported below		

CONTAINER	TEST		UNIT	TIMEPOINT			
				Initial (1)	24 months at 25°C (1)	24 months at 25°C	24 months at 25°C
				CAM-0199-001	CAM-0199-001	CAM-0229-001	Pack wash then CAM-0229-001
Bettix-Fluorinated-HDPE	Pelargonic Acid determination	Mean (2 containers, duplicate injection)	%w/w	3.99	3.61	3.99	N/A
		Change from Initial Time Point	%	N/A	-9.4	-0.1	N/A
VANGUARD-1L_HDPE		Pelargonic Acid (%w/w)	%w/w	4.02	3.49	3.76	N/A
		Change from Initial Time Point	%	N/A	-13.0	-6.3	N/A
		Mean (1 container, duplicate injection)	mg/mL	N/A	N/A	N/A	<0.05
VANGUARD_NESTED-3L_HDPE		Mean (2 containers, duplicate injection)	%w/w	4.04	3.70	4.00	N/A
		Change from Initial Time Point	%	N/A	-8.3	-0.9	N/A
VANGUARD_WANDA-5L_HDPE		Mean (2 containers, duplicate injection)	%w/w	4.11	3.72	4.08	N/A
		Change from Initial Time Point	%	N/A	-9.6	-0.8	N/A

(1) Data generated in Study number CEMS-7887.

Storage stability test – low temperature stability test for liquids	CIPAC MT 39.3	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Frozen after storage, 1 mL at the bottom seemed to thaw quickly, and it is of clear colourless nature, with some ice crystals floating in it. After a further 24 hours and one inversion. Sample is a	Benitez, 2017a	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
			uniformly white, opaque solution.		
	Freeze thaw test CRD chapter 3 Analytical method used: CAM-0199/001 (cf part 2.4)	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Content of AS after test : 4.14 % w/w	Benitez, 2017a	acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - light	Waiver		The active substance is not sensible to light. Based on the composition we cannot exclude a degradation by light of co-formulants as the shelf life data of the product has not been performed under light conditions. In absence of such data, the mitigation measure "store away from light" is added to the PAR and SPC		The mitigation measure "store away from light" is added to the PAR and SPC
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Waiver		Temperature stability is covered by elevated and ambient stability studies. Humidity not significant, as the RTU (aqueous) is stable.		acceptable
Effects on content of the active substance and technical characteristics of the biocidal product -			See long term storage stability studies.		-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
reactivity towards container material					
Wettability	Waiver	-	Not required for this formulation type.		acceptable
Suspensibility, spontaneity and dispersion stability	Waiver	-	Not required for this formulation type.		acceptable
Wet sieve analysis and dry sieve test	Waiver	-	Not required for this formulation type.		acceptable
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Neat: Spontaneous emulsion initially and uniform emulsion throughout.	Benitez, 2017a	acceptable
Disintegration time	Waiver	-	Not required for this formulation type.		acceptable
Particle size distribution, content of dust/fines, attrition, friability	Waiver	-	Biocidal product is packaged as spray. Particle size of droplet should have been provided. However, as inhalation is not a concern for human health, this property was therefore waived for this product.		acceptable
Persistent foaming	CIPAC MT 47.3	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Neat product tested 0 mL foam at 1 minute.	Benitez, 2017a	acceptable
Flowability/Pourability/Dustability	Waiver	-	Not required for this formulation type.		acceptable
Burning rate — smoke generators	Waiver	-	Not required for this formulation type.		acceptable
Burning completeness — smoke generators	Waiver	-	Not required for this formulation type.		acceptable
Composition of smoke — smoke generators	Waiver	-	Not required for this formulation type.		acceptable
Spraying pattern — aerosols		Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w)	Single spray test of formulation. Average discharge rate:	Benitez, 2017a	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
		Formulation Lot No. CH13092016 Packaging tested, PET (spray tested : «SP05 » sprayer, single mode of spray)	1.30 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Continuous spray test of formulation. Average discharge rate: 1.30 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Single spray test of DI water. Average discharge rate: 1.27 g/discharge Spray pattern/ area covered: Average height: 257 mm Average width: 236 mm Continuous spray test of DI water. Average discharge rate: 1.26 g/discharge Spray pattern/ area covered: Average height: 219 mm Average width: 215 mm		
		Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016 HDPE /1L (spray tested : «SP05 » sprayer, single mode of spray)	Single spray test of formulation. Average discharge rate: 1.30 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Continuous spray test of formulation. Average discharge rate: 1.30 g/discharge	Benitez, 2017a	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
			Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Single spray test of pack. Average discharge rate: 1.28 g/discharge Spray pattern/ area covered: Average height: 221 mm Average width: 215 mm Continuous spray test of pack. Average discharge rate: 1.28 g/discharge Spray pattern/ area covered: Average height: 221 mm Average width: 215 mm		
		Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016 HDPE /3L(Spray tested : Nested Sprayer, 2 modes of spray : narrow and wide)	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.44 g/discharge Wide: 1.47 g/discharge Spray pattern/ area covered: Average height: Narrow 91 mm Wide 166 mm Average width: Narrow 87 mm Wide 154 mm Continuous Spray Test of the RTU formulation. Average discharge rate:	Benitez, 2017a	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
			Narrow 1.44 g/discharge Wide 1.47 g/discharge Spray pattern/ area covered: Average height: Narrow 91 mm Wide 166 mm Average width: Narrow 87 mm Wide 154 mm Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow 1.44 g/discharge Wide 1.46 g/discharge Spray pattern/ area covered: Average height: Narrow 76 mm Wide 131 mm Average width: Narrow 66 mm Wide 124 mm Continuous spray test of Pack. Average discharge rate: Narrow 1.44 g/discharge Wide 1.46 g/discharge Spray pattern/ area covered: Average height: Narrow 72 mm Wide 131 mm Average width: Narrow 66 mm Wide 124 mm		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
		Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016 3L HDPE packaging (Spray tested : Wanda Sprayer, 3 modes of spray: narrow, medium and wide)	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 14.35 g/discharge Medium: 13.95 g/discharge Wide: 13.34 g/discharge Spray pattern/ area covered: Average height: Narrow 43 mm Medium 106 mm Wide 149 mm Average width: Narrow 35 mm Medium 93 mm Wide 144 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 14.35 g/discharge Medium 13.95 g/discharge Wide 13.34 g/discharge Spray pattern/ area covered: Average height: Narrow 43 mm Medium 106 mm Wide 149 mm Average width: Narrow 35 mm Medium 93 mm Wide 144 mm	Benitez, 2017a	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
			Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow 21.16 g/discharge Medium 19.44 g/discharge Wide 16.27 g/discharge Spray pattern/ area covered: Average height: Narrow 62 mm Medium 87 mm Wide 106 mm Average width: Narrow 51 mm Medium 79 mm Wide 93 mm Continuous spray test of Pack. Average discharge rate: Narrow 21.16 g/discharge Medium 19.44 g/discharge Wide 16.27 g/discharge Spray pattern/ area covered: Average height: Narrow 62 mm Medium 87 mm Wide 106 mm Average width: Narrow 51 mm Medium 79 mm Wide 93 mm		
Physical compatibility	Waiver	-	The product is not intended to be authorised for use with other biocidal products.		acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comments
Chemical compatibility	Waiver	-	The product is not intended to be authorised for use with other biocidal products.		acceptable
Degree of dissolution and dilution stability	Waiver	-	Not required for this formulation type.		acceptable
Surface tension	OECD 115, EEC A5	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Neat at 20 °C - 27.51 mN/m 1 g/L at 20 °C – 41.34 mN/m	Benitez, 2017	Acceptable Product is surface active
Viscosity	CIPAC MT 192, based on OECD 114	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	At 20 °C – 1.8 mPa s At 40 °C – 1.1 mPa s	Benitez, 2017	acceptable

Table 2.2.2-1 Accelerated storage stability, 8 weeks at 40°C, (Benitez, 2017a)

Property	**Method**	**Fluorinated HDPE/ 500 mL**	**PET / 1L**	**HDPE /1L**	**HDPE /3L**	**HDPE /5L**
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	Initial: 3.99 % w/w Post: 3.93 % w/w	Initial: 4.21 % w/w Post: 4.17 % w/w	Initial: 4.02 % w/w Post: 3.91 % w/w	Initial: 4.04 % w/w Post: 4.03 % w/w	Initial: 4.11 % w/w Post: 4.05 % w/w
Appearance		Initially: Liquid, mobile, opaque, white formulation, some black material observed at the bottom. Post: Liquid, mobile, opaque, white formulation	Initially: Liquid, mobile, opaque, white formulation. Post: Liquid, mobile, opaque, white formulation	Initially: Liquid, mobile, opaque, white formulation. Post: Liquid, mobile, opaque, white formulation	Initially: Liquid, mobile, opaque, white formulation. Post: Liquid, mobile, opaque, white formulation	Initially: Liquid, mobile, opaque, white formulation. Post: Liquid, mobile, opaque, white formulation
Weight loss of container / mean %		-0.10	-0.68	-0.12	-0.04	-0.04
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. Slight panelling observed.*	Packaging integrity good. Slight panelling observed.*	Packaging integrity good. Panelling observed.*
pH (neat)	CIPAC MT 75.3	Initial: 3.79 Post: 3.19	Initial: 3.92 Post: 3.79	Initial: 3.82 Post: 3.37	Initial: 3.86 Post: 3.65	Initial: 3.87 Post: 3.65
Acidity	CIPAC MT 191	Initial: 1.35 % as H_2SO_4 Post: 1.32 % as H_2SO_4	Initial: 1.40 % as H_2SO_4 Post: 1.36 % as H_2SO_4	Initial: 1.33 % as H_2SO_4 Post: 1.31 % as H_2SO_4	Initial: 1.34 % as H_2SO_4 Post: 1.33 % as H_2SO_4	Initial: 1.35 % as H_2SO_4 Post: 1.33 % as H_2SO_4
Emulsifiability, re-emulsifiability and emulsion stability (result after storage)	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.

Property	Method	Fluorinated HDPE/ 500 mL	PET / 1L	HDPE /1L	HDPE /3L	HDPE /5L
Spray ability (result after storage)		n/a	Single spray test of formulation. Average discharge rate: 1.29 g/discharge Spray pattern/ area covered: Average height: 241 mm Average width: 236 mm Continuous spray test of formulation. Average discharge rate: 1.24 g/discharge Spray pattern/ area covered: Average height: 242 mm Average width: 245 mm Single spray test of DI (Deionised) water. Average discharge rate: 1.27 g/discharge Spray pattern/ area covered: Average height: 257 mm Average width: 236 mm Continuous spray test of DI water.	Single spray test of formulation. Average discharge rate: 1.27 g/discharge Spray pattern/ area covered: Average height: 231 mm Average width: 245 mm Continuous spray test of formulation. Average discharge rate: 1.17 g/discharge Spray pattern/ area covered: Average height: 219 mm Average width: 229 mm Single spray test of DI water. Average discharge rate: 1.23 g/discharge Spray pattern/ area covered: Average height: 242 mm Average width: 252 mm Continuous spray test of DI water.	Single spray test of formulation. Average discharge rate: Narrow: 1.51 g/discharge Wide: 1.47 g/discharge Spray pattern/ area covered: Average height: Narrow 116 mm Wide 189 mm Average width: Narrow 117 mm Wide 194 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.55 g/discharge Wide 1.55 g/discharge Spray pattern/ area covered: Average height: Narrow 108 mm Wide 176 mm Average width: Narrow 115 mm Wide 172 mm Single Spray Test of the DI water. Average discharge rate:	Single spray test of formulation. Average discharge rate: Narrow: 15.72 g/discharge Medium: 15.82 g/discharge Wide: 14.12 g/discharge Spray pattern/ area covered: Average height: Narrow 40 mm Medium 121 mm Wide 136 mm Average width: Narrow 42 mm Medium 122 mm Wide 157 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 17.28 g/discharge Medium: 18.13 g/discharge Wide 15.27 g/discharge Spray pattern/ area covered: Average height: Narrow 56 mm Medium: 128 Wide 153 mm Average width:

Property	Method	Fluorinated HDPE/ 500 mL	PET / 1L	HDPE /1L	HDPE /3L	HDPE /5L
			Average discharge rate: 1.26 g/discharge Spray pattern/ area covered: Average height: 219 mm Average width: 215 mm	Average discharge rate: 1.26 g/discharge Spray pattern/ area covered: Average height: 158 mm Average width: 173 mm	Narrow 1.41 g/discharge Wide 1.41 g/discharge Spray pattern/ area covered: Average height: Narrow 76 mm Wide 120 mm Average width: Narrow 75 mm Wide 117 mm Continuous spray test of DI water. Average discharge rate: Narrow 1.52 g/discharge Wide 1.54 g/discharge Spray pattern/ area covered: Average height: Narrow 69 mm Wide 116 mm Average width: Narrow 73 mm Wide 123 mm	Narrow 59 mm Medium 118 mm Wide 157 mm Single Spray Test of the DI water. Average discharge rate: Narrow 20.10 g/discharge Medium 19.28 g/discharge Wide 16.99 g/discharge Spray pattern/ area covered: Average height: Narrow 42 mm Medium 78 mm Wide 98 mm Average width: Narrow 37 mm Medium 82 Wide 88 mm Continuous spray test of DI water. Average discharge rate: Narrow 21.73 g/discharge Medium 19.96 g/discharge Wide 17.50 g/discharge Spray pattern/ area covered: Average height:

Property	Method	Fluorinated HDPE/ 500 mL	PET / 1L	HDPE /1L	HDPE /3L	HDPE /5L
						Narrow 53 mm Medium 121 mm Wide 117 mm Average width: Narrow 48 mm Medium 119 mm Wide 119 mm

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not lost.

