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)

ENCLEAN PAE

Product type 2

Nonanoic acid

Case Number in R4BP: BC-RCO19989-24
NA-MIC Case Number in R4BP : BC-NG074811-38

Evaluating Competent Authority: FR

Date: October 2018
Updated: May 2020
Amended: October 2023

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Note to the reader:

This PAR for the first authorisation of ENCLEAN PAE, granted by France (FR) on 2018, have been updated after administrative change and mutual recognition in sequence.

In part 2.1 of the updated PAR the "proposal for decision" corresponds to the summary of product characteristics related to the updated decision.

- **Minor change application for ENCLEAN PAE – 2022:**

Change claimed in the frame of this minor change is modification of packagings, extent of shelf-life to 36 months, addition of active substance supplier and change of trade name.

History of the dossier

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	*FR*	BC-RC019989-24	15/10/2018	National authorisation
NA-TRS	*FR*	BC-HK050653-40	07/06/2019	Transfer of a national authorization (JADE to Belchim Crop Protection NV) and addition of trade names
NA-ADC	*FR*	BC-YX052849-80	07/10/2019	Addition of trade names
NA-ADC	*FR*	BC-GG056064-52	05/02/2020	Addition of trade names
NA-APP	*FR*	BC-RC019989-24	30/06/2020	Updated of national authorisation following mutual recognitions in sequence
NA-ADC	*FR*	BC-AL060548-36	22/07/2020	Addition of trade names
NA-MIC	*FR*	BC-NG074811-38	XX/10/2023	- Addition of new packaging, - shelf-life extended to 36 months, - addition of an active substance supplier - change of trade names

1 CONCLUSION

Conclusion for Physico-chemistry:

The product ENCLEAN PAE is Another Liquid (AL) formulation, ready-to-use. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogeneous yellowish liquid, with characteristic odour. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed in HDPE and PET packaging. Interim result after 1 year at ambient temperature in HDPE and PET packaging show that the product is stable. The shelf-life of the product is 24 months. Its technical characteristics are acceptable for an AL formulation.

The percentage of particles in mass with aerodynamic diameter <50 µm (before and after storage) must be established and provided in post-authorization.

The final long term storage study on the product ENCLEAN PAE is required in post-authorization.

The product ENCLEAN PAE is not explosive and has no oxidizing properties. The product is not considered as flammable.

- **Minor change application for ENCLEAN PAE – 2022 :**

The addition of new packaging has no impact on the conclusion of the APCP.
The new shelf-life is 36 months.

Conclusion for Efficacy:

In conclusion, in accordance with the submitted tests, the product ENCLEAN PAE is efficient against green algae (*Chlorophyta spp*.) by spraying on hard porous and non-porous surfaces for use outdoor by professional and non-professional users.

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

- **Minor change application for ENCLEAN PAE – 2022 :**

The minor changes have no impact on the conclusion of the efficacy assessment.

Conclusion for Human health:

No unacceptable risk is observed for professional and non-professional users.

For practical reasons, the larger packaging sizes (over 20L) will be restricted to professional users only.

- **Minor change application for ENCLEAN PAE – 2022 :**

The minor changes have no impact on the conclusion of the HH risk assessment.

Conclusion for Environment:

Considering the intended use of ENCLEAN PAE, the product shows unacceptable risks for terrestrial compartment via direct release.

Following risk mitigation measures shall be established in order to protect the environment:

- Products can only be used if the weather forecasts show no rain for the day of application.
- During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment.

Moreover, regarding the environmental profile of the a.s. (readily biodegradability, low potential of bioaccumulation, half-time life in soil and air...), the risk for environment can be considered acceptable.
This temporary exceedance of risk can only be accepted only for this product with nonanoic acid when considering all RMM.

- **Minor change application for ENCLEAN PAE – 2022 :**

The minor changes have no impact on the conclusion of the ENV risk assessment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
ENCLEAN PAE	FRANCE
GREENCLEAN PAE DECORUS PAE DALEP ECO ENVIRONET PAE GREEN GUARD GEBRUIKSKLAAR/PRET A L'EMPLOI GREENCLEAN GEBRUIKSKLAAR - PRET A L'EMPLOI *ANTI-DEPOTS VERTS PRÊT A L'EMPLOI* *ACTIF VEGETAL*	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	CERTIS BELCHIM BV
	Address	STADSPLATEAU 16 3521 AZ UTRECHT PAYS-BAS
Authorisation number	BC-NG074811-38	
Date of the authorisation	15/10/2018	
Expiry date of the authorisation	14/10/2028	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	IRIS
Address of manufacturer	1126 avenue du Moulinas, Route de saint privat- 30340 Salindres

[1] Please fill in here the identifying product name from R4BP.

	France
Location of manufacturing sites	1126 avenue du Moulinas, Route de saint privat- 30340 Salindres France

Name of manufacturer	DIACHEM
Address of manufacturer	Via Mozzanica, 9/11 24043 Caravaggio Italy
Location of manufacturing sites	Via Mozzanica, 9/11 24043 Caravaggio Italy

Name of manufacturer	CHEMINOVA
Address of manufacturer	Stader Elbstraße 28 21683 Stade Germany
Location of manufacturing sites	Stader Elbstraße 28 21683 Stade Germany

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

The owner of this source is Jade, which is now represented by Belchim Crop Protection NV/SA, following Art 95 list

Active substance	*Nonanoic acid (Pelargonic acid)*
Name of manufacturer	*Matrica **
Address of manufacturer	*Technologielaan 7 1840 Londerzeel* *Belgium*
Location of manufacturing sites	*Via Marco Polo 12* *07046 Porto Torres* *Sassari Italy*

** The owner of this source is Belchim Crop Protection NV/SA.*

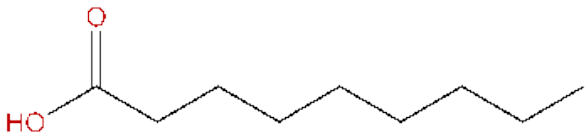
2.1.2 Product composition and formulation

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 (synonym: 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	
Minimum purity / content	962 g/kg
Structural formula	CH3(CH2)6CH2C OH O 

2.1.2.2 Candidate(s) for substitution

The active substance nonanoic acid contained in the biocidal products is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
Nonanoic acid	Nonanoic acid	Active substance (technical)	112-05-0	203-931-2	2.24

2.1.2.4 Information on technical equivalence

The decision on technical equivalence from ECHA published in January 2017 confirms that the alternative source of nonanoic acic manufactured by Nantong Shenyu Green Medicine CO is considered technically equivalent compared to the reference source from Jade.

- Minor change 2022 :

The decision on technical equivalence from ECHA published in January 2020 confirms that the alternative source of nonanoic acid manufactured by Belchim Crop Protection NV/SA is considered technically equivalent compared to the reference source (Case number BC-AE054992-47).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AL – Another liquid ready to use

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	None
Hazard statement	None
Labelling	
Signal words	None
Hazard statements	None
Precautionary statements	None
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Algaecide – Hard surfaces

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	Curative, algaecide effect on building materials, on all hard surfaces (porous and non-porous) in green spaces, on every roof type (except thatched roof).
Target organism (including development stage)	Green algae (*Chlorophyta spp.)*
Field of use	Outdoor
Application method(s)	Ready to use product. The product must be sprayed directly on the surfaces to be treated.
Application rate(s) and frequency	Application rate: 50 mL/m^2 For products sold in sprayers: about 37 pump strokes per m^2 The surface treated by packaging type is the following: F-HDPE bottles: - 1L is sufficient to treat 20 m^2, F-HDPE cans: - 3L is sufficient to treat 60 m^2, - 5L is sufficient to treat 100 m^2, - 10L is sufficient to treat 200 m^2, - 20L is sufficient to treat 400 m^2, F-HDPE barrels:

	- 200L is sufficient to treat 4000 m^2, - 640L is sufficient to treat 12800 m^2, F-HDPE tank: - 1000L is sufficient to treat 20000 m^2, Up to two applications per year
Category(ies) of users	Non-professional, Professional
Pack sizes and packaging material	Professional : F-HDPE/PET/HDPE sprayers: 500 mL, 750mL, 1L, 3L, 5L F-HDPE/PET/HDPE bottles: 1L Glass bottle: 0.2L F-HDPE/HDPE cans : 3L, 5L, 10L, 20L, 25L F-HDPE/HDPE barrels : 200L, 640L F-HDPE/HDPE tanks : 1000L Non-professional : F-HDPE PET/HDPE sprayers: 500 mL, 750mL, 1L, 2.5L, 3L, 5L F-HDPE/PET/HDPE bottles: 1L Glass bottle: 0.2L F-HDPE/HDPE cans : 3L, 5L, 10L, 20L

2.1.4.2 Use-specific instructions for use

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2.1.4.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.5 General directions for use

2.1.5.1 Instructions for use

- Avoid direct or indirect contact with food and feed. - Always read the label or leaflet before use and respect follow all the instructions provided. - Only apply this product with a handheld manually operated low pressure (3 bar or below) device preferably in combination with a spraying shield. - 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.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.1.5.2 Risk mitigation measures

- Products can only be used if the weather forecasts show no rain for the day of application.
- During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment.

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

- Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist.
- Keep the container or label available.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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

- Shelf life: 3 years.
- Keep in a dry, cool and ventilated area and in the original container.
- Protect from frost.
- Keep out of reach of children.

2.1.6 Other information

- Final results of long term storage study should be provided in post-authorization.
- The authorization holder has to report any observed incidents related to the efficacy to the Competent Authorities (CA).

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)

Glass bottle	0.2L	glass	Hermetically closed	Professional and non-professional users	Yes
Sprayer	0.5L, 0.75L, 1L, 3L, 5L	f-HDPE /PET /HDPE	Hermetically closed	Professional and non-professional users	Yes
Sprayer	2.5L	f-HDPE /PET /HDPE	Hermetically closed	non-professional users	Yes
Bottle	1L	f-HDPE/PET/HDPE	Hermetically closed	Professional and non-professional users	Yes
Can	3L, 5 L, 10L, 20L	f-HDPE/HDPE	Hermetically closed	Professional and non-professional users	Yes
Barrel	200L, 640L	f-HDPE/HDPE	Hermetically closed	Professional	Yes
Tank	1000L	f-HDPE/HDPE	Hermetically closed	Professional	Yes

For non-professional users, only packaging up to 20L are authorised.

Additional note from the industry on packaging in this minor change dossier:
*The spray device has **NOT** changed compared to the first authorization, we only changed the type of the packaging material, not the shape or size of the bottles.*

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Physico-chemistry:
Physico-chemical properties studies and analytical methods on the biocidal product ENCLEAN were provided by Jade.

Minor change – 2022
Several studies were submitted in the frame with this minor change application:

- Long term storage stability at 3 years for PET and HDPE packaging.
- Sprayability testing during shelf-life storage stability.
- MMDA study on fresh and 3 years old aged product.

For more detail, please refer to Annex 3. (3.1), list of studies. All the news studies are attached and summarized in the IUCLID file in section 3.

Efficacy:
The product ENCLEAN PAE has been tested in following efficacy studies:

- For Algae:
  - Three field studies conducted according to an in house method with the product ENCLEAN PAE (2.17% w/w nonanoic acid) on hard surfaces (cement pathway, plaster, glass)

Residue data:

No specific residue data were submitted in the context of this dossier. By definition, PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected. Considering the intended uses no data is required.