Table 2.2.2-2 Ambient storage stability, 24 months at 25°C, 500mL Fluorinated HDPE, (Seward, 2020)

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	3.99 % w/w	4.12 % w/w	3.97 % w/w	3.84 % w/w	3.61 % w/w (-9.4%)
Appearance		Liquid, mobile, opaque, white formulation, some black material observed at the bottom.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.
Weight loss of container / mean %		-	-0.03	-0.04	-0.07	-0.18
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. No product/ packaging interaction observed	Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*
pH (neat)	CIPAC MT 75.3	3.79 at 21.6 °C	-	3.25 at 19.8 °C	-	2.87 at 19.4 °C
Acidity	CIPAC MT 191	1.35 % as H_2SO_4	-	1.36 % as H_2SO_4	-	1.37 % as H_2SO_4
Persistent foam	CIPAC MT 47.3	0 mL foam after 1 minute	-	-	-	0 mL foam after 1 minute
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout. Except not recorded at 30 minutes after re-emulsification	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
					after 24 hours standing.	

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not modified.

Table 2.2.2-3 Ambient storage stability, 24 months at 25°C, 1L PET (not claimed), (Seward, 2020)

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	4.21 % w/w	4.19 % w/w	4.13 % w/w	4.04 % w/w	3.98 % w/w (-5.5%)
Appearance		Liquid, mobile, opaque, white formulation, some black material observed at the bottom.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.
Weight loss of container / mean %		-	-0.51	-0.21	-1.43	-2.19
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. Panelling observed.*	Packaging integrity good. No panelling observed.*
pH (neat)	CIPAC MT 75.3	3.92 at 21.4 °C	-	3.92 at 20.0 °C	-	3.78 at 19.3 °C
Acidity	CIPAC MT 191	1.40 % as H_2SO_4	-	1.39 % as H_2SO_4	-	1.74 % as H_2SO_4
Persistent foam	CIPAC MT 47.3	0 mL foam after 1 minute	-	-	-	0 mL foam after 1 minute

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout.	Neat: Spontaneous emulsion initially and uniform emulsion throughout.	Neat: Spontaneous emulsion initially and uniform emulsion throughout.	Neat: Spontaneous emulsion initially and uniform emulsion throughout.	Neat: Spontaneous emulsion initially and uniform emulsion throughout.
Spray ability		Single spray test of formulation. Average discharge rate: 1.31 g/discharge Spray pattern/ area covered: Average height: 243 mm Average width: 229 mm Continuous spray test of formulation. Average discharge rate: 1.31 g/discharge Spray pattern/ area covered: Average height: 243 mm Average width: 229 mm	Single spray test of formulation. Average discharge rate: 1.29 g/discharge Spray pattern/ area covered: Average height: 259 mm Average width: 254 mm Continuous spray test of formulation. Average discharge rate: 1.18 g/discharge Spray pattern/ area covered: Average height: 259 mm Average width: 260 mm	Single spray test of formulation. Average discharge rate: 1.30 g/discharge Spray pattern/ area covered: Average height: 254 mm Average width: 238 mm Continuous spray test of formulation. Average discharge rate: 1.14 g/discharge Spray pattern/ area covered: Average height: 219 mm Average width: 229 mm	Single spray test of formulation. Average discharge rate: 1.29 g/discharge Spray pattern/ area covered: Average height: 253 mm Average width: 247 mm Continuous spray test of formulation. Average discharge rate: 1.17 g/discharge Spray pattern/ area covered: Average height: 246 mm Average width: 256 mm	Single spray test of formulation. Average discharge rate: 1.29 g/discharge Spray pattern/ area covered: Average height: 228 mm Average width: 228 mm Continuous spray test of formulation. Average discharge rate: 1.16 g/discharge Spray pattern/ area covered: Average height: 222 mm Average width: 220 mm

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not lost.

Table 2.2.2-4 Ambient storage stability, 24 months at 25°C, HDPE /1L, (Seward, 2020)

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	4.02 % w/w	3.92 % w/w	3.81 % w/w	3.65 % w/w (-9.2%)	3.49 % w/w (-13%)
Appearance		Liquid, mobile, opaque, white formulation, some black material observed at the bottom.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.
Weight loss of container / mean %		-	-0.06	-0.15	-0.24	-0.31
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. No product/packaging interaction observed*	Packaging integrity good. Slight panelling observed*.	Packaging integrity good. Panelling observed *	Packaging integrity good. Panelling observed.*	Packaging integrity good. No panelling observed.
pH (neat)	CIPAC MT 75.3	3.82 at 21.4 °C	-	3.23 at 20.0 °C	-	2.89 at 19.2 °C
Acidity	CIPAC MT 191	1.33 % as H_2SO_4	-	1.32 % as H_2SO_4	-	1.33 % as H_2SO_4
Persistent foam	CIPAC MT 47.3	0 mL foam after 1 minute	-	-	-	0 mL foam after 1 minute
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Spray ability		Single spray test of formulation. Average discharge rate: 1.30 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Continuous spray test of formulation. Average discharge rate: 1.30 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm	Single spray test of formulation. Average discharge rate: 1.31 g/discharge Spray pattern/ area covered: Average height: 261 mm Average width: 250 mm Continuous spray test of formulation. Average discharge rate: 1.24 g/discharge Spray pattern/ area covered: Average height: 263 mm Average width: 264 mm	Single spray test of formulation. Average discharge rate: 1.25 g/discharge Spray pattern/ area covered: Average height: 270 mm Average width: 242 mm Continuous spray test of formulation. Average discharge rate: 1.22 g/discharge Spray pattern/ area covered: Average height: 246 mm Average width: 239 mm	Single spray test of formulation. Average discharge rate: 1.27 g/discharge Spray pattern/ area covered: Average height: 260 mm Average width: 254 mm Continuous spray test of formulation. Average discharge rate: 1.14 g/discharge Spray pattern/ area covered: Average height: 268 mm Average width: 248 mm	Single spray test of formulation. Average discharge rate: 1.25 g/discharge Spray pattern/ area covered: Average height: 238 mm Average width: 231 mm Continuous spray test of formulation. Average discharge rate: 1.22 g/discharge Spray pattern/ area covered: Average height: 217 mm Average width: 214 mm

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not lost.

Table 2.2.2-5 Ambient storage stability, 24 months at 25°C, HDPE /3L, (Seward 2020)

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	4.04 % w/w	3.97 % w/w	4.07 % w/w	3.86 % w/w	3.70 % w/w (-8.3%)
Appearance		Liquid, mobile, opaque, white formulation, some black material observed at the bottom.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.
Weight loss of container / mean %		-	-0.02	-0.05	-0.08	-0.14
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. No product/packaging interaction observed	Packaging integrity good. Slight panelling observed*.	Packaging integrity good. Panelling observed*	Packaging integrity good. Panelling observed.*	Packaging integrity good. No panelling observed.
pH (neat)	CIPAC MT 75.3	3.86 at 21.3 °C	-	3.56 at 20.1 °C	-	3.27 at 19.0 °C
Acidity	CIPAC MT 191	1.34 % as H_2SO_4	-	1.40 % as H_2SO_4	-	1.31 % as H_2SO_4
Persistent foam	CIPAC MT 47.3	0 mL foam after 1 minute	-	-	-	0 mL foam after 1 minute
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Spray ability	2 modes of spray tested: narrow or wide	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.44 g/discharge Wide: 1.47 g/discharge Spray pattern/ area covered: Average height: Narrow 91 mm Wide 166 mm Average width: Narrow 87 mm Wide 154 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.44 g/discharge Wide 1.47 g/discharge Spray pattern/ area covered: Average height: Narrow 91 mm Wide 166 mm	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.50 g/discharge Wide: 1.52 g/discharge Spray pattern/ area covered: Average height: Narrow 171 mm Wide 202 mm Average width: Narrow 158 mm Wide 204 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.15 g/discharge Wide 1.43 g/discharge Spray pattern/ area covered: Average height: Narrow 66 mm Wide 134 mm	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.51 g/discharge Wide: 1.51 g/discharge Spray pattern/ area covered: Average height: Narrow 130 mm Wide 187 mm Average width: Narrow 129 mm Wide 170 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.34 g/discharge Wide 1.44 g/discharge Spray pattern/ area covered: Average height: Narrow 119 mm Wide 171 mm	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.11 g/discharge Wide: 1.15 g/discharge Spray pattern/ area covered: Average height: Narrow 86 mm Wide 190 mm Average width: Narrow 84 mm Wide 184 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.46 g/discharge Wide 1.50 g/discharge Spray pattern/ area covered: Average height: Narrow 133 mm	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 1.39 g/discharge Wide: 1.24 g/discharge Spray pattern/ area covered: Average height: Narrow 146 mm Wide 194 mm Average width: Narrow 150 mm Wide 189 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 1.27 g/discharge Wide 1.44 g/discharge Spray pattern/ area covered:

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
		Average width: Narrow 87 mm Wide 154 mm	Average width: Narrow 62 mm Wide 129 mm	Average width: Narrow 119 mm Wide 170 mm	Wide 228 mm Average width: Narrow 134 mm Wide 209 mm	Average height: Narrow 94 mm Wide 166 mm Average width: Narrow 88 mm Wide 163 mm

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not lost.

Table 2.2.2-6 Ambient storage stability, 24 months at 25°C, HDPE /5L, (Seward, 2020)

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Active substance content Analytical method used: CAM-0199/001 (cf part 2.4)	CAM-0199	4.11 % w/w	4.12 % w/w	4.01 % w/w	3.93 % w/w	3.72 % w/w (-9.6%)
Appearance		Liquid, mobile, opaque, white formulation, some black material observed at the bottom.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.	Liquid, mobile, opaque, white uniform formulation.
Weight loss of container / mean %		-	-0.01	-0.03	-0.06	-0.13
Packaging Stability, Product/Packaging Interactions		Packaging integrity good. No product/packaging interaction observed	Packaging integrity good. Slight panelling observed.	Packaging integrity good. Panelling observed	Packaging integrity good. Panelling observed.	Packaging integrity good. No panelling observed.
pH (neat)	CIPAC MT 75.3	3.87 at 21.6 °C	-	3.61 at 20.3 °C	-	3.28 at 19.1 °C
Acidity	CIPAC MT 191	1.35 % as H_2SO_4	-	1.41 % as H_2SO_4	-	1.36 % as H_2SO_4
Persistent foam	CIPAC MT 47.3	0 mL foam after 1 minute	-	-	-	0 mL foam after 1 minute
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.	Neat: Spontaneous emulsion initially and uniform emulsion throughout the 24h test.

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
Spray ability	3 modes of spray tested: narrow, medium or wide	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 14.35 g/discharge Medium: 13.95 g/discharge Wide: 13.34 g/discharge Spray pattern/ area covered: Average height: Narrow 43 mm Medium 106 mm Wide 149 mm Average width: Narrow 35 mm Medium 93 mm Wide 144 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 14.35 g/discharge Medium 13.95 g/discharge	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 15.38 g/discharge Medium: 15.26 g/discharge Wide: 13.16 g/discharge Spray pattern/ area covered: Average height: Narrow 48 mm Medium 149 mm Wide 165 mm Average width: Narrow 45 mm Medium 148 mm Wide 167 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 14.97 g/discharge Medium 14.55 g/discharge	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 15.41 g/discharge Medium: 14.96 g/discharge Wide: 13.01 g/discharge Spray pattern/ area covered: Average height: Narrow 65 mm Medium 88 mm Wide 149 mm Average width: Narrow 67 mm Medium 81 mm Wide 158 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 14.88 g/discharge Medium 14.80 g/discharge	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 16.24 g/discharge Medium: 15.65 g/discharge Wide: 13.58 g/discharge Spray pattern/ area covered: Average height: Narrow 66 mm Medium 166 mm Wide 180 mm Average width: Narrow 59 mm Medium 158 mm Wide 172 mm Continuous Spray Test of the RTU formulation. Average discharge rate: Narrow 15.19 g/discharge Medium 14.20 g/discharge	Trigger spray test (single spray test of formulation, except for the initial time point: this is the initial for the continuous spray test for subsequent storage at 40°C and 25°C) Average discharge rate: Narrow: 16.09 g/discharge Medium: 15.31 g/discharge Wide: 13.52 g/discharge Spray pattern/ area covered: Average height: Narrow 61 mm Medium 153 mm Wide 165 mm Average width: Narrow 56 mm Medium 153 mm Wide 157 mm Continuous Spray Test of the RTU formulation. Average discharge rate:

Property	Method	Initial	6 months at 25 °C	12 months at 25 °C	18 months at 25 °C	24 months at 25 °C
		Wide 13.34 g/discharge Spray pattern/ area covered: Average height: Narrow 43 mm Medium 106 mm Wide 149 mm Average width: Narrow 35 mm Medium 93 mm Wide 144 mm	Wide 13.28 g/discharge Spray pattern/ area covered: Average height: Narrow 63 mm Medium 139 mm Wide 138 mm Average width: Narrow 60 mm Medium 132 mm Wide 144 mm	Wide 13.08 g/discharge Spray pattern/ area covered: Average height: Narrow 63 mm Medium 152 mm Wide 149 mm Average width: Narrow 69 mm Medium 169 mm Wide 157 mm	Wide 12.72 g/discharge Spray pattern/ area covered: Average height: Narrow 69 mm Medium 187 mm Wide 168 mm Average width: Narrow 57 mm Medium 171 mm Wide 169 mm	Narrow 15.03 g/discharge Medium 13.88 g/discharge Wide 12.39 g/discharge Spray pattern/ area covered: Average height: Narrow 53 mm Medium 145 mm Wide 146 mm Average width: Narrow 46 mm Medium 139 mm Wide 150 mm

* Panelling means that the sides of the bottles are slightly bent inwards. The packaging integrity was not lost.

Conclusion on the chemical and technical properties of the product
The physical, chemical and technical properties of the biocidal product SPEED EASY CLEAN are acceptable for the RTU formulations. The accelerated storage data for 8 weeks at 40°C show that the product is stable at temperature below 40°C. The mitigation measure do not store above 40°C is added to SPC. The shelf life stability studies (25°C, 24 months) show that the product is not stable in 1L HDPE packaging after 24 months. The shelf life of the product is then set at a lower acceptable tested product: 18 month. Particle size distribution of droplets of spray were not submitted. However, as inhalation is not a concern for human health, this property was waived for this product. For completion of the dossier, particle size distribution of droplets before and after storage are required in post authorisation within 2 years. Shelf life :18 months

Store the product at temperature below 40°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comment
Explosives	Waiver	-	The product comprises substances triggering possible explosive properties. See confidential annex for complete waiver consideration The product can be regarded to not have explosive properties.	-	The product is not classified as explosive
Flammable gases	Waiver	-	Not applicable to a liquid.	-	acceptable
Flammable aerosols	Waiver	-	Not applicable to a liquid.	-	acceptable
Oxidising gases	Waiver	-	Not applicable to a liquid.	-	acceptable
Gases under pressure	Waiver	-	Not applicable to a liquid.	-	acceptable
Flammable liquids	EEC A9	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. CH13092016	Flash point >135°C	Benitez, 2017a	acceptable
Flammable solids	Waiver	-	Not applicable to a liquid.		acceptable
Self-reactive substances and mixtures	Waiver	-	The product comprises substances triggering possible self-reactive properties. See confidential annex for complete waiver consideration The product can be regarded as not self-reactive.		acceptable
Pyrophoric liquids	Waiver	-	Experience in use indicates that the formulation is not pyrophoric.		acceptable
Pyrophoric solids	Waiver	-	Not applicable to a liquid.		acceptable
Self-heating substances and mixtures	Waiver	-	The study is not necessary because the formulation is a liquid. In addition, experience in use as a PPP indicates that the formulation does not self-heat.		acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR comment
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	Experience in use indicates that the formulation does emit flammable gases when in contact with water.		acceptable
Oxidising liquids	Waiver	-	The product comprises substances triggering possible oxidising properties. See confidential annex for complete waiver consideration The product can be regarded to not have oxidising properties.		acceptable
Oxidising solids	Waiver	-	Not applicable to a liquid.		acceptable
Organic peroxides	Waiver	-	The formulation is not an organic peroxide.		acceptable
Corrosive to metals	UN Test C.1	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. 2019RD008	The formulation is not corrosive to metals (steel and aluminium). Sample tested on complete immersion, half way immersion and above: Aluminium coupon: 76.2 mm x 12.7 mm x 1.6 mm Steel coupon: 76.2 mm x 12. 7 mm x 3.6 mm mass loss < 0.4% after 7 days at 55°C on all samples No localized corrosion > 10µm observed after 7 days at 55°C	Seward, 2019	Acceptable
Auto-ignition temperatures of products (liquids and gases)	EC, A15	Pelargonic Acid (Nonanoic acid) 43 g/L (4.3 % w/w) Formulation Lot No. 2019RD008	480°C	Seward, 2019	acceptable
Relative self-ignition temperature for solids	Waiver	-	Not applicable to a liquid.		acceptable
Dust explosion hazard	Waiver	-	Not applicable to a liquid.		acceptable

Conclusion on the physical hazards and respective characteristics of the product
The formulation is not classified for physical hazards.

2.2.4 Methods for detection and identification

2.2.4.1 Analytical methods for the analysis of the product

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Pelargonic acid in formulation	test item solution is diluted into an acetonitrile/water: 35% HCl solution and injected into an HPLC-UV (210 nm) CAM-0199/001	<80 % nominal (1.36 mg/mL) n = 6 >120 % nominal (2.72 mg/mL) n = 6	0.91 – 3.62 mg/mL This range was equivalent to 46.8 to 187.3 % of nominal analyte concentration R^2 = 0.9999 y = 146.25 x – 4.3572 n= 6 x 2	No interfering peaks were found in unfortified blank formulation extracts at the analyte retention time.	98.6 - 99.5 100.4 – 101.0	99.1 100.7	0.16	n/a	Benitez, 2017b
Pelargonic acid in formulation	test item is hydolyse with KOH ethanol solution at 100°C for 0.5 hour, the residue is diluted in acetonitrile/water/ 35% HCl solution and injected into	<80 % nominal (1.36 mg/mL) n = 6 >120 % nominal (2.72 mg/mL) n = 6	0.63-3.75 mg/mL This range is equivalent to 31.3-187.7% of nominal concentration R^2= 0.9999	No interfering peaks were found in unfortified blank formulation extracts at the analyte	99-101.7 95.4-97.6	98.4	1.78	n/a	Study report CeMR-7988 J. M. Gonzalez Benitez 2017

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	an HPLC-UV (210 nm) CAM-0229/001		Y=87.419x+ 1.8102	retention time.					

Method CAM-0199/001 is validated
Method CAM-0229/001 is validated. However, Pelargonic acid, being a carboxylic acid, is prone to esterification in the presence of alcohols. A hydrolysis step in the sample preparation of an analytical method would hydrolyse the ester to its corresponding carboxylic acid. In consequence the analytical method cannot distinguish the acid and ester substances and cannot be considered specific to the active substance. Therefore, this analytical method including hydrolysis step is not suitable for the determination of the active substance in the biocidal product.

2.2.4.2 Analytical methods for soil

Please refer to active substance dossier.

2.2.4.3 Analytical methods for air

Please refer to active substance dossier.

2.2.4.4 Analytical methods for water

Please refer to active substance dossier.

2.2.4.5 Analytical methods for animal and human body fluids and tissues

Please refer to active substance dossier.

2.2.4.6 Analytical methods for monitoring of active substances and residues in food and feeding stuffs

Please refer to active substance dossier.

2.2.4.7 Conclusion on the methods for detection and identification of the product

Acceptable method were provided for the determination of Pelargonic acid in the formulation.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main Group 01: Disinfectants

Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals

The product Speed Easy Clean is a ready-to-use product (43 g nonanoic acid/L) applied by spraying onto surfaces by non-professional users.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The biocidal product is intended to be used by the applicant for curative treatment against algae, fungi, yeast and lichen on hard surfaces (of multiple types i.e. wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc.). The product is used outdoors by non-professional users.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The nonanoic acid based products are intended to be used by the applicant in treatment against algae, fungi, yeast and lichen on hard surfaces. Nonanoic acid can penetrate the tissues of organisms and destroy the cell wall.

2.2.5.4 Mode of action, including time delay

Nonanoic acid is a naturally occurring fatty acid found in plants and animals. It has a physical effect on cell walls (algae, lichen) and affects cell wall integrity. Due to its lipophilic characteristics, the active substance quickly penetrates the tissue and disrupts normal cell membrane permeability. This causes a destruction of photosynthesis mechanisms and other membrane bound physiological processes.

Lichen are complex organisms composed of a fungus in symbiotic union with algae or cyanobacteria. Nonanoic acid will destroy the integrity of the cell wall of the algae or cyanobacteria, and therefore the lichen will be killed.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Fungicidal Yeasticidal	Use #1	Speed Ultra Clean (S19321 R537.001, nonanoic acid 565 g/L)	**Yeasts** *Candida albicans* ATCC 10231 **Fungi** *Aspergillus brasiliensis* ATCC 16404	EN 1650:2008	Phase 2 step 1 test (suspension test) Concentrations tested: 0.01%, 0.05%, 0.5%, 1.0%, 7.5% and 10.0% (v/v) Interfering substance: dirty conditions (3 g/L bovine albumin) Contact time: 6 hours Test temperature: 20°C Criteria: at least a 4 log reduction	Fungicidal activity demonstrated at 1% v/v. Yeasticidal activity demonstrated at 0.5% v/v.	Tyralla, B., 2019 Report No 5104180-06 IUCLID 6.7.1 R.I.: 2
Fungicidal Yeasticidal	Use #1	Speed Ultra Clean (S19321 R537.001, nonanoic acid 565 g/L)	**Yeasts** *Candida albicans* ATCC 1023 **Fungi** *Aspergillus brasiliensis* ATCC 16404	EN 13697:2015	Phase 2 step 2 test (non-porous surface test) Concentrations tested: 0.01%, 7.5% and 10.0% (v/v) Interfering substance: dirty conditions (3 g/L bovine albumin) Contact time: 6 hours Test temperature: 20°C. Criteria: at least a 3 log reduction	Yeasticidal and fungicidal activity demonstrated at 7.5% v/v.	Tyralla, B., 2019 Report No 5104180-08_V02 IUCLID 6.7.2 R.I.: 2
Algaecidal	Use #1	Speed Ultra Clean (S19321 R537.001,	**Algae** *Desmodesmus subspicatus*	OECD 201 Version July 2011	Algae suspension Test product application: 1.5 mg/L, 3.5 mg/L, 6.6 mg/L, 14.3 mg/L and 30.4 mg/L (corresponding to 0.85 mg/L, 1.98 mg/L, 3.73 mg/L and	Even if, inhibition of the growth rate after 72 hours and up to 39 % has been demonstrated against	Lebertz, H. and Vogel, S. 2019