2.1.8.2 Access to documentation

Jade is one applicant of the active substance nonanoic acid and has access to data on this active substance.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – algaecide

Product Type	2
Where relevant, an exact description of the authorised use	Curative, algaecide effect on building materials, on all hard surfaces in green spaces, on every roof type (except thatched roof).
Target organism (including development stage)	algae
Field of use	Outdoor
Application method(s)	Spraying: - Spray by wetting the moss to destroy - Let the product act for a few hours
Application rate(s) and frequency	50.0 mL/m² - 100 – 2 per year
Category(ies) of users	General public, Professional
Pack sizes and packaging material	Professional : F-HDPE sprayers: 500 mL, 750mL, 1L, 3L, 5L F-HDPE/PET/HDPE bottles: 1L Glass bottle: 0.2L F-HDPE/HDPE cans : 3L, 5L, 10L, 20L F-HDPE/HDPE barrels : 200L, 640L F-HDPE/HDPE tanks : 1000L Non-professional : F-HDPE sprayers: 500 mL, 750mL, 1L, 2.5L, 3L, 5L F-HDPE/PET/HDPE bottles: 1L Glass bottle: 0.2L F-HDPE/HDPE cans : 3L, 5L, 10L, 20L

2.2.2 Physical, chemical and technical properties

The biocidal product is Another Liquid AL, ready-to-use.
Hydrocarbons and H304 co-formulant content : ≤10%
Packaging: f-HDPE sprayers, f-HDPE/HDPE, F-HDPE/PET/HDPE and glass

- **Minor change application for ENCLEAN PAE – 2022 :**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results			Reference	Comment
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302 / 830.6303 / 830.6304	502 g/l of nonanoic acid Batch 20111102	Homogeneous liquid			Fieseler A., 2014 Report number 82929204	Acceptable
Colour at 20 °C and 101.3 kPa			yellowish				
Odour at 20 °C and 101.3 kPa			Characteristic				
pH Acidity / alkalinity	MT 191 MT 75.3	Enclean PAE Batch 14090	pH (1% diluted) for ENCLEAN product: 3,8 at 20°C Acidity: 0.68 % w/w H_2SO_4			C. Bär, 2016, S16-01013	Acceptable
Relative density / bulk density	EU Method A.3	Enclean PAE Batch 14090	D^{20}: 1.0047			C. Bär, 2016, S16-01010	Acceptable
Storage stability test – **accelerated storage**	MT 46.3 GC-FID method (project QR98RC) validated	21.7 g/l of nonanoic acid Batch 20180315-CV003		**Initially**	**After 14 days at 54°C in 1L HDPE**	B. De Ryckel, 2018 Study N° 24716	Acceptable ENCLEAN PAE is sold with a sprayer device, therefore the percentage of particles in mass with aerodynamic diameter <50 µm must be established (see below).
			Appearance (test item and container)	Translucent homogeneous liquid free from visible suspended matter and sediment. Colour : pale yellow. Odour : chemical odour.	Translucent but more opaque homogeneous liquid free from visible suspended matter and sediment. Colour : milky yellow (more dark than before storage) Odour : chemical odour . Container: no leak during shaking or turning no observable sign of test item contamination on the outer surface. Inside aspect no visual alteration of package by the test item.		
			Content of a.s.	2.15 % w/w	2.12 % w/w		

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>pH (1%, 20°C)</td><td>4.88</td><td>4.75</td></tr>
</table>
<table>
<tr><td></td><td>Initially</td><td>After 14 days at 54°C in 1L PET</td></tr>
<tr><td>Appearance (test item and container)</td><td>Translucent homogeneous liquid free from visible suspended matter and sediment.
Colour : pale yellow.
Odour : chemical odour.</td><td>Translucent but more opaque homogeneous liquid free from visible suspended matter and sediment.
Colour : milky yellow (more dark than before storage)
Odour : chemical odour .
Container: no leak during shaking or turning
no observable sign of test item contamination on the outer surface.
Inside aspect
no visual alteration of package by the test item.</td></tr>
<tr><td>Content of a.s.</td><td>2.19 % w/w</td><td>2.19 % w/w</td></tr>
<tr><td>pH (1%, 20°C)</td><td>4.87</td><td>4.76</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Technical Monograph No. 17
MT 46.3

GC-FID method</td><td>21.7 g/l of nonanoic acid
Batch 20180315-CV003</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 1year in HDPE</td></tr>
<tr><td>Appearance</td><td colspan="2">Translucent but more opaque homogeneous liquid free from visible suspended matter and sediment.
Colour : milky yellow (more dark than before storage)
Odour : chemical odour .</td></tr>
</table>
</td><td>De Ryckel, 2018

Study N° 24716</td><td>Acceptable
Product is stable after 1 year in HDPE and PET packaging.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td>(project QR98RC) validated</td><td></td><td>
<table>
<tr><td></td><td colspan="2">Container: no leak during shaking or turning
no observable sign of test item contamination on the outer surface.
Inside aspect
no visual alteration of package by the test item.</td></tr>
<tr><td>Content (%w/w)</td><td>2.15</td><td>2.11</td></tr>
<tr><td>pH</td><td>4.88</td><td>4.90</td></tr>
<tr><td></td><td>Initial</td><td>After 1year in PET</td></tr>
<tr><td>Appearance</td><td colspan="2">Translucent but more opaque homogeneous liquid free from visible suspended matter and sediment.
Colour : milky yellow (more dark than before storage)
Odour : chemical odour .
Container: no leak during shaking or turning
no observable sign of test item contamination on the outer surface.
Inside aspect
no visual alteration of package by the test item.</td></tr>
<tr><td>Content (%w/w)</td><td>2.19</td><td>2.19</td></tr>
<tr><td>pH</td><td>4.87</td><td>4.79</td></tr>
</table>
</td><td></td><td>Final results are required in post-authorization.</td></tr>
<tr><td>Minor change 2022
Storage stability test – long term storage at ambient temperature</td><td>GC method Envigo (QR98RC)</td><td>21.7 g/l of nonanoic acid Batch 20180315-CV003</td><td>
<table>
<tr><td></td><td>Initial</td><td>After 1year in HDPE at 20°C ± 2°</td><td>After 2 years in HDPE at 20°C ± 2°</td><td>After 3 years in HDPE at 20°C ± 2°</td></tr>
<tr><td>Appearance</td><td colspan="4">Physical state: Translucent homogeneous liquid free from visible suspended matter and sediment.
Colour : pale yellow
Odour : chemical odour .</td></tr>
</table>
</td><td>De Ryckel , 2021 Study N° 24716</td><td>Acceptable
Product is stable after 3 year in HDPE and PET packaging.

Shelf life of 3 years is validated.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td>PA-U10-METDESCR visual method

CIPAC MT 75.3</td><td></td><td>
<table>
<tr><td></td><td colspan="4">Container: no leak during shaking or turning, no observable sign of test item contamination on the outer surface.
Inside aspect: no visual alteration of package by the test item.

No modification of appearance of significant pack weight change.</td></tr>
<tr><td>Content (%w/w)</td><td>2.15</td><td>2.11 (-1.6%)</td><td>2.06 (-4.2%)</td><td>2.00 (-6.8%)</td></tr>
<tr><td>pH</td><td>4.88</td><td>4.90</td><td>4.91</td><td>4.96</td></tr>
<tr><td></td><td>Initial at 20°C ± 2°</td><td>After 1 year in PET at 20°C ± 2°</td><td>After 2 years in PET at 20°C ± 2°</td><td>After 3 years in PET at 20°C ± 2°</td></tr>
<tr><td>Appearance</td><td colspan="4">Physical state: Translucent homogeneous liquid free from visible suspended matter and sediment.
Colour : pale yellow
Odour : chemical odour .
Container: no leak during shaking or turning, no observable sign of test item contamination on the outer surface.
Inside aspect: no visual alteration of package by the test item.

No modification of appearance of significant pack weight change.</td></tr>
<tr><td>Content (%w/w)</td><td>2.189</td><td>2.193 (+0.2%)</td><td>2.186 (-0.1%)</td><td>2.198 (+0.4%)</td></tr>
<tr><td>pH</td><td>4.87</td><td>4.79</td><td>4.69</td><td>4.82</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>Minor change 2022
Sprayability testing – long term storage at ambient temperature</td><td>PA-U10-METDESCR visual method</td><td>21.7 g/l of nonanoic acid Batch 20180315-CV003

PA-U10-METSPRAY</td><td></td><td>V. DECOCK, 2021, Study report N°24749</td><td>Acceptable
Sprayability is homogenous and unchanged (negligible variation) after 3 years for PET sprayer.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td>Internal method for spray diameter</td><td>
<table>
<tr><th></th><th>Initial</th><th>After 1year in PET at 20°C ± 2°</th><th>After 2 years in PET at 20°C ± 2°</th><th>After 3 years in PET at 20°C ± 2°</th></tr>
<tr><td>Appearance and stability of the commercial package</td><td colspan="4">Translucent PET hand held sprayer.
No leak during shaking or turning.
No observable sign of test item contamination on the outer surface.
No visual alteration of package by the test item.
No modification of appearance of significant pack weight change.</td></tr>
</table>
For the tables below:
P2: Position 2 lines
P5: Position 5 lines
<table>
<tr><th colspan="2"></th><th>Initial</th><th colspan="2">After 1 year at 20°C ± 2°</th></tr>
<tr><th colspan="2"></th><th>PET - sprayer unused</th><th>PET - sprayer already used</th><th>PET - sprayer unused</th></tr>
<tr><td colspan="2">Blockage of nozzle</td><td colspan="3">No</td></tr>
<tr><td colspan="2">Number of pressures necessary to start the system</td><td>4</td><td>1</td><td>4</td></tr>
<tr><td colspan="2">Using the difference of weight of the sprayer</td><td>P2: 1.0 g
P5: 1.0 g</td><td>P2: 1.1 g
P5: 1.1 g</td><td>P2: 1.1 g
P5: 1.0 g</td></tr>
<tr><td colspan="2">Using the amount of test item sprayed in the flask</td><td>P2: 1.05 g
P5: 1.04 g</td><td>P2: 1.06 g
P5: 1.06 g</td><td>P2: 1.1 g
P5: 1.0 g</td></tr>
<tr><td rowspan="2">Spray diameter (distance: 30 cm; 1 spray</td><td>Spray diameter</td><td>P2: 8 cm
P5: 18 cm</td><td>P2: 8 cm
P5: 8-15 cm</td><td>P2: 9 cm
P5: 17 cm</td></tr>
<tr><td>Max radius of splash</td><td>P2: 26 cm
P5: 18 cm</td><td>P2: 17 cm
P5: 16 cm</td><td>P2: 18 cm
P5: 17 cm</td></tr>
</table>
</td><td></td><td>HDPE sprayers are claimed by the applicant, nevertheless, it can be expected that the sprayer system is the same between both packagings and no further data is required.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment

actuation)							
			Initial	**After 2 years at 20°C ± 2°**			
			PET sprayer unused	**PET sprayer already used**	**PET sprayer unused**		
Blockage of nozzle			No				
Number of pressures necessary to start the system			4	1	4		
Using the difference of weight of the sprayer			P2: 1.0 g P5: 1.0 g	P2: 1.1 g P5: 1.1 g	P2: 1.1 g P5: 1.0 g		
Using the amount of test item sprayed in the flask			P2: 1.05 g P5: 1.04 g	P2: 1.06 g P5: 1.06 g	P2: 1.06 g P5: 1.05 g		
Spray diameter (distance : 30 cm; 1 spray actuation)	Spray diameter		P2: 8 cm P5: 18 cm	P2: 9 cm P5: 13 cm	P2: 9 cm P5: 18 cm		
	Max radius of splash		P2: 26 cm P5: 18 cm	P2: 17 cm P5: 18 cm	P2: 19 cm P5: 17 cm		
			Initial	**After 3 year at 20°C ± 2°**			
			PET sprayer unused	**PET sprayer already used**	**PET sprayer unused**		
Blockage of nozzle			No				
Number of pressures necessary to			4	1	3		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			start the system		
			Using the difference of weight of the sprayer: P2: 1.0 g P5: 1.0 g / P2: 1.1 g P5: 1.1 g / P2: 1.1 g P5: 1.1 g		
			Using the amount of test item sprayed in the flask: P2: 1.05 g P5: 1.04 g / P2: 1.07 g P5: 1.07 g / P2: 1.08 g P5: 1.07 g		
			Spray diameter (distance: 30 cm; 1 spray actuation): Spray diameter: P2: 8 cm P5: 18 cm / P2: 11 cm P5: 14 cm / P2: 10 cm P5: 20 cm		
			Max radius of splash: P2: 26 cm P5: 18 cm / P2: 18 cm P5: 23 cm / P2: 21 cm P5: 15 cm		
Storage stability test – **low temperature stability test for liquids**	MT 39.3 MT 36.3 MT 75.3	502 g/l of nonanoic acid Batch 20111102	**Initially** / **After 7 days at 0°C** Appearance (test item and container): Homogeneous yellowish liquid, no precipitation or separated material was observed after the storage pH (1% and undiluted, 20°C): 3.8 / 3.8 Acidity (% H_2SO_4): 14.2 / 14.5 Emulsion characteristics: **After 30 min in water A:** 3% v/v: max 6mLof froth and cream At 7.5 % v/v: max 12 mL of froth and cream / **After 30 min in water A:** 3% v/v: max 3mLof froth and cream At 7.5 % v/v: max 5 mL of froth and cream **After 30 min in water D:** / **After 30 min in water D:**	Fieseler A., 2015 Report number 82928204	Acceptable Study was performed on the biocidal product ENCLEAN. Nevertheless, as the formulation of ENCLEAN PAE is an AL (ready-to-use), it considered acceptable. Furthermore, the note "protect from frost" is added on the label.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results			Reference	Comment
				3% v/v : max 6mLof froth and cream At 7.5 % v/v: max 10 mL of froth and cream	3% v/v: max 3mLof froth and cream At 7.5 % v/v: max 5 mL of froth and cream		
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		502 g/l of nonanoic acid Batch 20111102	The light, the temperature changes did not changed the content of active substance in the product. No degradation products are observed. No reactivity towards material is present.			Fieseler A., 2014 Report number 82929204	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Not required				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See accelerated storage.				
Wettability			Not required				
Suspensibility, spontaneity and dispersion stability			Not required				
Wet sieve analysis and dry sieve test			Not required				

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td>Emulsifiability, re-emulsifiability and emulsion stability</td><td>MT 36.3</td><td>502 g/l of nonanoic acid Batch 20111102</td><td>See detail results below table.</td><td>Fieseler A., 2014 Report number 82929204</td><td>Acceptable
As the product is undiluted in water, the test is not required.</td></tr>
<tr><td>Disintegration time</td><td></td><td></td><td>Not required</td><td></td><td></td></tr>
<tr><td>Particle size distribution, content of dust/fines, attrition, friability</td><td></td><td></td><td>Product is sold with a sprayer system.
For all biocidal products that are applied in a manner that generates exposure to aerosols, particles or droplets then the MMAD (mass medium aerodynamic diameter) must be determined. The percentage of particles in mass with aerodynamic diameter <50 µm must be established.”</td><td></td><td>Data required</td></tr>
<tr><td>Minor change 2022
Particle size distribution, content of dust/fines, attrition, friability – MMAD - long term storage at ambient temperature</td><td>CIPAC guideline MT187

SOP-PR-051</td><td>BCP1011H (batch 20180315-CV003): 21.7 g/L Pelargonic Acid</td><td>
<table>
<tr><th></th><th>Initially</th><th>After 36 months at 20°C</th></tr>
<tr><td colspan="3">Narrow setting (Mean values)</td></tr>
<tr><td>Dv (10 %) [µm]</td><td>144</td><td>155</td></tr>
<tr><td>Dv (50 %) [µm]</td><td>350</td><td>377</td></tr>
<tr><td>Dv (90 %) [µm]</td><td>690</td><td>710</td></tr>
<tr><td>%V < 10 µm [%]</td><td>0.28</td><td>0.3</td></tr>
<tr><td>%V < 50 µm [%]</td><td>0.85</td><td>0.9</td></tr>
<tr><td colspan="3">Wide setting (Mean values)</td></tr>
<tr><td>Dv (10 %) [µm]</td><td>61</td><td>144</td></tr>
<tr><td>Dv (50 %) [µm]</td><td>178</td><td>295</td></tr>
<tr><td>Dv (90 %) [µm]</td><td>488</td><td>634</td></tr>
<tr><td>%V < 10 µm [%]</td><td>0.56</td><td>0.4</td></tr>
<tr><td>%V < 50 µm [%]</td><td>7.14</td><td>1.9</td></tr>
</table>
</td><td>Sven Manka, Report number Mo7305

N.Rodriguez, Report number Mo6531</td><td>Acceptable</td></tr>
<tr><td>Persistent foaming</td><td>MT 47.2</td><td>502 g/l of nonanoic acid Batch 20111102</td><td>At 7.5% v/v:
After 10 sec : 15.3mL
After 1 min : 14.7 mL
After 3 min: 14.8 mL
After 12 min : 10.0 mL</td><td>Fieseler A., 2014 Report number 82929204</td><td>Acceptable
The test should be performed at maximum and minimum concentration application rate, but</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
					as the product is undiluted in water, the test is not required.
Flowability/Pourability/Dustability			Not relevant		
Burning rate — smoke generators			Not relevant		
Burning completeness — smoke generators			Not relevant		
Composition of smoke — smoke generators			Not relevant		
Spraying pattern — aerosols			Not relevant		
Physical compatibility			Not required		
Chemical compatibility			Not required		
Degree of dissolution and dilution stability			Not required		
Surface tension	Method A.5 OECD 115	Enclean PAE Batch 14090	71.6 mN/m at 20.5°C	C. Bär, 2016, S16-01006	Acceptable
Viscosity	MT 192 OECD 114	Enclean PAE Batch 14090	**At 20°C:** 12.63 mPa.s^{-1} at 5 s^{-1} shear rate to 10.36 mPa.s^{-1} at 100 s^{-1} shear rate **At 40°C:**	C. Bär, 2016, S16-01003	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			10.74 mPa.s^{-1} at 5 s^{-1} shear rate to 8.62 mPa.s^{-1} at 100 s^{-1} shear rate		

The product ENCLEAN PAE is Another Liquid (AL) formulation, ready-to-use. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogeneous yellowish liquid, with characteristic odour. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed in HDPE and PET packaging. Interim result after 1 year at ambient temperature in HDPE and PET packaging show that the product is stable. The shelf-life is fixed at 24 months. Its technical characteristics are acceptable for an AL formulation.

The percentage of particles in mass with aerodynamic diameter <50 µm (before and after storage) must be established and provided in post-authorization.

The final long term storage study on the product ECLEAN PAE is required in post-authorization.

Implication concerning labelling: protect from frost

Minor change – 2022

Sprayability results after 3 years at ambient temperature show that the system of pulverization is functional and unchanged (from initial data). MMAD studies at T0 & 3 years were also submitted and deemed acceptable.

Long term storage results after 3 years at ambient temperature in HDPE and PET packaging show that the product is stable (degradation of AS content below 10%) and physical characteristics unchanged.

The shelf-life is set at 36 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Explosives	Method A.14 OECD 113	Batch 201302262	A DSC-measurement in a closed glass crucible with the test item showed no thermal effect up to the final temperature range of 320 °C. The test was stopped due to pressure build up. Thus a total energy release of 328 J/g up to a temperature of 500 "C was recorded.	Dornhagen J., 2014 Study report 20130452.01	Tests should be performed on the biocidal product ENCLEAN PAE. Nevertheless, based on the MSDS, none of formulant has explosive properties. Therefore, it is not expected to have explosive properties.
Flammable gases			Not relevant		
Flammable aerosols			Not relevant		
Oxidising gases			Not relevant		
Gases under pressure			Not relevant		
Flammable liquids			The study does not need to be conducted for the aqueous solution because the product only contains volatile organic components with flash-points above 100°C.		Acceptable
Flammable solids			Not relevant		
Self-reactive substances and mixtures			According to ECHA guidance on the application of the CLP criteria, section 2.8 and annex I, 2.8.4.2, nonanoic acid product based doesn't contain of chemical groups present in the molecule associated with explosive or self-reactive properties as indicated in tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria.		Acceptable
Pyrophoric liquids			According to the additional classification considerations in CLP Annex I, 2.9.4, the classification procedure for		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
			pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)).		
Pyrophoric solids			Not relevant		
Self-heating substances and mixtures			According to Annex I 2.11.4.2 of the CLP Regulation, A self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). Nonanoic Acid is not in this case. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. Furthermore, Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is drastically reduced.		Acceptable
Substances and mixtures which in contact with water emit flammable gases			According to Annex I: 2.12.4.1.of CLP Regulation, The classification procedure for this class need not be applied if: a) the chemical structure of the substance or mixture does not contain metals or metalloids; or b) experience in handling and use shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
			c) the substance or mixture is known to be soluble in water to form a stable mixture.		
Oxidising liquids	Method A.21	Purity 519 g/l Batch 20130226-2	The test item has no oxidising properties under the test conditions in the sense of the European Commission Regulation (EC) No. 440/2008, Method A.21.	Dornhagen J., 2014 Study report 2013045203	Tests should be performed on the biocidal product ENCLEAN PAE. Nevertheless, based on the MSDS, none of formulant has oxidising properties. Therefore, it is not expected to have oxidising properties.
Oxidising solids			Not relevant		
Organic peroxides			Not relevant		
Corrosive to metals	No guideline and method	ENCLEAN Batch : 8306282011	Tests are provided on aluminium, zinc, stainless steel, copper and lead. On all metal samples, ENCLEAN product is pulverised. Samples are let dry (45° inclination) during 2h, 24h, 7days and 15days (with and without water rinsed after test). There is no loss of weight for all tests	BEB6-C-3043/1 M. Guironnet, 2012	Acceptable Product is not corrosive to metal. Test is not performed according to CLP regulation test C.1. Moreover, according to the results and the safety data sheet, none of the component

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
					is classified corrosive to metals H290. Therefore, it can be considered sufficient to state the corrosive to metal classification.
Auto-ignition temperatures of products (liquids and gases)	Method A15	Purity 519 g/l Batch 20130226-2	345°C	Dornhagen J., 2014 Study report 20130452.02	Acceptable
Relative self-ignition temperature for solids			Not relevant		
Dust explosion hazard			Not relevant		

Conclusion on the physical hazards and respective characteristics of the product

The product ENCLEAN PAE is not explosive and has no oxidizing properties. The product is not considered as flammable.