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		nonanoic acid 565 g/L)			8.08 mg/L a.s. concentration respectively) Contact time: 72 h Incubation temperature: 24 °C ± 1 °C Evaluation: average specific growth rate, and yield	*Desmodesmus subspicatus* with the test product, the cell number in the test solutions increased for all concentrations of product tested from t0 and t72 hours. Therefore, no algaecidal efficacy has been demonstrated based on this study.	Report No 5114758-01-V1 IUCLID 6.7.3 R.I.: 2
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp*.)	Field trial In-house method according to EPPO PP1/152 EPPO PP1/181 EPPO PP1/117	Test system: concrete surface (old silage concrete surface of a pig fattening plant) covered with algae at day 0 for untreated control 60.0% and up to 68.75% at day 29 Location: D-18276 Mistorf (Mecklenburg-Western Pomerania, Germany) Application by spraying on day 0 at 14-17°C Test product concentration: RTU product (Application volume 500 L/ha= 50mL/m^2) Replicates: 4 Randomized Complete Block (RCB) with a plot size of 1 x 1 m Controls: untreated plot (negative control)	17.5% efficacy after 3 hours, 75.0% efficacy after 1 day, 92.5% efficacy after 7 days, 97.25% after 14 days, 85.0% efficacy after 29 days	Lindemann F, 2019 Report No 100080 IUCLID 6.7.4. R.I.: 1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Evaluation: quotations (percentage of area covered by algae) at 3 hours, 1, 3, 7, 14 and 29 days after application		
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp.*)	Field trial In-house method according to EPPO PP1/152 EPPO PP1/181	Test system: Concrete paving slabs covered with algae (initial coverage between 77.5% and 88.8%) Location: Cardiff, UK. **Two applications** by spraying: on day 0 at 12.2°C and, on day 12 at 8.8°C Test product concentration: RTU product (Application volume 500 L/ha= 50mL/m^2) Replicates: 4 Randomized Complete Block (RCB) with a plot size of 1 x 1 m Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 2, 3, 7, 14, 30, 60, 90, 120, 150 and 180 days after application	80.8% efficacy after 30 days, 97.3% after 60 days, 94.3% efficacy after 180 days.	Gibson D, 2019 Report No 18/230 IUCLID 6.7.5. R.I.: 2 (slight decrease of the surface covered by algae in the controls during the trial, mean 75% at 180 days)
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp.*)	Field trial In-house method according to EPPO PP1/152 EPPO PP1/181	Test system: Concrete paving slabs covered with algae (between 77.5% and 85.0%) Location: Cardiff, UK. **Two applications** by spraying: on day 0 at 9.2°C and, on day 11 at 11.6°C	71.1% efficacy after 30 days, 95.2% after 60 days, 84.4% efficacy after 180 days.	Gibson D, 20019 Report No 18/231 IUCLID 6.7.6.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Test product concentration: RTU product (Application volume 500 L/ha= 50mL/m^2) Replicates: 4 Randomized Complete Block (RCB) with a plot size of 1 x 1 m Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 3, 7, 14, 30, 60, 90, 120, 150 and 180 days after application		R.I.: 2 (slight decrease of the surface covered by algae in the controls during the trial, mean 63.8% at 180 days)
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp.*)	Field trial In-house method according to EPPO PP1/152 EPPO PP1/181	Test system: Red brick covered with algae (46.3% at day 0 for untreated controls and up to 47.5% at day 180) Location: Gateshead, UK. **Two applications** by spraying: on day 0 at 3.2°C and, on day 15 at 6.5°C Test product concentration: RTU product (Application volume 500 L/ha= 50mL/m^2) Replicates: 4 Plot size: 1 m² Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 3, 7,	98.5% efficacy after 30 days, 99.9% after 62 days, 97.5% efficacy after 180 days	Gibson D, 2019 Report No 18/232 IUCLID 6.7.7. R.I.: 1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					15, 30, 62, 90, 120, 150 and 180 days after application		
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp.*)	Field trial In-house method according to EPPO PP1/152(4) EPPO PP1/181(4) EPPO PP1/135(4)	Test system: Wood fence covered with algae (87.5%) Location: 190 Chemin des Béluises 69480 Morancé, France. **Two applications** by spraying: on day 0 at 20°C and, on day 13 at 22°C Test product concentration: RTU product, application volume 500 L/ha= 50mL/m^2 Replicates: 4 Randomized Complete Block (RCB) with a plot size of 50 x 50 cm Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 3, 8, 15, 31, 63, 93, 122, 153, 183 days after application	82.5% after 8 days, 93.8% after 15 days, 98.8% after 31 days, 100.0% efficacy after 183 days	Raynaud, R. 2018 Report No FROC1801R 1 IUCLID 6.7.8. R.I.: 2 (slight decrease of the surface covered by algae in the controls during the trial, mean 61.3% at 183 days, and after two month, the algae on one replicate of negative control died and was excluded from the analysis)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** (*Chlorophyta spp.*)	Field trial In-house method according to EPPO PP1/152(4) EPPO PP1/181(4) EPPO PP1/135(4) EPPO PP1/117(3	Test system: Wood fence covered with algae (77.5% at day 4 for untreated controls and up to 92.5% at day 187) Location: 300 route des Chères 69480 Morancé, France. **Two applications** by spraying: on day 0 at 28°C and, on day 15 at 19°C Test product concentration: RTU product, application volume 500 L/ha= 50mL/m^2 Replicates: 4 Plot size: 0,250 m^2 = 50cm X 50cm Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 4, 7, 14, 18, 22 29, 43, 64, 75, 124 and 187 days after application	94.5% after 4 days, 95.3% after 14 days, 90.0% after 43 days and 100.0% efficacy after 187 days	Neyrand, S. 2019 Report No FROC1803N 1 IUCLID 6.7.9. R.I.: 1
Efficacy against Lichen	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Lichen**	Field trial In-house method according to EPPO PP 1/117 EPPO PP1/135 EPPO PP 1/152	Test system: Concrete pavement slabs covered with lichens (33% at day 0 for untreated controls and up to 35.5% at day 226) Location: Ipswich, UK **Two applications** by spraying: on day 0 at 18.2°C and, on day 15 at 7.0°C	Colour changes: 78.7% efficacy after 38 days, 77.8% efficacy after 62 days, 83.5% efficacy after 182 days 92.5 % after 226 days Ground cover:	Lisiecki, M. 2019 Report No GBOC1801/ 1 IUCLID 6.7.10. R.I.: 1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				EPPO PP1/181	Test product concentration: RTU product, application volume 500 L/ha= 50mL/m^2 Plot size: 0.48 m² = 0.8 m X 0.6 m Replicates: 4 Controls: Untreated plot (negative control) Evaluation: Visual estimation of control against Lichen – based on colour change [%] (1, 3, 7, 15, 23, 38, 62, 94, 182 and 226 days after treatment application)	39.5% at D0 and 9.8% after 226 days.	
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Green algae** *Chlorella vulgaris*	Field trial In-house method according to EPPO PP1/152 EPPO PP1/181 EPPO PP1/117	Test system: plastic (non-porous) covered with algae (42.5% at day 0 for untreated controls and up to 58.8% at day 182) Location: Braine-le-Château, Belgium. **Two applications** by spraying: on day 0 at 17.2°C and, on day 16 at 7.5°C Test product concentration: RTU product, application volume 500 L/ha= 50mL/m^2 Replicates: 4 Randomized Complete Block (RCB) with a plot size of 3 x 0.5 m Controls: Untreated plot (negative control),	100.0% efficacy after 1 day and up to 182 days	Devos M, 2019 Report No R151-18H IUCLID 6.7.11. R.I.: 1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Evaluation: quotations (percentage of area covered by algae) at 1, 3, 7, 16, 30, 62, 91, 118, 149 and 182 days after application		
Efficacy against Lichen	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Lichen** (grey and yellow)	Field trial In-house method according to EPPO PP 1/117 EPPO PP1/135 EPPO PP 1/152 EPPO PP1/181	Test system: Concrete pavement slabs covered with lichens (39.5% at day 0 for untreated controls and up to 78.8% at day 182) Location: Ipswich, UK **Two applications** by spraying: on day 0 at 13.8°C and on day 15 at 9.5°C Test product concentration: RTU product, application volume 300 L/ha= 30mL/m^2 Replicates: 4 Plot size: 0.354 m^2 Controls: Untreated plot (negative control) Evaluation: Visual estimation of control against lichen – based on colour change [%] (3 hours, 1, 4, 8, 14, 21, 28, 61, 96 and 186 days after treatment application)	Colour changes: 85.74% after 21 days, 87.30% after 61 days and 84.75% after 186 days. Ground cover: 40% at D0 and 14.8% after 186 days.	Lisiecki, M. 2019 Report No GBOC1901/1 IUCLID 6.7.12. R.I.: 1
Algaecidal	Use #1	Speed Easy Clean (S19690 R586.009, nonanoic acid 43 g/L)	**Red algae** (*Rhodophyta spp.)*	Field trial In-house method according to EPPO PP1/181	Test system: concrete wall covered with algae (31.3% at day 0 for untreated controls and up to 43.8% at day 154) Location: Longvic, France.	31.3% efficacy after 29 days, 98.3% after 121 days, 99.3% efficacy after 154 days	Rouane W, 2019 Report No EU 19260JV31 1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				EPPO PP1/225 EPPO PP1/152	**Two applications** by spraying: on day 0 at 14.8°C and, on day 15 at 23.1°C Test product concentration: RTU product, application volume 500 L/ha= 50mL/m^2 Replicates: 4 Randomized Complete Block (RCB) with a plot size of 1 x1.05 m Controls: Untreated plot (negative control) Evaluation: quotations (percentage of area covered by algae) at 1, 3, 7, 15, 29, 121 and 154 days after application		IUCLID 6.7.13. R.I.: 1

Please note that no criteria have been included in the ECHA "Guidance on the Biocidal Products Regulation. Volume II Efficacy -Assessment and Evaluation (Parts B+C). Version 3.0, April 2018" regarding the efficacy requirements for algaecidal or efficacy against lichens when the product is used as a remedial treatment in PT 2.

In general, the same principles as for PT2 should be applied and therefore we consider that for field tests, at least >90% reduction in surface coverage should be demonstrated to support an algaecidal effect or a surface discoloration >90% should be demonstrated to support a lichenicidal effect.

Efficacy against fungi and yeast

To support the efficacy against fungi and yeast, the applicant has provided laboratory studies with the product SPEED ULTRA CLEAN (S19321 R537.001).

The composition of this product is presented in the confidential section of the PAR with a justification for the proposed cross-reading with the product SPEED EASY CLEAN (S19690 R586.009).

Taking into account the variations of the co-formulants between these products, and considering that the product SPEED EASY CLEAN is a ready to use product, the efficacy results of this product is considered as relevant to support the efficacy of the product SPEED EASY CLEAN.

In the laboratories tests provided (EN 1650 and EN13697) the contact time tested were 6 hours whereas the maximum contact time authorised/specified in these method. However, as all controls are validated, these studies are considered as acceptable.

Nevertheless, it is considered that these studies are not suitable/representative to support the claimed use as the tests are performed at 20°C which is not consistent with outdoor use. Indeed, as clearly stated in the efficacy guidance volume II parts B/C section 5.4.2.3.2.for hard surface disinfectant it is required that for tests provided simulate "practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.)".

Therefore, we consider that the efficacy against yeast and fungi is not demonstrated based on the efficacy data provided.

Efficacy against algae

Green algae:

To prove the basic efficacy of the product, a suspension test based on the OECD 201 against *Desmodesmus subspicatus* was conducted with the product Speed Ultra Clean. However, even if inhibition of the growth rate after 72 hours and up to 39 % has been demonstrated against *Desmodesmus subspicatus*, the cell number in the test solutions increased for all concentrations of product tested from t0 and t72 hours.

Therefore, no algaecidal/algaestat efficacy has been demonstrated based on this study.

Nevertheless, we consider that suspension tests are not representative of the conditions of the use claimed (algaecide on hard surfaces – outdoor) and this test could be waived as robust field tests have been provided.

The applicant has provided 8 field studies performed with the product SPEED EASY CLEAN (S19690 R586.009) according to an in-house methodology based on the guidelines available

via the European and Mediterranean Plant Protection Organisation (EPPO). These guidelines are used in assessing the efficacy of plant protection products for the control of weeds on hard and semi-permeable surfaces. Efficacy is assessed by visually measuring the percentage of target organisms in treated versus untreated plots.

In these studies, the efficacy of the ready to use product was demonstrated against green algae (*Chlorophyta* spp.):

- On concrete (porous surface), when applied once, after 7 days (92.5% efficacy) at an application rate of 50 mL/m^2.
- On concrete paving slabs (porous surface), when applied twice (12 days apart), after 60 days (94.3% efficacy) at an application rate of 50 mL/m^2.
- On concrete paving slabs (porous surface), when applied twice (11 days apart), after 60 days (100% efficacy) at an application rate of 50 mL/m^2.
- On red brick (porous surface), when applied twice (15 days apart), after 30 days (98.5% efficacy) at an application rate of 50 mL/m^2.
- On wood fence (porous surface), when applied twice (13 days apart), after 15 days (93.8% efficacy) at an application rate of 50 mL/m^2.
- On wood fence (porous surface), when applied once, after 4 days (94.5% efficacy) at an application rate of 50 mL/m^2.
- On plastic (non-porous surface), when applied once, after 1 day (100% efficacy) at an application rate of 50 mL/m^2.

Therefore, we consider that efficacy is demonstrated against green algae (*Chlorophyta spp.)* on porous and non-porous surfaces at an application rate of 50 mL/m^2 with at least one application.

Red algae:
The efficacy of the product was also demonstrated against red algae (*Rhodophyta spp.*):

- On concrete wall (porous surfaces), when applied twice (15 days apart), after 121 days (98.3% efficacy) at an application rate of 50mL/m^2.

Therefore, we consider that efficacy is demonstrated against red algae (*Rhodophyta spp.*) on porous surfaces only, at an application rate of 50 mL/m^2 with at least two applications (2 weeks spaced).

The efficacy of the product at an application rate of 50 mL/m^2 with only one application or on non-porous surfaces is not demonstrated against red algae based on the efficacy data provided.

Efficacy against lichen

Similar to the field tests submitted to support the algaecidal claims, field studies were performed according to an in-house methodology based on the guidelines available via the EPPO. However, lichens consist of a symbiotic association of fungus and algae, and sometimes several species are mixed. Nonanoic acid will kill the micro-organisms but the structure will often remain attached on its porous support (wood, concrete…). So, in the field tests, the efficacy has been assessed by discoloration which indicates that the organism is dead and not by reduction in coverage as for algae.

Based on the field tests provided, the efficacy of the product SPEED EASY CLEAN (S19690 R586.009) was demonstrated against lichen:

- On concrete paving slabs (porous surfaces), when applied twice (15 days spaced), after 226 days (92.5% efficacy/discoloration) at an application rate of 50 mL/m^2.

- On concrete paving slabs (porous surfaces), when applied twice (15 days spaced), after 61 days (87.30% efficacy/discoloration) at an application rate of 30 mL/m^2.

Please note that no field test on non-porous surfaces was provided against lichen but according to the applicant this kind of surfaces are not relevant for this target organism as "lichens grow on porous surfaces only". Therefore, for lichens, only efficacy on porous surfaces is demonstrated/authorised based on the efficacy data provided.

Furthermore, the applicant indicated that for lichens, 2 applications of the product spaced 2 to 4 weeks apart are claimed.

Therefore, we consider that efficacy is demonstrated against lichens on porous surfaces only at an application rate of 50 mL/m^2 with at least two product applications (2 weeks spaced).

Conclusion on the efficacy of the product
French competent authorities (FR CA) assessed that the ready to use product SPEED EASY CLEAN has shown a sufficient efficacy by spraying at an application rate of 50 mL/m^2 against: - green algae (*Chlorophyta spp.)* on porous and non-porous surfaces (one product application) - red algae (*Rhodophyta spp.*) on porous surfaces only (two product applications, 2 weeks spaced) - lichen on porous surfaces only (two product applications, 2 weeks spaced) However, the efficacy of the product is not demonstrated based on the efficacy data provided against yeast and fungi. The efficacy is also not demonstrated against red algae with only one application or on non-porous surface.

2.2.5.6 Occurrence of resistance and resistance management

No cases of resistance against nonanoic acid have been reported in the literature.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

2.2.6 Risk assessment for human health

SPEEDY EASY CLEAN is a PT2 product used for the disinfection of hard surfaces and acting like an algaecide for non-professional users in outdoor.
The product contains 4.46% a.s (technical) and is be used at a maximal application rate of 50 mL biocidal porduct/m^2 as a RTU (Ready To Use) product.

2.2.6.1 Assessment of effects on Human Health

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on SPEED EASY CLEAN.
Classification of the products has been carried out according to the calculation rules laid down in the CLP regulation.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating nor corrosive to the skin
Justification for the value/conclusion	No study has been performed on the product SPEED EASY CLEAN. Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin irritation.
Classification of the product according to CLP	Not classified.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eyes
Justification for the value/conclusion	No study has been performed on the product SPEED EASY CLEAN. Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for eye irritation.
Classification of the product according to CLP	Not classified.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the value/conclusion	No study has been performed on the product SPEED EASY CLEAN. Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation.
Classification of the product according to CLP	Not classified.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to the skin
Justification for the value/conclusion	No study has been performed on SPEED EASY CLEAN. Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin sensitization. However, the CMIT-MIT classified as sensitizing (Skin Sens 1A) is present at a concentration greater or equal to 1/10 of its SCL. Therefore, EUH208 labelling for this ingredient is needed. For more details, please see confidential annex.
Classification of the product according to CLP	Not classified. Additional labelling information EUH208 required due to the presence of C(M)IT/MIT.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract
Justification for the value/conclusion	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitisation.
Classification of the product according to CLP	

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route.
Justification for the selected value	The classification has been determined using the calculation method. None of the co-formulants/ingredients classified for acute oral toxicity is present at a relevant concentration to be taken into account in the calculation.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via inhalation route.
Justification for the selected value	The classification has been determined using the calculation method. None of the co-formulants/ingredients classified for acute inhalation toxicity is present at a relevant concentration to be taken into account in the calculation.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by dermal route
Justification for the selected value	The classification has been determined using the calculation method. None of the co-formulants/ingredients classified for acute dermal toxicity is present at a relevant concentration to be taken into account in the calculation.
Classification of the product according to CLP	Not classified

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption
Justification	Only local effect are considered for pelargonic acid. Dermal absorption value is not required.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, SPEED EASY CLEAN does not contain any substance of concern for human health.

Available toxicological data relating to a mixture

None

Other
None

2.2.6.2 Exposure assessment

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a	n.a	yes	n.a	n.a	No	No
Dermal	n.a	n.a	yes	n.a	n.a	yes	No
Oral	n.a	n.a	no	n.a	n.a	No	No

Summary table: exposure scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing and loading	**Primary exposure – Dermal and inhalation exposure** Before application, the product may be loaded into a sprayer.	Non professionals
2.	Application by trigger spray	**Primary exposure – dermal and inhalation exposure** The product is applied by spray application using a trigger spray.	Non professionals
3.	Post application	**Secondary exposure – toddlers crawling on treated areas**	General public

Reference values to be used in risk characterisation

In the CAR on the active substance nonanoic acid, no systemic effect has been observed and no systemic toxicological reference value has been derived. No local AECs have been set. Only a qualitative risk assessment (RA) has been performed.

Industrial exposure

Not applicable.
The product is intended to be used by non-professional users only.

Professional exposure

Not applicable.
The product is intended to be used by non-professional users only.

Non-professional exposure

Scenario [1] – Mixing and loading task

During the loading phase occuring during the refill of the sprayer, non-professional users can be in contact with the product that is not classified for human health. As there is no identified hazard for human health, no risk is expected and exposure assessment is not required.

Scenario [2] – Application by trigger spray

During the application of the product, non-professional users are in contact with the product that is not classified for human health. As there is no identified hazard during the handling of the product, no risk is expected and exposure assessment is not required.

Exposure of the general public

Scenario [3]: **Post application task: dermal contact with wet treated surfaces**

Secondary exposure of the general public occurs with the non-classified product after the application (dermal contact with the freshly treated surfaces).
Considering that no hazard is identified with the product, no risk is expected for the general public.

Monitoring data

Not submitted.

Dietary exposure

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

Residue definitions
Not relevant.

List of scenarios
Not relevant.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Fatty acids (C_7 to C_{20}): Herbicides, acaricides, insecticides, plant growth regulators on onamentals and lawns	No MRL required (annex IV of Regulation EU 396/2005)
2.	Food additives	Fatty acids (E570): food additives	No limit required (Substances included in Annex IV without prejudice to Regulation (EC) No 1333/2008 on food additives)

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

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

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

Exposure associated with production, formulation and disposal of the biocidal product

Summary of exposure assessment

In the CAR on the active substance, no systemic effect have been observed and no systemic reference toxicological value has been derived. Only a qualitative RA has been performed.

Risk characterisation for human health

Reference values to be used in Risk Characterisation

No systemic reference values are available for nonanoic acid.
Only local effects have been considered in the CAR on the active substance.

Risk for industrial users

Not applicable

Risk for professional users

Not applicable

Risk for non-professional users

Local effects

The product SPEED EASY CLEAN being not classified for human health, no hazard has been identified.
Therefore, no risk assessment is required.

Conclusion

The risk is considered acceptable for non-professional users.

Risk for the general public

Local effects

Exposure of the general pubic occurs after application of the product.
No classification being required for the product, no risk assessment is necessary.

Conclusion

An acceptable risk is assumed for general public.

Maximum residue limits or equivalent

Not relevant.

Risk for consumers via residues in food

Not relevant. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

2.2.7 Risk assessment for animal health

Considering the type of application of the product, it is assumed that animals might walk over the surface freshly treated with the product.
As the risk of secondary exposure of general public to the dilution is deemed acceptable, no adverse effects are expected for animals.

2.2.8 Risk assessment for the environment

The product SPEED EASY CLEAN is a PT2 Ready to use product containing nonanoic acid (CAS No.112-05-0, 4.46% w/w technical value) used by non-professionals for the control of algae and lichens. The product is applied by spray (50 mL/m²) outdoor on hard surfaces such as wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc. For several target species, a second application is necessary two weeks after the first one. A maximum of two applications per year is intended by the applicant.

Substance of Concern:
The coformulant CMIT-MIT (CAS No 55965-84-9, 0.00125% w/w technical value) is identified as a Substance of Concern for the surface water compartment (direct emissions only, see Confidential Annex).

Therefore, the risk assessment takes into account both nonanoic acid and CMIT-MIT for every scenarios with direct emissions to the surface water. For the rest of the scenarios, the risk assessment is carried out for the active substance only.

2.2.8.1 Effects assessment on the environment

No new environmental studies have been carried out with the product SPEED EASY CLEAN. All data pertaining to the active substance are therefore derived from the revised CAR of nonanoic acid (2013).

	$PNEC_{STP}$	**$PNEC_{water}$**	**$PNEC_{sediment\ EPM}$**	**$PNEC_{soil,\ INITIAL}$**	**$PNEC_{oral,\ birds}$**	**$PNEC_{oral,\ mammals}$**
	[mg/L]	[mg/L]	[mg/kg_{ww}]	[mg/kg_{ww}]	[mg/kg]	[mg/kg]
Nonanoic acid	5.65E+00	5.68E-02	1.22E-01	9.90E-02	3.31E-01	5.00E+00
CMIT-MIT*	n.r	4.90E-05	n.r	n.r	n.r	n.r

n.r: not relevant as risk assessment for these compartments is covered by the risk assessment of nonanoic acid
*See section "Substance of concern" above

Atmosphere:
According to the information from the CAR (2013), nonanoic acid presents a Henry's law constant of 3.33E-01 Pa m^3/mol and exhibits only a slight fugacity from water to air. Once in the air, the active substance is not expected to display adverse biotic effects on the atmospheric environment and is eliminated by a quick photodegradation ($DT50_{air}$ of 13.15 to 39.44 hours).
Therefore, the atmosphere is not a compartment of concern, no PNEC value is available and no risk assessment is conducted.

Sediments:
No ecotoxicological data was generated for sediment dwelling organisms and the PNEC value for this compartment was derived through equilibrium partitioning. Therefore, the risk assessment for the surface water covers the risk for the sediment and no PEC value is presented for this compartment.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

According to the latest harmonized classification, nonanoic acid is classified H412, harmful to aquatic life with long lasting effects and CMIT-MIT is classified H400/H410 with acute and chronic M factors of 100.

By calculation, the product SPEED EASY CLEAN (4.46%, technical content of nonanoic acid and 0.00125% of CMIT-MIT) is therefore not classified for the environment according to Regulation (EC) No.1272/2008 (CLP).

Further Ecotoxicological studies

No new ecotoxicological studies have been carried out with the product. The assessment is based on the available ecotoxicological data on nonanoic acid and CMIT-MIT.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	-
Justification	No data is available, the assessment is based on the available ecotoxicological data on nonanoic acid and CMIT-MIT.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	-

Justification	This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product used as a spray. Therefore, no additional study is deemed necessary to address this point.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	-
Justification	This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product used as a spray. Therefore, no additional study is deemed necessary to address this point.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Data waiving	
Information requirement	-
Justification	The product is used on hard surfaces in garden, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the product and it can be concluded that no secondary ecological effect is expected when using the product according to the label recommendations.

Foreseeable routes of entry into the environment on the basis of the use envisaged

See section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	-
Justification	No data is available, the assessment is based on the available ecotoxicological data on nonanoic acid and CMIT-MIT.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	-
Justification	No data is available, the assessment for soil is based on the available ecotoxicological data on nonanoic acid.

Testing for distribution and dissipation in water and sediment (ADS)

Data waiving	
Information requirement	-
Justification	No data is available, the assessment is based on the available ecotoxicological data on nonanoic acid and CMIT-MIT.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	-
Justification	No data is available, the assessment is based on the available ecotoxicological data on nonanoic acid and CMIT-MIT.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Data waiving	
Information requirement	-
Justification	Not necessary as the product is sprayed outside on hard surfaces such as wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc and direct emissions of the product to surface water (incl. sediment) are unlikely. In a conservative approach, a scenario considering worst-case emission inputs and aquatic toxicity data of the the a.s. and SoC has been conducted in the risk assessment (Bridge over the pond scenario)

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Data waiving	
Information requirement	-
Justification	Not necessary as the product is sprayed outside on hard surfaces such as wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc that are not preferably visited by bees or are a standard habitat of non-target arthropods. The toxicity data on bees and non-target arthropods give sufficient information and direct large scale emission of bees and non-target arthropods to the products are unlikely.

2.2.8.2 Exposure assessment

The product SPEED EASY CLEAN is a PT2 Ready to use product containing nonanoic acid (CAS No.112-05-0, 4.46% w/w technical value) used by non-professionals for the control of algae and lichens. The product is applied by spray (50 mL/m²) outdoor on hard surfaces such as wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc. An application on roof is not intended. For several target species, a second application is necessary two weeks after the first one. A maximum of two applications per year is intended by the applicant.

General information

Assessed PT	PT 2
Assessed scenarios	**Disinfection of house outdoor surfaces** Scenario 1: City scenario – *Via* the STP (mixed sewer system) Scenario 2: City scenario – *Via* rainwater (separate sewer system) Scenario 3: Countryside scenario – House Scenario 4: Countryside scenario – Bridge over the pond
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC Scientific and Technical reports, 2011 Emission for Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives, OECD 2013. Emission scenario document for biocides used as masonry preservatives, PT 10, EUBEES, 2002 Assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10), UBA, 2014
Approach	Scenarios 1/2/3/4: Average consumption
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017) Assessment report: Nonanoic acid, Product-type 2 (2013) Assessment report: CMIT-MIT, Product-type 6 (2015)

	Technical Agreements for Biocides, July 2021
Groundwater simulation	Yes (FOCUS PEARL v.4.4.4)
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1/2/3/4: Production: No Formulation No Use: Yes (Application) Service life: Yes (Weathering)
Remarks	-

2.2.8.2.1 Emission estimation

There is no existing Emission Scenario Documents (ESD) for PT2 covering use on outdoor surfaces; therefore, the assessment of environmental emissions for the product has been conducted using several guidance documents. The assessment is based on models simulating spray application on hard surfaces likely to be treated by non-professionals from ESDPT10 (2002) and ESDPT8 (2013).

Disinfection of outdoor surfaces: General information

Emission steps:

The environment may be exposed during the **Application** of the product (*via* runoff or spray drift) and during **Service life** (*via* potential rain events).

Locations:

According to the ESD PT10 (2002) and ESD PT8 (2013), several relevant locations can be differentiated:
- In the city (urban area), the product is likely to enter paved ground during application or weathering phase to the sewer system subsequently reaching the sewage treatment plant (**scenario 1 – City, *via* the STP**) or directly the surface water *via* direct rainwater discharge (**scenario 2 – City, *via* rainwater**). The bypass scenario is not used considering that application of the product will not occur during or shortly before a storm event.
- In the countryside (rural area), the product directly reaches the soil (**scenario 3 – Countryside, House**) or surface water (**scenario 4 – Countryside, Bridge Over the pond**) after the application and the rain event.

2.2.8.2.1.1 Scenario 1 - City scenario, *via* the STP (mixed sewer system), House/Terrace

Treated area, AREA:

The claimed use is quite large on vertical and horizontal hard surfaces (multiple types i.e. wood, plastic, fabric (as in patio furniture), bricks, paving, cement, concrete etc.) but the product is not intended to be applied on roof. Therefore, the area to take into account to cover the use are walls of a house (vertical surface, **125 m²**) and terrace (horizontal surface, **30 m²**).

Emission pathway:

The emissions of a treatment of horizontal surfaces like terrace and pathway are added up to the emissions of the treatment of vertical surfaces as they can be treated the same day, ending up in the municipal STP.

Number of houses treated daily, N_{house}:

Simultaneity factor is calculated based on consumer's behaviour, i.e with one to two applications per year.

Max. Fsim = 2/365 = 0.00547 use/house/year

Environmental modelling considers a default city of 4000 houses, including 2500 houses possessing a garden (TAB 07/2021, ENV140).
Therefore:
- 4000 x 0.00547 = ~**22** houses can simultaneously be treated in a day,
- 2500 x 0.00547 = ~**14** terraces can simultaneously be treated in a day.

Large buildings are not considered as the product is restricted to non-professionals.

Fraction released to water, F_{water}:

As a worst case, it is considered that releases from application and service life (weathering) from house and terrace treatment arise the same day with 100% emissions at the day of application and a fraction of release to waste water (F_{water}) of 1.

The following input parameters are used to calculate the local emissions to the STP.

Substances considered:
As emission from scenario 2 (with direct emission to surface water) are based on Elocal value from scenario 1, CMIT-MIT calculations are included in scenario 1 either.