Implication concerning labelling:
None

- **Minor change application for ENCLEAN PAE – 2022 :**

Not relevant

2.2.4 Methods for detection and identification

Analytical method for determining the active substance and relevant component in the biocidal product

Report:	**Dr. Matthias Eichler., Silke Herrmann, 2014**
Title:	Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087
Document No	Project 83241101
Test facility	Institut für Biologische Analytik und Consulting IBACON GmbH Arheilger Weg 17 64380 Rossdorf Germany
Guidelines:	SANCO/3030/99 rev.4
GLP	Yes

Preparation of accuracy samples:

299.70 mg and 751.74 mg of the reference item Nonanoic Acid were weighed into separate 10 mL volumetric flasks and made up to the mark using methanol.

Approximately 70 mg of the blank formulation were weighed precisely into a centrifuge tube. 1 mL of the reference item stock solution (30 g/L) and 1 mL internal standard stock solution (Tridecanoic Acid) were added.

Approximately 25 mg of the blank formulation were weighed precisely into a centrifuge tube. 1 mL of the reference item stock solution (75 g/L) and 1 mL internal standard stock solution (Tridecanoic Acid) were added.

The solutions were derivatised with 2 mL of boron trifluoride-methanol solution were added to the tube. It was shaken and heated at 50 °C during 15 minutes. After half of the time had passed the solutions were stirred or swirled for a short time. At the end of the reaction the tubes were cooled at ~4° C for 30 minutes and then slightly shaken. Methanol (1.5 mL) was added for better phase separation in the following extraction step. Thus, iso-octane (10 mL) and saturated sodium chloride solution (3 mL) were added and the tubes were shaken vigorously by hand and then centrifuged for at least 15 minutes. The top layer was separated and the extraction repeated twice with 10 mL iso-octane each time. The extracts were combined and an aliquot was transferred into an autosampler vial and then analysed by GC-FID.

Validation of the analytical method:

Specificity	Interferences from impurities in control samples prepared from blank formulation and blank solvent (methanol) were evaluated by comparison of total mean peak area of the target analyte in the test item samples. No interference above 3% of total peak area for target analyte. Blank, calibration and fortified samples chromatograms were provided.	
Linearity	The calibration curve was obtained by correlation of peak area of eight concentrations.	
	Compound	Linearity data

	Nonanoic acid	10 to 100 mg a.i. Y = 0.0187 X + 0.0143 R^2 = 0.9995 N=8
Precision	Repeatability was evaluated with 5 independent determinations of the formulated product, no outlier.	
	Compound	Repeatability (RSD)
	Nonanoic acid	RSD = 0.7% < 1.48% (RSD calculated with modified equation of Horwitz)
Accuracy	Accuracy was determined by analysis of 10 independent determinations (five at 300 g a.s./kg and five at 750 g a.s./kg) in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate.	
	Compound	Accuracy (recovery)
	Nonanoic acid	300 g a.s./kg: 101% 750 g a.s./kg: 98%

C. Pointer, 2016 : Ready to use (RTU): Method Validation
Envigo Study Number : QR98RCGLP

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

Weigh (to the nearest 0.1 mg) about 1000 mg of test item into a 10 mL volumetric flask. Fill to the mark, at 20°C ± 1°C, with methanol. Mix thoroughly. Transfer by pipette 1 mL of the sample solution into a centrifuge tube. Add 1 ml of internal standard solution. To the centrifuge tube, add 2 ml of boron trifluoride-methanol. Mix and heat in an oven at 50°C during 7.5 minutes.
Swirl solution and place in the oven at 50°C during 7.5 minutes. Place solutions in a cooled refrigerator for 30 minutes. Mix. Add 1.5 mL of methanol, 3 mL of satured aqueous sodium chloride solution and 10 mL of 2,2,4 trimethylpentane. Shake by hand for 1 minute. Centrifuge for 15 minutes at 2500 RPM and the separated top layer removed and retained.
This extraction is repeat twice more with 10 mL of 2,2,4 trimethylpentane each time. The extracts are combined and mixed.

Analytical method	Fortification range / Number of measurements	Linearity N=6	Specificity	Recovery rate (%)			Reference
				Range	Mean N=5	RSD	

GC-FID	Two fortification levels: 75% samples (approximately 16 g/L) 125% samples (approximately 27 g/L) Five replicates per fortification levels	The calibration was found to be linear over a range 0.5-5mg of active substance, with a regression coefficient of 1.0000.	No interference	98.99-100.6 100.8-101.7	99.79 101.1	0.59 0.35	Pointer C., 2016 QR98RC

Specificity, linearity, precision and accuracy were checked and are found acceptable.

Analytical methods for determining relevant components and/or residues in different matrices

Residues in soil
The degradation of Nonanoic acid applied to soil occurs very rapidly (DT50(12°C) = 2.1 days, DT90(12°C) = 3.4 days) by microbial means (Study A 7.2.1/02, Doc. III-A 7.2.1/02), not through hydrolysis or photolysis. In addition, Nonanoic acid is an active substance that has been found to occur naturally in low concentrations in soil.
The natural occurrence in the environment, and the rapid metabolism and degradation of Nonanoic acid to substances, of which no concern is to be expected (please see chapter 4.1.1.1 of this document), abrogates the need to quantify Nonanoic acid residues from applications as a biocide.

Residues in animal and human body fluids and tissues
As the active substance Nonanoic acid is not classified as toxic or very toxic an analytical method for the determination of residues in animal and human body fluids and tissues is not required (see also Doc. III-A
4.2.d).

Residues in food/feedstuffs
No analytical method for the determination of Nonanoic acid in plant material is presented, because the formulation (Katzenschreck) is not designed for the application on crops intended for food or feed. In addition, Katzenschreck is not foreseen to be used in a manner which may cause contact with food and feedstuffs (see also Doc. III-A 4.3.).

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	St. dev.(%)		
Soil	Not required according to the Draft Proposal for Revision of TNsG on Data Requirements, Chapter 2, Point 4 "Analytical Methods for Detection and Identification"									
Air	Formulation containing 36.8% ammonium salts of Nonanoic acid	GC/FID	20 mg Formulation/L 3 measurements	0-10.52 mg Formulation /mL	Yes	7.6-8.75	8.3	n.s.	n.s.	**Study B 6.1.3, Doc. III-A 4.2b**
Water	Nonanoic acid (Emery 1202)	LC/MS	5–50 µg/L 5 measurements	7.5-75 µg/L	Yes (partly)	35-102*	82*	21*	8 µg/L	**Study A 4.2c, Doc. III-A 4.2c**
Body fluids and tissues	Not required according to TGD on data requirements									
Residues in food / feed	Not required according to TGD on data requirements									

n.s. – not stated in report

* - values given over all fortification levels

Conclusion on the methods for detection and identification of the product

An analytical method for the determination of active substance in the formulation was provided and validated.

Methods for analysis of residues were validated for Nonanoic acid in air and water:
The determination of residues in air can be performed by air-sampling of the fatty acid ingredients (i.e. Nonanoic acid) followed by acidification and esterification and determination by gas chromatography. It has to be kept in mind that Nonanoic acid is a naturally occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of biocide usage.

Nonanoic acid has been found to occur naturally in low concentrations in water. Although the degradation of Nonanoic acid applied to water happens rapidly a LC/MS method has been developed to analyze residues in water with a limit of quantification of 10 µg/L.

As Nonanoic acid is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.
An analytical method for the determination of residues of Nonanoic acid in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

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 ENCLEAN PAE is ready-to-use and sprayed directly on hard surfaces to kill green algae by professional and non-professional users.

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

According to the uses claimed by the applicant, the product ENCLEAN PAE is intended to be used for curative treatment against green algae on hard surfaces.
The aim of using this product is to keep the surfaces free of algae in outdoor environment.
It is also claimed the product must be applied on the targets by spraying and one application is needed. A second application is sometimes needed (2 per year).

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product ENCLEAN PAE is used as algaecide on hard surfaces. The active substance nonanoic acid penetrates the organisms and destroys the cell walls leading to a lysis.

2.2.5.4 Mode of action, including time delay

The mechanism of action of nonanoic acid is the destruction of algae cell membranes. This results in an unspecific and uncontrolled release of cell contents and photosynthesis can no longer take place. Due to its lipophilic characteristics the active substance quickly penetrates into the algal cells and disrupts cell membrane permeability. The result is the destruction of the photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell contents occurs.
After application of the biocidal product the treated area is not rinsed. As the active substance is a fatty acid it will not tend to stick to the treated surface.
Hence an application has to be done only if no rain is expected.

2.2.5.5 Efficacy data

There is no standard test method for algaecide efficacy testing that is currently recommended in the draft guidance on efficacy assessment of biocides PT 2.

Field studies were conducted with the product ENCLEAN PAE according to an in-house methodology.
The results are summarized in the table below.

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**
algaecide	Walls, rooftops, pathway, driveway …	ENCLEAN PAE nonanoic acid 21.7g/L	*Chlorophyta spp.* *Chaetophoraceae* (genus: *Pleurococcus*) *Prasiolaceae* (species: *Desmococcus olivaceus*) *Chlorellaceae* (genus: *Apatococcus*) *Prasiolaceae* (species: *Stichococcus bacillaris Nageli*)	Direct application by spraying on hard surface (plaster) covered with algae (85-88% of the total area). 6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment)	At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L). Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application.	250L/ha (25 mL produit/m^2): 95,5% efficacy at D7 and 99,7% efficacy at D14 519L/ha (52 mL de produit/m^2): 100% efficacy at D7 and D14 percentage of area covered by algae at 14 DA for untreated control: 96.7% (85% at D0)	REYNENS P., 2017 H17NNNNN01-SE01 IC: 1

algaecide	Walls, rooftops, pathway, driveway …	ENCLEAN PAE nonanoic acid 21.7g/L	*Chlorophyta spp.* *Chlorella vulgaris*	Direct application by spraying on hard surface (cement pathway) covered with algae (100% of the total area). 6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment)	At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L). Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application.	250L/ha (25 mL produit/m^2): 39.2% efficacy at D7 and 41,7% efficacy at D14 519L/ha (52 mL de produit/m^2): 80.8% efficacy at D7 and 90,8% efficacy D14 percentage of area covered by algae at 14 DA for untreated control: 100%	Mc CONNELL K., 2017 H17NNNNN01-UK01 IC: 1
algaecide	Walls, rooftops, pathway, driveway …	ENCLEAN PAE nonanoic acid 21.7g/L	*Chlorophyta spp.*	Direct application by spraying on hard surface (glass) covered with algae (62-73% of the total area). 6 replicates per tested treatment (2 different application rates with ENCLEAN PAE, a control without treatment)	At the application rates of 250 L/ha and 519 L/ha, for nonanoic acid (21.7g/L). Quotations (percentage of area covered by algae) were made at 2 hours, 1, 3, 7, 14 days after application.	250L/ha (25 mL produit/m^2): 94% efficacy at D7 and 92% efficacy atD14 519L/ha (52 mL de produit/m^2): 100% efficacy at D7 and D14 percentage of area covered by algae at 14 DA for untreated control: 83% (62% at D0)	KEMEZYS H., 2017 R042-17H IC: 1

These trials showed that the product ENCLEAN PAE is an effective algaecide (efficacy >90%) against green algae (*Chlorophyta spp.*) when applied on porous and non-porous hard surface (plaster, cement and glass). The product has been tested in climatic conditions representative of uses (Belgium, Sweden, UK) as well as on several genus and species of *Chlorophyta.*

The product has been tested according to an in-house method and the application rate of 250 L/ha (25 mL produit/m^2) showed a minimum efficiency of 39.2% in curative treatment at 7 days (41.7% at 14 days).
The product has been tested according to an in-house method and the application rate of 519 L/ha (52 mL de produit/m^2) showed a minimum efficiency of 80.8% at 7 days in curative treatment (90.8% at 14 days).

Conclusion on the efficacy of the product
In conclusion, in accordance with the submitted tests, the product ENCLEAN PAE is efficient against green algae (*Chlorophyta spp.*), at the application rate of 50 mL product /m², by spraying on porous and non-porous hard surfaces for use outdoor by professional and non-professional users. The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.6 Occurrence of resistance and resistance management

For algaecide application on hard surfaces with nonanoic acid-containing products, cases of resistances are not reported or known up to the time being.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) assessed that the product ENCLEAN PAE, ready-to-use, has shown a sufficient efficacy, for the uses in curative treatment against green algae (*Choloryphyta spp.*), at the application rate of 50 mL product/m², by spraying on hard surfaces in green spaces and on every roof type (except thatched roof) by professional and non-professional users.

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)

The product ENCLEAN PAE is not intended to be used with another biocidal product.

2.2.6 Risk assessment for human health

ENCLEAN PAE is a product used for the disinfection and acts like an algaecide for professional and non-professional users.
ENCLEAN PAE contains 2.24 % a.s (technical) and should be used at the application rate of 50 mL pb/m^2.
The product is applied up to twice per year with a minimal interval of six months.

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 ENCLEAN PAE.
Classification of the products has been carried out according to the calculation rules laid down in the CLP regulation.

- **Minor change application for ENCLEAN PAE – 2022 :**

The addition of new packaging has no impact on the conclusion.

Skin corrosion and irritation

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	No study has been performed on ENCLEAN PAE. 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. The a.s being the only classified ingredient of the formulation and its content being below the threshold value for classification as corrosive or skin irritant, no classification is required.

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	No study has been performed on ENCLEAN PAE. 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. The a.s being the only classified ingredient of the formulation and its content being below the threshold value for classification as eye irritant, no classification is required.

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No study has been performed on ENCLEAN PAE.

	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. The a.s being the only classified ingredient of the formulation and no respiratory irritant properties being reported for the a.s, no classification is required.

Skin sensitization

Data waiving	
Information requirement	Skin sensitization
Justification	No study has been performed on ENCLEAN PAE. 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. The a.s being the only classified ingredient of the formulation and its content being below the threshold value for classification as skin sensitizer, no classification is required.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Respiratory sensitization
Justification	No study has been performed on ENCLEAN PAE. 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 sensitization. The a.s being the only classified ingredient of the formulation and no respiratory sensitization properties being reported for the a.s, no classification is required.

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	Oral acute toxicity
Justification	No study has been performed on ENCLEAN PAE. 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 oral acute toxicity. The a.s being the only classified ingredient of the formulation and no classification for acute oral toxicity being reported for the a.s, no classification is required.

Acute toxicity by inhalation

Data waiving	
Information requirement	Inhalation acute toxicity
Justification	No study has been performed on ENCLEAN PAE. 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 inhalation acute toxicity. The a.s being the only classified

	ingredient of the formulation and no classification for acute dermal toxicity being reported for the a.s, no classification is required.

Acute toxicity by dermal route

Data waiving	
Information requirement	Dermal acute toxicity
Justification	No study has been performed on ENCLEAN PAE. 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 dermal acute toxicity. The a.s being the only classified ingredient of the formulation and no classification for acute inhalation toxicity being reported for the a.s, no classification is required.

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption
Justification	Only local effect are considered. Derma 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, ENCLEAN PAE does not contain any substance of concern. Both co-formulants have no classification (harmonised classification of MSDS) and no Community Workplace Exposure value is available.

Available toxicological data relating to a mixture

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	No	yes	yes	No	No	No	
Dermal	No	yes	yes	no	yes	yes	
Oral	No	no	no	no	no	no	

List of 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 exposure** Before application, the product may be loaded into a sprayer.	Professionals and non-professionals
2.	Application by spraying	**Primary exposure – dermal and inhalation exposure** The product is applied by spray application.	Professionals and non-professionals

In the CAR of the active substance nonanoic acid, no systemic effect have been observed and no systemic reference toxicological value has been derived. Only a qualitative risk assessment (RA) has been performed. In this context, the same approach is performed for ENCLEAN PAE containing 2.24 % of nonanoic acid.
Since the active substance approval of nonanoic acid, a discussion about the local risk assessment has been initiated at the WG II 2018. This discussion will be taken in consideration at the active substance renewal.

Industrial exposure

Not applicable

Professional exposure

Scenario [1] – Mixing and loading phase

During the mixing and loading phase, professional users are in contact with the product that is not classified. If there is no identified hazard for the handling of the product, no risk is expected and exposure assessment is not required.

Scenario [2] – Application phase

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

Non-professional exposure

Scenario [1] – Mixing and loading phase

During the mixing and loading phase, non-professional users are in contact with the product that is not classified. If there is no identified hazard for the handling of the product, no risk is expected and exposure assessment is not required.

Scenario [2] – Application phase

During the application phase, non-professional users are in contact with the product that is not classified. 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

Exposure to the general public occurs with the non classified product after application. Considering that no hazard is identified with the product, no risk is expected.

Monitoring data

[Please add any information on surveys or studies with the actual product or with a surrogate.]

Dietary exposure

The product ENCLEAN PAE is intended to be used on building as disinfectant and algaecide. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

Information of non-biocidal use of the active substance
[Please include a section for each area of other (non-biocidal) use of the active substance. Please insert or delete rows as needed.]

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

Aggregated exposure

Not applicable

Summary of exposure assessment

In the CAR of the active substance nonanoic acid, no systemic effect have been observed and no systemic reference toxicological value has been derived. Only a qualitative risk assessment has been performed.
In this context, the same approach is performed for ENCLEAN PAE conatining 2.24 % of nonanoic acid.

2.2.6.3 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.

Maximum residue limits or equivalent

Not required.

Specific reference value for groundwater
[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.]

Risk for industrial users

Not applicable

Risk for professional users

Local effects

The product ENCLEAN PAE being not classified, no hazard has been identified.
Therefore, no local risk assessment is required.

Conclusion
The risk is considered acceptabe for professioanl users.

Risk for non-professional users

Local effects

The product ENCLEAN PAE being not classified, no hazard has been identified.
Therefore, no local risk assessment is required.

Conclusion

The risk is considered acceptabe for non-professioanl users.

- **Minor change application for ENCLEAN PAE – 2022 :**

The addition of new packaging has no impact on the conclusion.

Risk for the general public

Local effects

The product ENCLEAN PAE being not classified, no hazard has been identified.
Therefore, no local risk assessment is required.

Conclusion

The risk is considered acceptabe for general public.

- **Minor change application for ENCLEAN PAE – 2022 :**

The addition of new packaging has no impact on the conclusion.

Risk for consumers via residues in food

The product ENCLEAN PAE is intended to be used on building. It will not get in contact with food or feed. Residue in food or feed are not expected.

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

Not applicable.

2.2.7 Risk assessment for animal health

Not applicable.

2.2.8 Risk assessment for the environment

The active substance, Nonanoic acid, is used as disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2).

FR-CA box 1: *FR Opinion*

Please notice that the environmental risk assessment is reported as provided by the applicant, if the FR CA does not agree with the applicant values or assessment, it is reported in the green boxes. Otherwise the values presented by the applicant are used. Please note that the default input values are issued from ESD PT10.

2.2.9 Aquatic compartment (incl. sediment)

To determine the risks associated with potential exposure to Nonanoic acid in surface waters, the toxicity data are summarised in IUCLID Dataset Section 9. In accordance with the Guidance on

the Biocidal Products Regulation Volume IV Environment - Part B Risk Assessment, assessment factors (AF) are applied to aquatic toxicity endpoints to derive a PNEC (predicted no effect concentration), which is compared to PEC (predicted environmental concentrations) data for surface waters.

Acute data are available for all three key trophic levels (fish, invertebrates and primary producers). Chronic data are available for all three key trophic levels (fish, invertebrates and primary producers). The selected endpoint for PNEC derivation was a 72-hour NOE_yC of 0.46 mg $_{Nonanoic\ acid}.l^{-1}$ from an algal study.

Taxonomic Group	**Acute data LC/EC_{50} ($mg.l^{-1}$)**	**Chronic data $NOEC/EC_{10}$ ($mg.l^{-1}$)**	**AF**	**PNEC ($\mu g.l^{-1}$)**
Fish	41.9	21	10	**46**
Invertebrates	56.8	19.3		
Algae	9.56	0.46		

PNEC aqua freshwater = 46 $\mu g.l^{-1}$

In the absence of ecotoxicological data, a provisional PNECsediment (freshwater) is calculated using the equilibrium partitioning method. The calculation is done as following: PNECsediment = (Ksusp-water*PNECaqua*1000)/RHOsusp with Ksusp-water = 2.08 $m^3.m^{-3}$ (with a Koc of 47.3 $l.kg^{-1}$) and RHOsusp = 1150 $kg.m^{-3}$.

Sediment organisms	**PNECsed ($mg.kg\ sediment_{wwt}^{-1}$)**
	0.0833

PNEC freshwater sediment = 0.0833 $mg.kg\ sediment_{wwt}^{-1}$

2.2.10 Sewage treatment plants (STP)

Based on decision No. DSH-63-3-D-0009-2014 to grant permission to refer to the relevant study, the $PNEC_{stp}$ is taken from the Competent Authority Report for Nonanoic acid as:

PNEC microorganisms = 5.652 $mg.l^{-1}$

2.2.11 Atmosphere

The vapour pressure of Nonanoic acid at ambient temperature is 0.9 Pa (20°C) and Henry's law constant is 0.33 $Pa.m^3.mol^{-1}$ at 20°C (with on a water solubility of 0.2027 $g.l^{-1}$). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

2.2.12 Terrestrial compartment

To determine the risks associated with potential exposure to Nonanoic acid in soil, the toxicity data are summarised in IUCLID Dataset Section 9.

In accordance with the Guidance on the Biocidal Products Regulation Volume IV Environment - Part B Risk Assessment, assessment factors (AF) are applied to terrestrial toxicity endpoints to derive a PNEC (predicted no effect concentration), which is compared to PEC (predicted environmental concentrations) data for the terrestrial compartment.

Terrestrial toxicity data are available for soil microorganisms (OECD 216 and OECD 217), plants (OECD 227 – 6 species and OECD 208 – 10 species) and earthworms (OECD 207). All these studies were performed with biocide product ENCLEAN PAE and results are converted to standard soil which is defined as a soil with an organic matter content of 3.4% using the following equation:

$NOEC_{standard} = NOEC_{exp} \times F_{om, soil\ standard} / F_{om, soil\ exp}$

(BPR Guidance Vol IV, april 2015, Eq. 71, Infobox 9).

OECD 207 Short-term (14-day) toxicity to earthworms

Original data: 14d-EC_{50} = 908 mg $_{ENCLEAN\ PAE.}kg_{soil\ dw^{-1}}$
(Test soil organic matter content: 5% sphagnum peat) equivalent to 14d-EC_{50} = 546.6 mg a.s.kg $soil^{-1}$.
Normalised data: 14d-EC_{50} = 371.6 mg a.s.kg $soil^{-1}$ ($F_{om, soil\ standard}$ = 3.4%).