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
	Nonanoic acid	**CMIT-MIT**		
Quantity of product applied [Q_{bp}]	5.00E-02		L/m²	S – 50 mL/m²
Fraction of active substance in the product [Fai]	4.46E-02	1.25E-05	-	S
Density of product [$RHO_{product}$]	999.7		kg/m^3	S
Treated surface [AREA]: - House - Terrace	 125 30		m²	House: Default value (ESD PT10, 2013) Terrace: TAB (07/2021, ENV 154)

Number of daily disinfection [N_{house}]: - Houses - Terrace	22 14		/d	Calculated, see explanation above
Fraction released to water [F_{water}]	1		-	Worst-case value, see explanation above
Market factor [F_{penetr}]: -households uses	0.5		-	TAB (07/2021, ENV 25)
House: Local emission to STP from walls treatment [$Elocal_{water\ house}$]	**3.07E+00**	**8.59E-04**	kg/d	O – AREA x Q_{bp} x Fai x N_{house} x $RHO_{product}$ x 0.001 x F_{water}
Terrace: Local emission to STP from terrace treatment [$Elocal_{water\ terrace}$]	**4.68E-01**	**1.31E-04**	kg/d	
Total (House + Terrace) - Local emission to STP [$Elocal_{water}$]	**3.53E+00**	**9.90E-04**	kg/d	O – **$Elocal_{water\ house}$** + **$Elocal_{water\ terrace}$**

2.2.8.2.1.2 Scenario 2 - City scenario, *via* rainwater (separate sewer system), House/Terrace

Some cities have a separate sewer system, in which the wastewater and rainwater are collected in distinct canalisations. Wastewater is directed to a STP, while rainwater is emitted directly to surface water.

In such cities, the products that are used outside of houses will be collected by the rainwater sewer system, resulting in their direct emission to surface waters. For an outdoor surfaces treatment, the assessment of the risk to the surface water compartment in case of a separate sewer system is thus relevant.

The emitted quantity will be identical to that calculated for scenario 1 above, but it will be directed to the surface water compartment rather than to the STP.

	Nonanoic acid	**CMIT-MIT**		
Total (House + Terrace) - Local emission to surface water [$Elocal_{water}$]	**3.53E+00**	**9.90E-04**	kg/d	See scenario 1 calculations

2.2.8.2.1.3 Scenario 3 – Countryside scenario, House/Terrace

AREAtreated:

As a worst case, it is considered that vertical and horizontal surfaces are treated on the same day. The "façade" scenario (ESDTP10, 2002) is used to cover the treatment of vertical surfaces of a house and the terrace scenario (area from the TAB of July 2021, ENV 154) is used to cover the treatment of horizontal surfaces. The terrace is adjacent to the small side of the house (7.5 m x 4 m, see Figure 1). The product is not intended to be applied on roof.

AREAhouse = **125 m²**,
AREA of 1 wall of the house adjacent to the terrace: 7.5 x 2.5 = **18.75 m²**,
AREAterrace = **30 m²**.

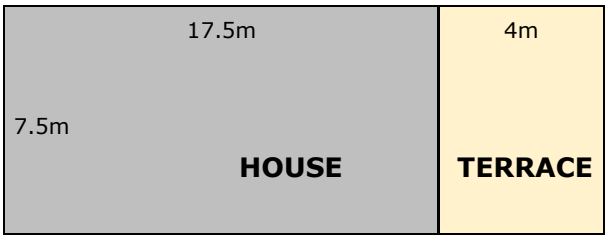

Figure 1: Sizing of the house/terrace

Volume of soil of the receiving area:

In the ESD for PT10 (2002), two areas of soil are delimited:
- The soil area which receives the emission due to runoff: the **adjacent soil**,
- The soil area which receives the emission due to spray drift: the **distant soil**.

The volumes associated to the adjacent and the distant soils are dependant of the treated surfaces, therefore, they are calculated below. To ease the reading of the assessment, only worst-case locations are considered.

- Volume of adjacent soil in worst-case location $V_{soil,adjacent\ (1wall+terrace)}$:

Considering that the adjacent soil has a distance to the treated area of 0.5 m, the worst-case concentrations in soil are located around the terrace as at this location, the soil receives the product used to treat one wall and the terrace (this receiving area of soil is represented by the brown area of the Figure 2).

The volume adjacent to the wall and the terrace, based on a soil depth of 0.5 m, is $V_{soil,adjacent\ (1wall+terrace)}$ = ((4.5 x 8.5)–(4 x 7.5)) x 0.5 = **4.125 m³** (receiving adjacent soil for treated area of 18.75 m^2 + 30 m^2 = **48.75 m²**).

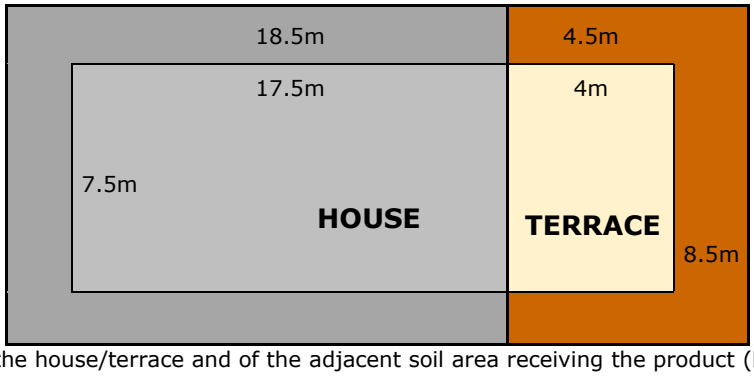

Figure 2: Sizing of the house/terrace and of the adjacent soil area receiving the product (brown = worst-case location)

- Volume of distant soil in worst-case location $V_{soil,distant\ (4\ walls)}$:

The distance travelled by spray drift is dependent of the wind and the height of the treated area. For terrace, no value is available and as it is a large horizontal surface, the emission due to the drift is considered negligible and the distant soil is not exposed.

Thus, the distant soil is only relevant for the treatment of vertical surfaces (walls).

Therefore, the worst-case location for the distant soil is the one exposed to the emissions from the walls of a whole house. It is calculated as the volume of the soil band between 1 m and 1.5 m distance from the wall and 50 cm depth around the house (considering a wind speed of 1.5 m/s, height of release 2.5 m, and a droplet settling velocity of 2.46 m/s, in accordance to ESD PT 8, paragraph 403, p.112).

The volume distant to the 4 walls of an entire house, based on a soil depth of 0.5 m, is $V_{soil,distant\ (4walls)}$ = ((20.5 x 9.5)–(19.5 x 8.5)) x 0.5 = **15 m³** (receiving distant soil for treated wall areas of **125 m²**).

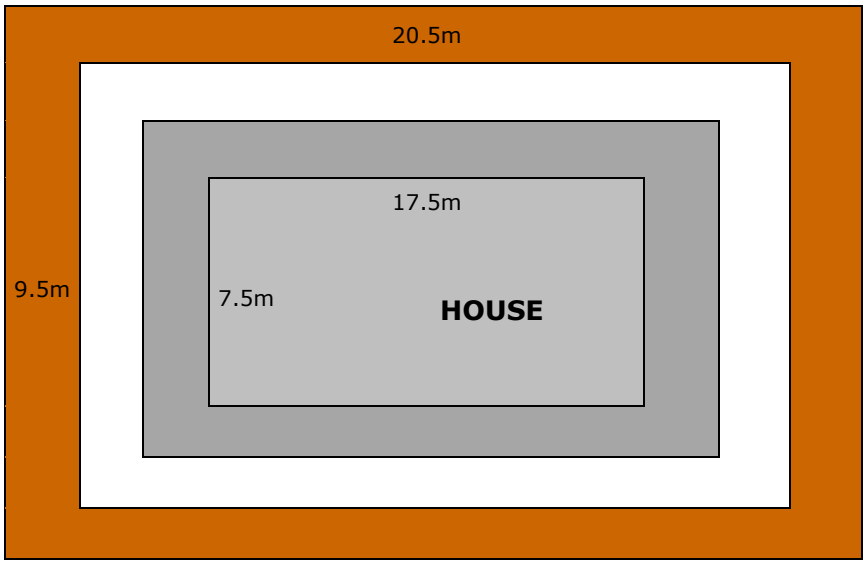

Figure 3: Sizing of the house and of the distant soil area receiving the product (brown = worst-case location)

Frunoff+drift$_{appli}$ and Fdrift$_{appli}$:

For the application phase:
- In Tier I, the fraction of product lost *via* runoff to the adjacent soil is added to the fraction lost *via* drift. Therefore, the Frunoff+drift$_{appli}$ = 0.2 + 0.1 = **0.3**.
- In Tier II, an impermeable sheet such as a tarpolin is used to cover the adjacent soil during application. In this situation, only the distant soil is relevant and a fraction of deposition of 0.33 (Fdep) is added to the Fdrift of 0.1.

Frunoff$_{rinse/weathering}$:

As there is no rinsing intended for this product, the fractions released during the service-life cover the weathering. As a worst case, it is considered that the remaining fractions after application (70%) is released to the adjacent soil. Thus, a Frunoff$_{rinse/weathering}$ value of **0.7** is considered for the assessment.

Consideration of a 2nd treatment:

For some species, a second treatment is needed two weeks after the first one. No Elocal values are calculated for the second application, the calculations are directly gathered in the section "Calculated PEC values".

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
General			
Quantity of product applied [Q_{bp}]	5.00E-02	L/m²	S
Fraction of active substance in the product [Fai]	4.46E-02	-	S
Density of product [$RHO_{product}$]	999.7	kg/m^3	S
Treated surface [AREA]: - 1 wall + Terrace - 4 walls	 48.75 125	m²	Calculated, (see explanation above) TAB (July 2021, ENV 154)
Volume of soil receiving emission due to run-off – adjacent soil of 1 wall + terrace [$V_{soil\ adjacent,\ 1wall+terrace}$]	4.125	m^3	Calculated (see explanation above)
Volume of soil receiving emission due to drift – distant soil of 4 walls [$V_{soil,\ distant,\ 4\ walls}$]	15	m^3	Calculated (see explanation above)
Bulk density of wet soil [RHOsoil]	1700	kg_{ww}/m^3	D
Application – Adjacent soil (Tier 1) – 1 wall + terrace			
Fraction of product lost during application due to runoff and drift [$Frunoff+drift_{appli}$]	0.3	-	D
Local emission to adjacent soil from the application on 1 wall + terrace, T=0 d [$Elocalsoil_{adjacent,1wall+terrace,appli}$]	**3.26E-02**	kg/d	O – AREA x Q_{bp} x Fai x $RHO_{product}$ x 0.001 x $Frunoff+drift_{appli}$
Application – Distant soil (Tier 2) – 4 walls only			
Fraction of product lost during application due to drift [$Fdrift_{appli}$]	0.1	-	D (ESDPT10, 2002)
Fraction of spray drift depositing to a 0.5 m wide soil band 1-1.5m distant from the house [Fdep]	0.33	-	D (ESDPT10, 2002)
Local emission to distant soil from the application on 4 walls, T=0 d [$Elocalsoil_{distant,4\ walls,appli}$]	**9.20E-03**	kg/d	O – AREA x Q_{bp} x Fai x $RHO_{product}$ x 0.001 x $Fdrift_{appli}$ x Fdep
Service life (weathering) – Adjacent soil – 1 wall + terrace			
Fraction of product lost during weathering [$Frunoff_{weathering}$]	0.7	-	D (ESDPT10, 2002)
Local emission to adjacent soil from the weathering of 1 wall + terrace due to runoff, T=0 d [$Elocalsoil_{adjacent,1wall+terrace,weathering}$]	**7.61E-02**	kg/d	O - AREA x Q_{bp} x Fai x $RHO_{product}$ x 0.001 x Frinse x $Frunoff_{weathering}$

2.2.8.2.1.4 Scenario 4 - Countryside scenario, Bridge over the pond

Characteristics of the bridge are from ESD PT8 and models and parameters governing spray application (losses of product, etc.) are from ESD PT10.

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
	Nonanoic acid	**CMIT-MIT**		
Quantity of product applied [Q_{bp}]	5.00E-02		L/m²	S
Fraction of active substance in the product [Fai]	4.46-02	1.25E-05	-	S
Density of product [$RHO_{product}$]	999.7		kg/m³	S
Treated surface [AREA]	10		m²	Default value (ESD PT8, 2013)
Water volume under a bridge [V_{water}]	1000		m³	Default value (ESD PT8, 2013)
TOTAL				
Total – Local emission to surface water [$Elocalwater_{TOTAL}$]	**2.23E-02**	**6.25E-06**	**kg/d**	O - Application + Weathering

2.2.8.2.2 Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway						
	Surface water	Sediment	STP	Air	Soil	Groundwater
Scenario 1 – City, *via* the STP, House/terrace	+	+ (covered by surface water assessment)	++	-	+	+
Scenario 2 – City, *via* rainwater, House/terrace	++	+ (covered by surface water assessment)	-	-	-	-
Scenario 3 – Countryside, House/terrace	-	-	-	-	++	+
Scenario 4 – Countryside, Bridge Over the pond	++	+ (covered by surface water assessment)	-	-	-	-

++: direct exposure *+: indirect exposure* *-: not exposed*

Input parameters for calculating the fate and distribution of the active substance in the environment are selected from the Revised AR of **nonanoic acid** (2013) and are gathered in the table below.

The input associated to the Substance of concern **CMIT-MIT** are not presented as this substance is a concern for scenario with direct emissions to the surface water only and that none of the parameters set in the table below are needed to calculate the PEC_{SW}.

Input parameters (only set values) for calculating the fate and distribution of nonanoic acid in the environment		
Input	**Value**	**Unit**
Molecular weight	158.2	g/mol
Vapour pressure	0.9 (20°C)	Pa
Water solubility	445 (25°C and pH5)	mg/l
Log Octanol/water partition coefficient	3.52	Log 10
Organic carbon/water partition coefficient (Koc)	63.1	L/kg
Biodegradability	Readily biodegradable, fulfilling the 10d window	-
DT_{50} for degradation in soil (at 12ºC)	2.10	d
BCF_{fish}	195.88	L/kg_{wwt}
$BCF_{earthworm}$	40.57	L/kg_{wwt}
Kbiosoil	3.30E-01	-
Kvolat (arable land as a worst case)	5.82E-03	-
Kleach (arable land as a worst case)	1.15E-03	-
Ktotal (arable land as a worst case)	3.37E-01	-

In the STP, the fractioning of the active substance between air, water, sludge and degradation has been calculated with Simple Treat 4.0 and is indicated in the following table.