OECD 216/217 Effects on soil microorganisms

Original data: No adverse effects observed down to 27.8 mg $_{ENCLEAN\ PAE.}kg_{soil\ dw^{-1}}$ and up to 139 mg $_{ENCLEAN\ PAE.}kg_{soil\ dw^{-1}}$ (test soil Total Organic Carbon content: 0.99%) equivalent to 21 mg a.s.kg soil-1 and 103 mg a.s.kg $soil^{-1}$.
Normalised data: No adverse effects observed down to 42.4 mg a.s.kg $soil^{-1}$ and 208 mg a.s.kg $soil^{-1}$. (Foc, soil standard = 2%).

OECD 227 Acute toxicity to plants (6 species)

Original data: the lowest 21d-EC_{50} was 3862 g.ha^{-1} (*Cucumis sativus*, fresh weight) ($F_{oc, test}$ = 0.94%).

The original ecotoxicity values are provided as L.ha^{-1} of formulated product and were converted as g of active substance per hectare. Then, conversion of the test result expressed to g a.s.ha^{-1} to mg a.s.kg^{-1} are derived from the test by using a default soil depth of 10 cm and soil density of 1500 kg.m^{-3} dry soil as recommended in BPR Guidance Vol IV (April 2015, Infobox 11):

Original ecotoxicity value / (10,000 x 0.1 x 1,500).
21d-EC_{50} = 2.58 mg/kg soil dw (*Cucumis sativus*, fresh weight) (Foc, test = 0.94%).

Normalised data: 21d-EC50 = 9.31 mg.kg soil dw^{-1} (*Cucumis sativus*, fresh weight) ($F_{om, soil\ standard}$ = 3.4%).

OECD 208 Acute toxicity to plants (10 species)

Original data: the lowest 21d-EC_{50} was 15935 g.ha^{-1} (*Lolium perenne*, dry weight). The lowest 21d-

The original ecotoxicity values are provided as L/ha of formulated product and were converted as g of active substance per hectare. Then, conversion of the test result expressed to g a.s./ha to mg a.s./kg are derived from the test by using a default soil depth of 10 cm and soil density of 1500 kg/m^3 dry soil as recommended in BPR Guidance Vol IV (April 2015, Infobox 11):

Original ecotoxicity value / (10,000 x 0.1 x 1,500).
21d-EC_{50} was 10.6 mg.kg soil dw^{-1} (*Lolium perenne*, dry weight)

Normalised data: 21d-EC_{50} was 14.4 mg.kg soil dw^{-1} (*Lolium perenne*, dry weight) ($F_{om, soil\ standard}$ = 3.4%)

Plants are significantly more sensible than microorganism and earthworm. Therefore, and in accordance with the European Assessment Report of Nonanoic Acid, the 21d EC_{50} value of 9.31 mg as/kg dwt^{-1} (Cucumis sativus) is chosen to derive the PNEC soil. An AF of 100 is applied still in accordance with the AR of Nonanoic Acid. The PNEC soil is then of, 0.0931 mg $_{as}$/kg $_{dwt}^{-1}$.

PNEC soil = 0.0931 mg as/kg dwt

FR-CA box 2: *FR Opinion*

Applicant proposed to derive environmental PNEC values from new toxicity data supplied by JADE on nonanoic acid.

The alternative source of active substance, nonanoic acid, included in the formulation of ENCLEAN PAE product is considered technically equivalent compared to the reference source. Moreover the active substance supplied by JADE is included in the substances and suppliers list (Article 95 list).
Considering that data supplied by JADE falls within the range values of ecotoxicity data supplied in the assessment report of Nonanoic acid, PT2, July 2013, PNEC values derived from data of the JADE source have not been taken into account.

Consequently all the data are coming from the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013).

Summary of PNECs of the active substance Nonanoic acid

Compartment	Nonanoic acid
Freshwater	5.68E-02 $mg.l^{-1}$
Soil	0.099 $mg.kg_{wwt}^{-1}$
STP	5.652 $mg.l^{-1}$
Oral bird	0.331 mg.kg $_{food}^{-1}$
Oral small mammal	5 mg.kg $_{food}^{-1}$

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

FR-CA box 3: *FR Opinion*

The active substance nonanoic acid is classified according to Regulation (EC) No.1272/2008 (CLP) as Aquatic Chronic 3, H412, Harmful to aquatic life with long lasting effects.

The other co-formulants of the ENCLEAN PAE product are not classified for the environment and are not considered as substances of concern for the environment. Therefore, the co-formulants are not expected to have a significant impact on the ecotoxicological classification of the ENCLEAN PAE product. Therefore, ENCLEAN PAE product is not classified according to Regulation (EC) No.1272/2008 (CLP).

Further Ecotoxicological studies

FR-CA box 4: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

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

FR-CA box 5: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

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

FR-CA box 6: *FR Opinion*

No data is available. This endpoint is relevant only for products in the form of bait or granules. The ENCLEAN PAE product is a liquid.

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

FR-CA box 7: *FR Opinion*

No data is available. This endpoint is relevant only for products in the form of bait or granules. The ENCLEAN PAE product is a liquid.

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

FR-CA box 8: *FR Opinion*

No data is available. The ENCLEAN PAE product 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 ENCLEAN PAE 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

FR-CA box 9: *FR Opinion*

Please refer to section Fate and distribution in exposed environmental compartments.

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

FR-CA box 10: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

Leaching behaviour (ADS)

FR-CA box 11: *FR Opinion*

No relevant for this product.

Testing for distribution and dissipation in soil (ADS)

FR-CA box 12: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

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

FR-CA box 13: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

Testing for distribution and dissipation in air (ADS)

FR-CA box 14: *FR Opinion*

No data is available. As the ENCLEAN PAE product does not contain any substance of concern, the assessment is based on the available ecotoxicological data on nonanoic acid.

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)

FR-CA box 15: *FR Opinion*

Not relevant.

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)

FR-CA box 16: *FR Opinion*

Not relevant.

2.2.12.1 Exposure assessment

General information

Product PT 2 ENCLEAN PAE (500 $g_{a.s.}l^{-1}$) is an algaecide used for the curative treatment of construction materials. According to the claimed conditions of use, ENCLEAN PAE product is diluted before application to obtain a final use concentration of 18 $g_{a.s.}l^{-1}$. The application rate of the diluted preparation is of 0.05 $l.m^{-2}$.
There is no existing Emission Scenario Documents (ESD) for PT2 covering use of an algaecide on construction materials; therefore, the assessment of environmental emissions for ENCLEAN PAE 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 ESD for PT10 (Emission scenario document for biocides used as masonry preservatives, EUBEES 2002) and ESD for Product Type 8 (Revised Emission Scenario Document for Wood Preservatives, OECD 2013).

Estimation of environmental concentrations due to use and service life of ENCLEAN PAE was conducted considering three hard surface models:

- House (walls and roof) from ESD PT10
- Fence, from ESD PT8
- Bridge over pond, from ESD PT8

Releases of product are expected during application due to spray drift and run-off. Releases are also expected during service life resulting from leaching of product from treated surfaces.

FR-CA box 17: *FR Opinion*

Please note that this product does not need to be diluted. According to the claimed conditions of use a final use quantity of 1.093 ga.s.m-2 has been used in the environmental exposure assessment.

Parameter	Symbol	Unit	Value	Source
Volume of product applied on area	V_{form}	$l.m^{-2}$	0.05	S
Content of active substance (w/w)	F_{form}	-	0.0227	S
Product Density	Density	$g.l^{-1}$	963	D
Quantity of active substance applied on area	$M_{a.s.}$	$g.m^{-2}$	1.093	O

Note that the applicant has changed the a.s. content value at the last moment during the commenting phase and the correct value was the one in the confidential part of the PAR (2.245% w/w). Nevertheless, the assessment was kept with the previous value of 2.27% w/w, as it was a worst case. Moreover, note that the concentrate product density is used (963 g/L) instead of the experimental density value (1004.7 g/L). Nevertheless, we checked that these changes do not impact the conclusions, using a quantity of active substance applied on area of $1.12 g.m^{-2}$.

Fence scenario is covered by House scenario and consequently, Fence approach is not presented.

Fate and distribution in exposed environmental compartments

A comprehensive review of the available information on the properties of the active substance Nonanoic acid is given here below.
A summary table of some of the key characteristics of the active substance used in the exposure assessments are given below.

Physico-chemical properties

Physical chemical properties	Values
Molecular weight ($g.mol^{-1}$)	158.2
Melting point	-
Boiling point	-
Vapour pressure (Pa, at 20°C)	0.452
Octanol-water partition coefficient (as log)	2.4
Water solubility ($mg.l^{-1}$ at 25°C)	202.7

Degradation properties

Degradation properties	Study results		Values used
	Half-lives	IUCLID-5 Dataset Point	Half-lives
Hydrolysis as a function of pH	No hydrolysis expected	10.1.1.1.a	N/A
Ready biodegradability	Readily biodegradable	10.1.1.1.b	0.693 h in STP
Biodegradation in aerated sediment (biodegradability)	Waived	10.1.1.2	N/A(1)
Biodegradation in surface water	Waived	10.1.1.2	N/A(1)
Biodegradation in soil	3 d (20°C)	10.2.1	N/A(1)
Degradation in air	1.096 d	10.3.1	N/A

(1): not defined since assessment is carried out at local scale

Partition coefficients (adsorption)

Study on adsorption/desorption as presented and reviewed in the DAR reviewed by EFSA. An estimation of Koc by QSAR is obtained:

Adsorption properties	Values used
Koc	47.3 $l.kg^{-1}$

FR-CA box 18: *FR Opinion*

Phase	STP	Surface water		Sediment		Soil		Groundwater	
		Direct Release	*Via* STP	Direct Release	*Via* STP	Direct Release	*Via* STP	Direct Release	*Via* STP
Application	yes	yes	yes	yes	yes	yes	yes	yes	yes
Rinsing	yes	yes	yes	yes	yes	yes	yes	yes	yes

In the CAR of the active substance (Doc IIC, p17), a worst case service-life scenario was calculated assuming that 100% of the applied amount will be washed off in one day immediately after application due to e.g. a heavy rain event and ignoring any possible RMM. However, in our assessment, the rinsing scenario is a worst-approach compared to the leaching scenario proposed in the CAR, therefore this approach covers the service life phase. Moreover, specifics RMM have been added to avoid the release to the environment during the day of application. In addition, if we change this value to 100% (representing the release to adjacent soil or STP of the whole amount of a.s. during the application), the risk is acceptable after 15 days (application + rinsing). The overall conclusions would remain the same.

Even if a rinsing scenario has been assessed, it is important to underline that rinsing after application is not allowed.

Active substance: Nonanoic acid

Input parameters used in the environmental exposure assessments according to the CAR (July, 2013)	
Input	**Value**
Molecular weight [$g.mol^{-1}$]	158.2
Vapour pressure [Pa]	0.9 (20°C)
Water solubility [$mg.L^{-1}$]	445 (25°C, pH 5)
Henry's law constant [$Pa.m^3.mole^{-1}$]	0.33
Kow [Log 10]	3.52
Koc [$L.kg^{-1}$]	63.1
SLUDGERATE [$kg.d^{-1}$]	790
Biodegradability	Readily biodegradable
DT_{50} soil [d]	2.1 (12°C)

Calculated fate and distribution in the STP according to the CAR (EUSES model 2.1.2)	
Compartment	**Percentage [%]**
Degraded in STP	86.72%
Water	12.60%
Sludge	0.591%
Air	0.0894%

Emission estimation

2.2.12.1.1.1 HOUSE SCENARIO

In order to estimate emissions during service life, emissions during rinse right after application were considered as a worst-case.
According to ESD for PT10, assessment of emissions has been performed for two types of houses: house in the country side for which all loses of product during application go to local soil and house in a city for which all loses go to storm water.