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Nonanoic acid	
Air	0.0959	Simple Treat v4.0, considering a concentration suspended solids effluents (Css) of 30 mg/L or 0.03 kg/m^3 (TAB 07/2021, ENV 9)
Water	7.96	
Sludge	0.59	
Degraded in STP	91.36	

2.2.8.2.3 Calculated PEC values

For the calculations of PECs, all inputs (volume of receiving compartments etc…) are included in the emission table of the corresponding scenario, considering the following:

Scenario 1 – City scenario, *via* the STP, House/Terrace

For indirect emissions to environmental compartments (*via* the STP), there is no further specific guidance in the ESDTP8 or 10 for calculation of PEC values and hence the standard assumptions in the Volume IV Part B+C (2017) were used to develop concentrations in STP, surface water, soil and groundwater, considering that:

The PEC_{soil} initial is calculated to take into account the fact that the PNEC value corresponds to an initial concentration in soil.

Scenario 2 – City scenario, *via* rainwater, House/Terrace

The PEC_{water} is calculated based on the document "Assessment of direct emission to surface water in urban areas" (UBA, 2014).

Scenario 3 – Countryside scenario, House/Terrace

At first, the PECs soil were calculated without considering removal through degradation processes. As a refinement and according to the CAR of the active substance (July 2013), a scenario taking into account degradation processes has been carried out to estimate the number of days (t) it will take to reach an acceptable risk for soil. As for scenario 1, this PEC_{soil} is the initial concentration after t days to take into account the fact that the PNEC value corresponds to an initial concentration in soil.

First application:
The following equation is considered to calculate the refined PEC_{soil} (14 days after the beginning of the treatment, the number of days needed to reach acceptable risks):

$PEC_{soil,\ 1st\ appli}$ (14 days, refined) = (Elocalsoil / (RHOsoil x V_{soil})) x $e^{(-kt)}$ with:

k = ktotal = 3.37E-01
t= 14 days
Elocalsoil and V_{soil} are presented and discussed in the emission section.

As for several target species, a second application is necessary two weeks after the first one, the calculations of a PEC at 28 days after the beginning of the first treatment is also presented.

Second application:
$PEC_{soil,\ 2nd\ appli}$ (28 days, refined) = [(Elocalsoil / (RHOsoil x V_{soil})) + $PEC_{soil,\ 1st\ appli}$ (14 days)] x $e^{(-kt)}$ with:

k = ktotal = 3.37E-01
t = 14 days of degradation for the substance emitted during the second application

A summary of the calculated PEC values for each scenario and environmental compartment is indicated in the following table. For simplification, most of the PECs consider application + weathering steps. For the refined PECs, application and weathering were separated.

Summary table on calculated PEC values					
Emission steps	**Receiving compartments**	**PEC_{STP}**	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/L]	[mg/L]	[mg/kg_{ww}]	[µg/L]
Scenario 1 – City, *via* the STP, House/terrace					
Application + Weathering, t=0 d	STP	1.41E-01	1.41E-02	3.88E-02	**0.52***
Scenario 2 – City, *via* rainwater, House/terrace					

Application + Weathering, t=0 d		Surface water	n.r	Nonanoic acid: 5.89E-01 CMIT-MIT: 1.65E-04	n.r	n.r
Scenario 3 – Countryside, House/terrace						
1st Treatment t=0 d	Application + Weathering	Adjacent soil	n.r	n.r	1.55E+01	**12590**
		Distant soil	n.r	n.r	3.61E-01	**293.0**
1st Treatment **Refinement** t=14 d	Application	Adjacent soil	n.r	n.r	4.15E-02	**33.7**
		Distant soil	n.r	n.r	3.22E-03	**2.6**
	Weathering	Adjacent soil	n.r	n.r	9.69E-02	**78.7**
		Distant soil	n.r	n.r	n.r	n.r
2nd Treatment t=14 d (after the first treatment)	Application + Weathering	Adjacent soil	n.r	n.r	1.56E+01	**12702**
		Distant soil	n.r	n.r	3.64E-01	**295.6**
2nd Treatment **Refinement** t=28 d (after the first treatment)	Application	Adjacent soil	n.r	n.r	4.19E-02	**34.0**
		Distant soil	n.r	n.r	3.25E-03	**2.6**
	Weathering	Adjacent soil	n.r	n.r	9.77E-02	**79.4**
		Distant soil	n.r	n.r	n.r	n.r
Scenario 4 – Countryside, Bridge Over the pond						
Application + Weathering, t= 0		Surface water	n.r	Nonanoic acid: 2.23E-02 CMIT-MIT: 6.25E-06	n.r	n.r

n.r: not relevant
t = number of days after the first application when a second application is necessary
*PEC_{GW} calculated with the time weighted concentrations in soil after 180 days.

PEC_{GW}:
For all scenarios that leads to emissions to groundwater (scenarios 1 and 3), the resulting groundwater concentrations are higher than the threshold value of 0.1 µg/L. Thus, the FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment.

2.2.8.2.3.1 Groundwater

FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment for scenarios 1 and 3.

In scenario 1, groundwater is exposed indirectly by application of sewage sludge on grassland or agricultural land.

In scenario 3, groundwater is exposed after direct releases into soil. For soil risk assessment of this scenario, the emission due to the treatment of one wall and the terrace was

considered in the Emission estimation section, as it is a worst case situation for the calculations of the PEC_{soil}. For groundwater assessment, the emission due to the treatment of the entire house and the terrace is considered, as the totality of the product used can reach the groundwater compartment and inputs from the scenario 1 are used.
Thus, $Elocal_{soil}$ (4 walls+terrace): = $[Q_{bp}]$ x [Fai] x $[AREA_{4walls+terrace}]$ x $RHO_{product}$ x 0.001
= 5.00E-02 x 4.46E-02 x (125+30) x 999.7 x 0.001
= 3.46E-01 kg/one application/one house.

Emissions to Groundwater : Input for refinement (FOCUS PEARL 4.4.4)		
Input parameters related to Active Substance		
	Value	**Reference**
Molecular weight (g/mol)	158.2	Revised AR of Nonanoic acid
Water solubility (mg/l) at 25°C and pH5	445	
Koc (L/kg)	63.1	
Saturated vapour pressure (Pa) at 20°C	0.9	
DT50 in soil (d) at 12°C	2.1	
Kom (=Koc/1.724) (L/kg)	36.6	Calculated
1/n	1	TAB (07/2021, ENV 165)
Plant uptake factor	0	
Molar activation energy (kJ/mol)	65.4	
Input parameters related to Scenarios		
Scenario 1 (INDIRECT EXPOSURE)		
Crop	Agricultural land (maize)	Grassland (alfalfa)
Sewage sludge application rate (kg/ha)	5000 kg/ha	1000 kg/ha
Number of applications/interval (d)	1 sewage sludge application /yr	
Application date	Relative application: 20 days before crop event "emergence"	Absolute application: 1st of March
Incorporation depth (cm)	20	10
$Elocal_{STP}$ [kg/d]	3.53E+00	3.53E+00
Concentration of a.s. in dry sewage sludge, Csludge (mg/kg)	2.64E+01	2.64E+01
Application rate (kg Nonanoic acid/ha)	1.32E-01	2.64E-02
Scenario 3 (DIRECT EXPOSURE)		
Crop	Grassland (alfala)	
Application date	Absolute application: 1st day of each month	
Incorporation depth (cm)	Application to the soil surface	

Elocalsoil (kg/d/house, considering the treatment of 4 walls and a terrace, see explanations above)	3.46E-01
Number of house per hectare	16
Number of application	2 applications/yr
Number of house treated per month considering the number of application per year	16 x 2 / 12 = 2.67 houses treated/month
Elocalsoil (kg/ha/month) to use in FOCUS simulation	9.21E-01

The resulting groundwater concentrations are lower than the threshold value of 0.1 µg/L (See the tables below).

Emissions to Groundwater : PEC_{gw} in µg/L, (FOCUS PEARL 4.4.4)		
Output		
Scenario 1 (INDIRECT EXPOSURE)		
Crops	Agricultural land (maize)	Grassland (alfalfa)
CHATEAUDUN	0.000000	0.000000
HAMBURG	0.000000	0.000000
JOKIOINEN	n.c	0.000000
KREMSMUENSTER	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000
PIACENZA	0.000000	0.000000
PORTO	0.000000	0.000000
SEVILLA	0.000000	0.000000
THIVA	0.000000	0.000000
Scenario 3 (DIRECT EXPOSURE)		
Crops	Grassland (alfalfa)	
CHATEAUDUN	0.000005	
HAMBURG	0.000001	
JOKIOINEN	0.000002	
KREMSMUENSTER	0.000000	
OKEHAMPTON	0.000008	

PIACENZA	0.000063
PORTO	0.000009
SEVILLA	0.000006
THIVA	0.000000

n.c: not calculated

2.2.8.3 Risk characterisation

A summary of the calculated RCR and PEC_{GW} values for the relevant environmental compartments is presented in the following table.

Summary table on calculated RCR and PEC_{GW} values						
Emission steps		**Primary Receiving compartment**	**RCR_{STP}**	**RCR_{water}**	**RCR_{soil}**	**PEC_{GW*}**
			[-]	[-]	[-]	[µg/L]
Scenario 1 – City, *via* the STP, House/terrace						
Application + Weathering, t=0 d		STP	2.49E-02	2.48E-01	3.92E-01	<0.1
Scenario 2 – City, *via* rainwater, House/terrace						
Application + Weathering, t=0 d		Surface water	n.r	Nonanoic acid: **1.04E+01** CMIT-MIT: **3.37E+00**	n.r	n.r
Scenario 3 – Countryside, House/terrace						
1st Treatment t=0 d	Application + Weathering	Adjacent soil	n.r	n.r	**1.57E+02**	<0.1
		Distant soil	n.r	n.r	**3.64E+00**	<0.1
1st Treatment **Refinement** t=14 d	Application	Adjacent soil	n.r	n.r	4.19E-01	<0.1
		Distant soil	n.r	n.r	3.25E-02	<0.1
	Weathering	Adjacent soil	n.r	n.r	9.78E-01	<0.1
		Distant soil	n.r	n.r	n.r	n.r
	Application + Weathering	Adjacent soil	n.r	n.r	**1.40E+00**	<0.1
		Distant soil	n.r	n.r	3.25E-02	<0.1
2nd Treatment t=14 d (after the first treatment)	Application + Weathering	Adjacent soil	n.r	n.r	**1.58E+02**	<0.1
		Distant soil	n.r	n.r	**3.68E+00**	<0.1
2nd Treatment **Refinement** t=28 d (after the first treatment)	Application	Adjacent soil	n.r	n.r	4.23E-01	<0.1
		Distant soil	n.r	n.r	3.28E-02	<0.1
	Weathering	Adjacent soil	n.r	n.r	9.87E-01	<0.1
		Distant soil	n.r	n.r	n.r	n.r
	Application + Weathering	Adjacent soil	n.r	n.r	**1.41E+00**	<0.1
		Distant soil	n.r	n.r	3.28E-02	<0.1
Scenario 4 – Countryside, Bridge Over the pond						
Application + Weathering, t= 0		Surface water	n.r	Nonanoic acid: 3.92E-01 CMIT-MIT: 1.28E-01	n.r	n.r

n.c: not calculated

n.r: not relevant
t = number of days after the first application when a second application is necessary
*Concentration in groundwater according to FOCUS 4.4.4

Atmosphere

According to the information from the CAR (IIA, 2013), Nonanoic acid presents a Henry's law constant of 3.33E-01 Pa m^3/mol and exhibits only a slight fugacity from water to air. Once in the air, the a.s is not expected to display adverse biotic effects on the atmospheric environment and is eliminated by a quick photodegradation ($DT50_{air}$ of 13.15 to 39.44 hours).

Conclusion: the atmosphere is not a compartment of concern and no risk assessment is conducted.

Sewage treatment plant (STP)

Conclusion: A RCR < 1 is calculated for the STP compartment, therefore the use leads to acceptable risks for the STP microorganisms.

Aquatic compartment

Regarding indirect emissions to surface water *via* the STP (scenario 1) or direct emission to surface water (scenario 4), a risk ratio <1 is calculated and therefore, no unacceptable risk are foreseen for the aquatic compartment. For scenario 4, the addition of toxicity of CMIT-MIT to nonanoic acid does not modify the conclusions (see Mixture toxicity section).

Regarding the indirect emission to surface water *via* the separate sewer system, unacceptable risks are calculated for the environment. It is worth noting that the calculations does not consider that the active substance rapidly degrades in the environment. The direct discharge scenario is a Tier 1 approach (WGII2018) and in absence of available refinement, the results of the scenario should be considered with care as worst case values. It presumably overestimates releases of the active substance and the Soc to the sewer, because it is generally based on worst-case assumptions.
Pending agreement on the definition of a Tier 2 assessment, RMM preventing the emission of the product during application and service life are proposed in the conclusion for the terrestrial compartment and could also mitigate the risk for the aquatic compartment.

Concerning CMIT-MIT especially,

- When the product dries (and as long as no water is added on the surface), it is assumed that the CMIT-MIT is not mobile and degrades during the drying process on the wall. This process is also supported by the risk mitigation measure "Do not rinse treated surfaces with water after application".
- CMIT-MIT may degrade to a certain amount on the way to surface water, especially if rainwater is collected in retention basins.

Conclusion: The risk for aquatic organisms can be considered acceptable with the application of risk mitigation measures (see Conclusion for the terrestrial compartment below).

Terrestrial compartment

First application:

RCR ratios for the adjacent and the distant soil compartments are not acceptable on the day of application.