Scenario	Receiving compartments
House in a city	Surface water, Soil, Sediment
House in the countryside	Soil near to application area

Calculations were done for an area of 270 m² (145 m² roof + 125 m² walls) according to the model house proposed in OECD (2002) (used in ESD PT10).

FR-CA box 19: FR Opinion

Concerning the soil distant to a treated horizontal surface, the risk can be considered to be covered by the assessment of vertical surfaces as the spray drift will be lower. Regarding soil adjacent to a treated horizontal surface, run-off is more likely and cannot be mitigated.
For vertical surfaces both facade and roof were considered for the risk assessment. Compared to a horizontal surface with a smaller treated area releasing product to the adjacent soil compartment, this assessment can be considered as a worst case situation.

2.2.12.1.1.2 EMISSIONS DURING APPLICATION

Table 1 Emission scenario for calculating the releases from a house treated by sprayer (ESD PT10)

Parameter	Symbol	Unit	Value	Source
Treated area per day	AREA	$m^2.d^{-1}$	270	D
Volume of product applied on area	V_{form}	$l.m^{-2}$	0.05	S
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D
Soil volume distant to treated surface	$V_{soil(d)}$	m^3	142.81	D CAR (PT10)
Soil volume adjacent to surface treated	$V_{soil(a)}$	m^3	13	D CAR (PT10)
Bulk density of wet soil	RHO_{soil}	$kg_{wwt}.m^{-3}$	1700	D

Model calculation for spray application:
Local emission of active substance during application due to spray drift
$Elocal_{drift} = AREA \times V_{form} \times C_{form} \times F_{drift} E^{-3}$

Local emission of active substance during application due to runoff
$Elocal_{runoff} = AREA \times V_{form} \times C_{form} \times F_{runoff} E^{-3}$

House in the countryside:
Concentration in distant soil due to spray application
Clocal $_{soil\ (d)}$ *= Elocal* $_{drift}$ */ (V soil (d)x RHOsoil)*

Concentration in adjacent soil due to spray application
Clocal $_{soil\ (a)}$ *= Elocal* $_{runoff}$ */ (V soil (a)x RHOsoil)*

Table 2 Concentrations in local soil due to direct emissions

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($kg.kg_{wwt}^{-1}$)	Concentration in local soil ($mg.kg_{wwt}^{-1}$)	Concentration in local soil ($mg.kgd_{wt}^{-1}$)
ESD PT10 House in the countryside	Clocal $_{soil(d)}$	Soil distant to treated surface	1.00E-07	1.00E-01	1.13E-01
	Clocal $_{soil(a)}$	Soil adjacent to treated surface	2.20E-06	2.20	2.49

House in a city:
Local emission of active substance during application to storm water
Elocal $_{water}$ *= Elocal* $_{drift}$ *+ Elocal* $_{runoff}$

Table 3 Emission to local storm water

Usage scenario	Symbol	Receiving Compartment	Emission rate to waste water ($kg.d^{-1}$)
ESD PT10 House in a city	Elocal $_{water}$	Storm water (connected to the sewer system)	7.30 E-2

The potential environmental loadings from storm water are considered to determine PECs in STP, surface water and sediment.
Emission rate to storm water is used to calculate the PEC in the relevant compartments based on models described in EU Technical Guidance on Risk Assessment TGD (2003).

FR-CA box 20: *FR Opinion*

House scenario – Application

The equations from the ESD PT10 have been considered with the revised soil volumes as defined for the approbation of the active substance nonanoic acid. The surface area of a facade (125 m^2) and a roof (145 m^2) were summed up. Concentrations in local soil and emission to local storm water have been revised considering a use quantity of 1.093 $g_{a.s.}m^{-2}$ following this approach:

Concentrations in local soil due to direct emissions

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($mg.kg_{wwt}^{-1}$)
ESD PT10 House in the countryside	$Clocal_{soil(d)}$	Soil distant to treated surface	1.22E-01
	$Clocal_{soil(a)}$	Soil adjacent to treated surface	2.67

Emission to local storm water

Usage scenario	Symbol	Receiving Compartment	Emission rate to waste water (kg/d)
ESD PT10 House in a city	$Elocal_{water}$	Storm water (connected to the sewer system)	8.85E-2

2.2.12.1.1.3 EMISSIONS DURING SERVICE-LIFE: RINSE (100% WASH-OFF)

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost were not considered as application and rinse are performed during the same day.

Table 4 Emission scenario for calculating the releases from a house during rinse (ESD PT10)

Parameter	Symbol	Unit	Value	Source	Guidance document
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D	ESD PT10
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D	ESD PT10

Treated area per day	AREA	$m^2.d^{-1}$	270	D	ESD PT10
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S	ESD PT10
Volume of diluted product applied on area	V_{form}	$l.m^{-2}$	0.05	S	
Fraction of rinsing solution lost during rinse due to runoff	$F_{runoff\ rinse}$	-	0.75	D	ESD PT10
Fraction of rinsing solution lost during rinse by spray drift	$F_{drift\ rinse}$	-	0.25	D	ESD PT10
Soil volume distant to treated surface	$V_{soil(d)}$	m^3	142.81	D	ESD PT10
Soil volume adjacent to surface treated	$V_{soil(a)}$	m^3	13	D	ESD PT10
Bulk density of wet soil	RHO_{soil}	$kg_{wwt}.m^{-3}$	1700	D	ESD PT10
Concentration in soil distant to treated surface	$Clocal_{soil(d)}$	$Kg.Kg_{wwt}^{-1}$	-	O	
Concentration in soil adjacent to treated surface	$Clocal_{soil(a)}$	$Kg.Kg_{wwt}^{-1}$	-	O	

Model calculation for releases during rinse
Local emission of active substance during rinse due to drift
$Elocal_{rinse\ drift} = AREA \times V_{form} \times C_{form} \times F_{drift\ rinse} \times (1-(F_{drift} + F_{runoff})) E^{-3}$

Local emission of active substance during rinse due to runoff
$Elocal_{rinse\ runoff} = AREA \times V_{form} \times C_{form} \times F\ d_{rift\ runoff} \times (1-(F_{drift} + F_{runoff})) E^{-3}$

Table 5 Emissions during rinse

Usage scenario	**Symbol**	**Local emission of active substance during rinse ($kg.d^{-1}$)**
ESD PT10 House in the countryside	$Elocal_{rinse\ drift}$	4.26E-02
	$Elocal_{rinse\ runoff}$	1.28E-01

House in the countryside:
Concentration in distant soil due to spray application and rinse
$Clocal_{soil\ rinse\ (d)} = Elocal_{rinse\ drift} / (V_{soil\ (d)} \times RHO_{soil}) + C\ local_{soil\ (d)}$

Concentraton in adjacent soil due to spray application and rinse
$Clocal_{soil\ rinse\ (a\ )} = Elocal_{runoff\ drift} / (V_{soil\ (a)} \times RHO_{soil}) + C\ local_{soil\ (a)}$

Table 6 Concentrations in local soil due to direct emissions

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($kg.kg_{wwt}^{-1}$)	Concentration in local soil ($mg.kg_{dwt}^{-1}$)
ESD PT10 House in the countryside	Clocal $_{soil\ (d)}$	Soil distant to treated surface	2.76E-07	3.12E-01
	Clocal $_{soil\ (a)}$	Soil adjacent to treated surface	7.98E-06	9.02

House in a city:
Local emission of active substance during application to storm water
$Elocal_{\ water\ rinse} = Elocal_{\ drift\ rinse} + Elocal_{\ runoff\ rinse}$

Table 7 Emission to local storm water

Usage scenario	Symbol	Receiving Compartment	Emission rate to waste water ($kg.d^{-1}$)
ESD PT10 House in a city	Elocal $_{water}$	Storm water (connected to the sewer system)	1.28E-01

The potential environmental loadings for these usage scenarios are considered to determine the PECs in STP, surface water and sediment.
The emission rates are used to calculate the PEC in the relevant compartments based on models described in EU Technical Guidance on Risk Assessment TGD (2003).

FR-CA box 21: *FR Opinion*

House scenario – Rinsing (by a rainfall event)

Considering a final use quantity of 1.093 $g_{a.s.m^{-2}}$, concentrations in local soil and emission to local storm water have been revised.

Emissions during rinse

Usage scenario	Symbol	Local emission of active substance during rinse only ($kg.d^{-1}$)
ESD PT10 House in the countryside	$Elocal_{rinse\ drift}$	5.16E-02
	$Elocal_{rinse\ runoff}$	1.55E-01

Concentrations in local soil due to direct emissions following rinsing only

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($mg.kg_{wwt}^{-1}$)
ESD PT10 House in the countryside	$Clocal_{soil\ (d)}$	Soil distant to treated surface	2.13E-01
	$Clocal_{soil\ (a)}$	Soil adjacent to treated surface	7.01

Concentrations in local soil due to direct emissions following application and rinsing

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($mg.kg_{wwt}^{-1}$)
ESD PT10 House in the countryside	$Clocal_{soil\ (d)}$	Soil distant to treated surface	3.34E-01
	$Clocal_{soil\ (a)}$	Soil adjacent to treated surface	9.68

Emission to local storm water following rinsing only

Usage scenario	Symbol	Receiving Compartment	Emission rate to waste water ($kg.d^{-1}$)
ESD PT10 House in a city	$Elocal_{water}$	Storm water (connected to the sewer system)	2.07E-01

FR-CA box 22: *FR Opinion*

Please note that the emission estimation for "house in a city" was performed for a mixed sewer system, only. Direct release to surface water via separate sewer systems was not considered. However, since the submission of the product was in 2015, the scenario is not yet relevant regarding the decision on product authorisation.
Note that the scenario will be relevant for reauthorisation of the product.

2.2.12.1.1.4 EMISSIONS DUE TO THE USE OF THE PRODUCT ON BRIDGE OVER POND

Calculations were done considering two guidance documents. Characteristics of the bridge are from ESD PT8 and models and parameters governing spray application (losses of product, etc.) are from ESD PT10.

2.2.12.1.1.5 EMISSIONS DURING APPLICATION

Table 8 Emission scenario for calculating the releases from a bridge treated by sprayer (ESD PT10 and ESD PT8)

Parameter	Symbol	Unit	Value	Source	Guidance document
Treated area per day	AREA	$m^2.d^{-1}$	10	D	ESD PT8
Volume of product applied on area	V_{form}	$l.m^{-2}$	0.05	S	ESD PT8
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S	ESD PT8
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D	ESD PT10
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D	ESD PT10
Water volume under bridge	V_{water}	m^3	1000	D	ESD PT8

Fraction of product lost during brush application initially described in ESD PT8 is replaced by fractions of product lost due to spray drift and runoff described in ESD PT10 (spray application on House).

Local emission of active substance during application due to spray drift
$Elocal_{drift} = AREA \times V_{form} \times C_{form} \times F_{drift} E^{-3}$

Local emission of active substance during application due to runoff
$Elocal_{runoff} = AREA \times V_{form} \times C_{form} \times F_{runoff} E^{-3}$

Emission to local water during day of emission
$Elocal_{water} = Elocal_{drift} + Elocal_{runoff}$

Local concentration in water (pond) during day of emission
$Clocal_{water} = Elocal_{water} / V_{water}$

Table 9 Emission to local water and concentration in water during application

Usage scenario	Symbol	Receiving Compartment	Output
PT10: Spray application PT8: Pond under bridge	Elocal water	Pond under bridge	**Emission rate to water (kg.d^{-1}):** 2.70 E-06
	Clocal water	Pond under bridge	**Concentration in water (Kg.l^{-1}):** 2.70 E-09

FR-CA box 23: *FR Opinion*

Bridge over pond scenario – Application

Considering a final use quantity of 1.093 $g_{a.s.m^{-2}}$, emission to local water and concentration in water during application have been revised.