Similar results were calculated in the CAR of the active substance (July 2013) and therefore, refinements were proposed:

- A scenario taking into account degradation processes, with acceptable risks for the distant soil 16 days after the application.
- Risk mitigation measures which consider a protection of the adjacent soil during the application.

For the product SPEED EASY CLEAN, acceptable RCR ratios for the distant soil are reached earlier than for the product of the CAR (on day 14 after the application) and such RMM can also be proposed.

Second application:

Similarly, if a second treatment is necessary 14 days after the first treatment, acceptable RCR ratios for the distant soil are reached on day 14 after the second application (28 days after the beginning of the treatment).

➔ In order to reduce at a maximum emissions to the soil, the following risk mitigation measures and instructions of use are recommended:

- The area adjacent to the treated surface shall be protected by an impermeable cover (width of 1 m minimum) during application of the product.
- Do not apply the product in case rain is expected within 24 hrs.
- Do not rinse treated surfaces with water after application.
- Areas covered by plants, which may have been exposed unintentionally shall be watered extensively in order to avoid any damage to plants.
- Do not apply the product when there is wind, in order to avoid transfer to other areas by drift.

Additional arguments from the CAR (Assessment Report of Nonanoic acid, PT2, July 2013) are presented below:

"*The mode of action of the active substance is a physical effect on plant cell walls which affects cell wall integrity. Due to its lipophilic characteristics, the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. Because of this quick penetration, it is expected that after 6 hours only a fractional amount is disposable. Additionally, Nonanoic acid is readily biodegradable and has a* $DT50_{soil}$ *of 2.1 days at 12°C. Its potential for bioaccumulation is expected to be low based on the rapid metabolism within organisms via common pathways. Calculating the risk by assuming a rinsing application (representative of a rain event) immediately after application is an overestimation of the risk for several reasons and only possible if the proposed RMM above are ignored.*"

Nevertheless, we underline the importance to clearly distinguish Nonanoic acid from other products with algaecide properties with a much worse environmental profile: the temporary

exceedance of risk can only be accepted for this specific product with Nonanoic acid considering all RMMs.

Conclusions: In accordance with the conclusions of Nonanoic acid CAR and based on the PEC/PNEC calculations in combination with the properties of Nonanoic acid and the proposed risk mitigation measures, the risk for soil organisms through direct exposure to Nonanoic acid is considered acceptable.

Groundwater

Refined estimations of releases to groundwater (FOCUS 4.4.4, see section Groundwater) after one application are lower than the threshold value of 0.1 µg/L (< 1E-04 µg/L).

Conclusion: Thus, requirements for acceptable risk to groundwater according to the Guidance for BPR are met.

Primary and secondary poisoning

Primary poisoning

According to the ESD for PT18 (2008), primary poisoning mainly occurs with products applied as granular formulations or with food attractant. The product SPEED EASY CLEAN is a liquid applied by spraying, therefore, no primary poisoning is expected.

Bees:
The risk assessment for pollinators will be further detailed when the corresponding guidance will be available. In the meantime, data and arguments from the CAR of the active substance are considered sufficient to cover the use. The product assessed in the CAR contains a higher concentration of active substance (20%) than this product and is not toxic to bees. Therefore, a risk assessment for bees for this product is not relevant.

Secondary poisoning

The log K_{ow} of Nonanoic acid is 3.52, slightly higher than the threshold value of 3 indicates the substance may bioaccumulate (according to the guidance on the BPR: Volume IV – Part B).

However, it should be considered that:

- Nonanoic acid is rapidly biodegradable;

- Nonanoic acid is a fatty acid. Fatty acids are ubiquitous available in the environment and important naturally occurring biological molecules, found in all living organisms. They may be regarded as having fundamental roles (i.e. they are the building blocks of structurally important molecules in cellular membranes and also serve as sources of energy for biological systems). Thus in predators no negative effects would be expected in concentrations higher than the concentrations tested and used for risk assessment accordingly.

- Nonanoic acid is metabolized via ß-oxidation. This is quantitatively the most significant pathway for catabolism of fatty acids and results in the final products CO_2 and acetyl-CoA which as such are further metabolized to CO_2 and water.

The calculated BCF_{fish} for Nonanoic acid is 195.88 $L.kg^{-1}$ and the BCF in earthworms is 40.57 $l.kg^{-1}$. In addition to the facts and arguments given above, together with the knowledge on metabolism and biological properties of fatty acids, sufficient evidence is given of the non-bioaccumulating properties of Nonanoic acid.

Considering all arguments above, the risk for fish eating and worm eating predators is acceptable. The non-compartment specific effects of secondary poisoning are low for the aquatic and terrestrial food chain.

Mixture toxicity

CMIT-MIT is a substance of concern for scenarios with direct emissions to the surface water. Therefore, the additive RCR for nonanoic acid and CMIT-MIT are presented for scenario 2 and 4 below:

Scenarios / Substances	Separated RCR_{sw}	Summed RCR_{sw}
Scenario 2 – City, *via* rainwater, House/terrace		
Nonanoic acid	**1.04E+01**	**1.37E+01**
CMIT-MIT	**3.37E+00**	
Scenario 4 – Countryside, Bridge Over the pond		
Nonanoic acid	3.92E-01	5.20E-01
CMIT-MIT	1.28E-01	

In conclusion, the addition of CMIT-MIT toxicity to nonanoic acid leads to the same conclusions than for nonanoic acid alone.

Aggregated exposure (combined for relevant emission sources)

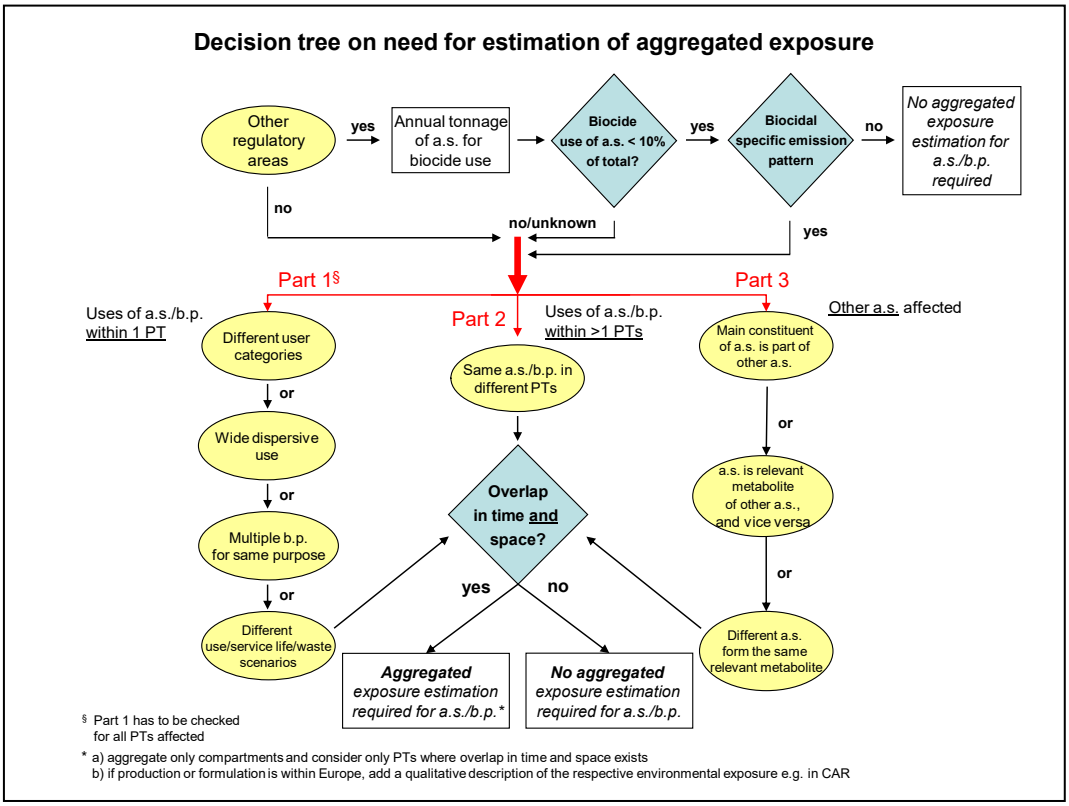

Figure 1: Decision tree on the need for estimation of aggregated exposure

Conclusion: Only one use is claimed for this product, therefore, an aggregated exposure assessment is not relevant.

Overall conclusion on the risk assessment for the environment of the product
The risk assessment has been conducted for the active substance and the substance of concern CMIT-MIT (for surface water in case of direct emissions only). Acceptable risks are reached for the environment for the claimed use, and considering the following risk mitigations measures and instructions of use: - The area adjacent to the treated surface shall be protected by an impermeable cover (width of 1 m minimum) during application of the product. - Do not apply the product in case rain is expected within 24 hrs. - Do not rinse treated surfaces with water after application. - Areas covered by plants, which may have been exposed unintentionally shall be watered extensively in order to avoid any damage to plants. - Do not apply the product when there is wind, in order to avoid transfer to other areas by drift.

2.2.9 Measures to protect man, animals and the environment

See the Summary of Products Characteristics.

2.2.10 Assessment of a combination of biocidal products

Not relevant

2.2.11 Comparative assessment

Not relevant

3. ANNEXES[3]

4.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	[redacted]	Physical/chemical properties and storage stability testing on pelargonic acid RTU formulation EW S19690 R586.009 in five product packaging types CEM Analytical Services Limited (CEMAS), UK, Report No.: CEMR-7887 interim GLP/Unpublished	Y	Evergreen
[redacted]	[redacted]	Physical/chemical properties and storage stability testing on pelargonic acid RTU formulation EW S19690 R586.009 in five product packaging types Report No.: CEMR-7887 GLP/Unpublished	Y	Evergreen
[redacted]	[redacted]	Physical testing of Pelargonic acid EC formulation S19321 and Pelargonic acid RTU formulation EW S19690 Report No.: CEMR-8948 GLP/Unpublished	Y	Evergreen
[redacted]	[redacted]	Validation of an analytical method for the determination of pelargonic acid content in RTU formulation S 19690 CEM Analytical Services Limited (CEMAS), UK, Report No.: CEMR-7886 GLP/Unpublished	Y	Evergreen
[redacted]	[redacted]	Report 5104180-06: Quantitative suspension test of fungicidal and yeasticidal activity based on DIN EN 1650 SGS INSTITUT FRESENIUS GmbH, im Maisel 14, D-65232 Taunusstein, Germany	Y	Evergreen

3 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

		Report no. 5104180-06. Unpublished.		
[redacted]	[redacted]	Report 5104180-08_V02: Quantitative non-porous surface test of fungicidal and levurocidal activity following DIN EN 13697 SGS INSTITUT FRESENIUS GmbH, im Maisel 14, D-65232 Taunusstein, Germany Report no. Report 5104180-08_V02. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Determination of the Toxicity of Products towards green Algae SGS INSTITUT FRESENIUS GmbH, im Maisel 14, D-65232 Taunusstein, Germany Report no. 5114758-01-V2. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Registration - Evaluation of biocides efficacy against algae on hard surface in Germany, EPPO Maritime, 2019 Hetterich Fieldwork GbR, Bamberger Str. 50, D-97359 Schwarzach a. Main, Germany Report no. 100080. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Efficacy evaluation of Pelargonic acid based products against algae on hard surfaces(Evergreen Trial Reference: GBOC1801X) (Study Code: 18/230) i2L Research Ltd, Capital Business Park Wentloog Cardiff, CF3 2PX UK Report no. 18/230. Unpublished	Y	Evergreen
[redacted]	[redacted]	Efficacy evaluation of Pelargonic acid based products against algae on hard surfaces (Evergreen Trial Reference: GBOC1801X) (Study Code: 18/231) i2L Research Ltd, Capital Business Park Wentloog Cardiff, CF3 2PX UK Report no. 18/231. Unpublished.	Y	Evergreen

[redacted]	[redacted]	Efficacy evaluation of Pelargonic acid based products against algae on hard surfaces (Evergreen Trial Reference: GBOC1801X) (Study Code: 18/232) i2L Research Ltd, Capital Business Park Wentloog Cardiff, CF3 2PX UK Report no. 18/232. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Hard Surface Cleaner – Efficacy Algae / Hard surface Evergreen Garden Care – Station de Morancé Report no. FROC1801R1. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Hard Surface cleaner – Efficacy on Algae Evergreen Garden Care – Station de Morancé Report no. FROC1803N1. Unpublished	Y	Evergreen
[redacted]	[redacted]	Hard surface cleaner - Algae or lichen on hard surface (GBOC1801/1) Evergreen Garden Care UK Ltd, 1 Archipelago, Lyon Way, Frimley, Surrey, GU16 7ER Report no. GBOC1801/1. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Pelargonic acid / algae / hard surface (Belgium – Trial season 2018-2019) Redebel S.A., Rue de Chassart 4, B-6221 Saint-Amand, Belgium Report no. R151-18H. Unpublished.	Y	Evergreen
[redacted]	[redacted]	Hard surface cleaner - Algae or lichen on hard surface (GBOC1901/1) Evergreen Garden Care UK Ltd, 1 Archipelago, Lyon Way, Frimley, Surrey, GU16 7ER Report no. GBOC1901/1. Unpublished.	Y	Evergreen
[redacted]	[redacted]	The efficacy of different biocides against algae on hard surface: Trial season 2019 - ANADIAG Trial ID: EU19260JV311 - ANADIAG Protocol ID: EU 19 260 - Location: France North	Y	Evergreen

		(Maritime EPPO zone) Anadiag France SAS, 174 Impasse du Plan d'Eau, 38300 Ruy-Montceau Report no. EU19260JV311. Unpublished.		

4.2 Output tables from exposure assessment tools

4.3 New information on the active substance

4.4 Residue behaviour

Not relevant. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

4.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

4.6 Confidential annex

See the confidential PAR

4 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.