Emission to local water and concentration in water during application

Usage scenario	Symbol	Receiving Compartment	Output
PT10: Spray application PT8: Pond under bridge	Elocal water	Pond under bridge	**Emission rate to water (kg.d^{-1}):** 3.28E-03
	Clocal water	Pond under bridge	**Concentration in water (mg.l^{-1}):** 3.28E-03

2.2.12.1.1.6 EMISSIONS DURING SERVICE-LIFE: RINSE (100% WASH-OFF)

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost during the same day were not considered as application and rinse are performed during the same day.

Table 10 Emission scenario for calculating the releases from a bridge during rinse

(ESD PT10)

Parameter	Symbol	Unit	Value	Source	Guidance document
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D	ESD PT10
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D	ESD PT10
Treated area per day	AREA	$m^2.d^{-1}$	10	D	ESD PT10
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S	ESD PT10
Volume of diluted product applied on area	V_{form}	$l.m^{-2}$	0.05	S	
Fraction of rinsing solution lost during rinse due to runoff	$F_{runoff\ rinse}$	-	0.75	D	ESD PT10
Fraction of rinsing solution lost during rinse by spray drift	$F_{drift\ rinse}$	-	0.25	D	ESD PT10
Water volume under bridge	V_{water}	m^3	1000	D	ESD PT8

Model calculation for releases during rinse

Local emission of active substance during rinse due to drift

$$Elocal_{rinse\ drift} = AREA \times V_{form} \times C_{form} \times F_{drift\ rinse} \times (1-(F_{drift} + F_{runoff})) \times E^{-3}$$

Local emission of active substance during rinse due to runoff

$$Elocal_{rinse\ runoff} = AREA \times V_{form} \times C_{form} \times F_{drift\ runoff} \times (1-(F_{drift} + F_{runoff})) \times E^{-3}$$

$$Clocal_{water\ rinse} = Clocal_{water} + (Elocal_{rinse\ drift} + Elocal_{rinse\ runoff}) / V_{water}$$

Table 11 Concentration in local water due to spray application and rinse

Usage scenario	Symbol	Receiving Compartment	Output
PT10 : Spray application PT8: Pond under bridge	$Clocal_{water\ rinse}$	Pond under bridge	**Concentration in water ($mg.l^{-1}$):** 9.01E-09

FR-CA box 24: *FR Opinion*

Bridge over pond scenario – Application + rinsing (by a rainfall event)

Considering a final use quantity of 1.093 $g_{a.s.m^{-2}}$, concentration in local water due to spray application and rinse (by a rainfall event) has been revised.

Concentration in local water due to spray application and rinse

Usage scenario	Symbol	Receiving Compartment	Output
PT10 : Spray application PT8: Pond under bridge	Clocal $_{water\ rinse}$	Pond under bridge	**Concentration in water ($mg.l^{-1}$):** 1.09E-02

2.2.12.1.1.7 EMISSIONS DUE TO THE USE OF THE PRODUCT ON FENCE:

Calculations were done considering two guidance documents. Characteristics of the fence are from ESD PT8 and models and parameters governing spray application (losses of product, volume of soil receiving product, etc.) are from ESD PT10.

2.2.12.1.1.8 EMISSIONS DURING APPLICATION

Table 12 Emission scenario for calculating the releases from a fence treated by sprayer (ESD PT10 and ESD PT8)

Parameter	Symbol	Unit	Value	Source	Guidance document
Treated area per day	AREA	$m^2.d^{-1}$	2	D	ESD PT8
Volume of product applied on area	V_{form}	$l.m^{-2}$	0.05	S	ESD PT8
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S	ESD PT8
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D	ESD PT10
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D	ESD PT10
Soil volume distant to treated surface	$V_{soil(d)}$	m^3	2.85	D Based on ANSES recommandations for House scenarios *	ESD PT10
Soil volume adjacent to surface treated	$V_{soil(a)}$	m^3	0.26	D Based on ANSES recommandations for House scenarios *	ESD PT10
Bulk density of wet soil	RHO_{soil}	$kg_{wwt}.m^{-3}$	1700	D	ESD PT8

*Input parameter calculated from default values of dimensions of receiving compartment considering spraying application, provided by ANSES for ESD PT 10 House model.

Concentration in distant soil due to spray application
$Clocal_{soil\ (d)} = Elocal_{drift} / (V_{soil\ (d)} \times RHO_{soil})$

Concentration in adjacent soil due to spray application
$Clocal_{soil\ (a)} = Elocal_{runoff} / (V_{soil\ (a)} \times RHO_{soil})$

Table 13 Concentration in local soil due to direct emissions

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($mg.kg_{wwt}^{-1}$)	Concentration in local soil ($mg.kgd_{wt}^{-1}$)
PT10 : Spray application PT8: Pond under bridge	Clocal soil(d)	Soil distant to treated surface	5.2E-09	5.82E-03

PT10 : Spray application PT8: Pond under bridge	Clocal soil(a)	Soil adjacent to treated surface	2.12E-05	23.96

2.2.12.1.1.9 EMISSIONS DURING SERVICE-LIFE: RINSE (100% WASH-OFF)

For estimations of environmental concentrations due to releases of active substance during rinse, removal processes such as evaporation, degradation or lost during the same day were not considered as application and rinse occurred during the same day.

Table 14 Emission scenario for calculating the releases from a fence during rinse (ESD PT10)

Parameter	Symbol	Unit	Value	Source	Guidance document
Fraction of product lost during application by spray drift	F_{drift}	-	0.1	D	ESD PT10
Fraction of product lost during application due to runoff	F_{runoff}	-	0.2	D	ESD PT10
Treated area per day	AREA	$m^2.d^{-1}$	2	D	ESD PT10
Concentration on active substance	C_{form}	$g.l^{-1}$	18	S	ESD PT10
Volume of diluted product applied on area	V_{form}	$l.m^{-2}$	0.05	S	
Fraction of rinsing solution lost during rinse due to runoff	$F_{runoff\ rinse}$	-	0.75	D	ESD PT10
Fraction of rinsing solution lost during rinse by spray drift	$F_{drift\ rinse}$	-	0.25	D	ESD PT10
Concentration in soil distant to treated surface	$Clocal_{soil\ (d)}$	$Kg.kg_{wwt}^{-1}$	-	O	
Concentration in soil adjacent to treated surface	$Clocal_{soil\ (a)}$	$Kg.kg_{wwt}^{-1}$	-	O	

Model calculation for releases during rinse

Local emission of active substance during rinse due to drift

$$Elocal_{rinse\ drift} = AREA \times V_{form} \times C_{form} \times F_{drift\ rinse} \times (1-(F_{drift} + F_{runoff}))E^{-3}$$

Local emission of active substance during rinse due to runoff

$$Elocal_{rinse\ runoff} = AREA \times V_{form} \times C_{form} \times F_{drift\ runoff} \times (1-(F_{drift} + F_{runoff}))E^{-3}$$

Concentration in distant soil due to spray application and rinse

$$Clocal_{soil\ rinse\ (d)} = Clocal_{soil\ (d)} + Elocal_{rinse\ drift} / (V_{soil\ (d)} \times RHO_{soil})$$

Concentration in adjacent soil due to spray application and rinse

$$Clocal_{soil\ rinse\ (a)} = Clocal_{soil\ (a)} + Elocal_{runoff\ drift} / (V_{soil\ (a)} \times RHO_{soil})$$

Table 15 Concentration in local soil due to direct emissions

Usage scenario	Symbol	Receiving Compartment	Concentration in local soil ($Kg.kg_{wwt}^{-1}$)	Concentration in local soil ($mg.kg_{dwt}^{-1}$)
PT10: Spray application PT8: Pond under bridge	$C_{local\ soil\ (d)}$	Soil distant to treated surface	1.41E-08	1.60E-02
PT10: Spray application PT8: Pond under bridge	$C_{local\ soil\ (a)}$	Soil adjacent to treated surface	7.69E-05	86.87

FR-CA box 25: *FR Opinion*

Fence scenario

Emission scenario for calculating the releases from a fence is covered by house scenario. No further comments.

Calculated PEC values

2.2.12.1.1.10 PEC IN STP, SURFACE WATER, AND SEDIMENT

PEC in STP, surface water and sediment have been calculated for "House in a city" scenario, where environmental emissions are made to the drains and potential concentrations of the active substance can be expected in these compartments.
Emissions due to losses during application and service life of ENCLEAN PAE product on houses in a city (270 m² of treated area) previously estimated were used for calculations.
The predicted environmental concentration (PEC) of the active substance Nonanoic acid in STP, surface water and sediment has been determined using the general procedures for exposure to STP described in the Technical Guidance Document (TGD) on risk assessment[2].
This level of assessment is deemed adequate for the purposes of this exposure assessment and further refinements are not considered necessary.
The PEC calculations are based on the environmental emissions determined above. The local emissions are assumed to be discharged to a STP facility and the concentration of Nonanoic acid entering the STP is calculated using TGD models.
Emissions from indirect environmental exposure was calculated considering several number of potential treated houses connected to the same STP. The scenarios are described as below:

[2] Technical Guidance document (TGD) on Risk Assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Part II (2003).

- One treated house per day connected to a STP

- *3152 treated houses per day connected to the same STP, based on 15 million of potentially concerned houses in France according to JADE's previsions without any refinement (60 million of French people, divided by 4 manufacturers that produce similar biocide product as ENCLEAN PAE). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[3]). The obtained fraction of potentially treated houses was then reported to the default number of 4000 houses connected to the same STP provided by ESD PT10 for city scenario. This simulation is considered as a worst case, as it considers that 100% (80% of French individual houses) the potentially concerned houses are treated the same day with ENCLEAN PAE product.*

- *57 treated houses per day connected to the same STP. Based on the maximum number of houses treated the same day leading to an acceptable risk for all environmental compartments without any refinement. A rate of 57 houses per STP corresponds to a number of 271 305.8 houses (based on the previous INSEE ref.) at a national scale (1% of French individual houses).*

- *1909 treated houses connected to the same STP. In order to provide a more realistic evaluation, a factor of simultaneity of treatments of houses with ENCLEAN PAE was taken into account as for a refinement. The number of 1909 houses corresponds to the maximum number of treated houses leading to acceptable risks for environmental compartments considering a factor of simultaneity of 0.03. This factor is provided by the ESD for PT18 "Emission Scenario Document For Insecticides, Acaricides and Products to control Arthropods for Household and Professional Uses"[4], 2008. It is used to estimate emission rates of an active substance to the sewage system per day following applications of outdoor insecticides. This factor is considered as sufficiently conservative as outdoor algaecides are intended to be used at a lower frequency than outdoor insecticides. A rate of 1909 houses per STP corresponds to a number of 9 362 086.8 houses at a national scale (48 % of French individual houses which is a realistc worst case).*

FR-CA box 26: *FR Opinion*

Take into account a number of 3152 treated houses per day connected to the same STP, or of 1909 treated houses, appears unrealistic. A default number of houses connected to the same STP of 4000 is provided in the guidance on the Biocidal Products Regulation, Volume IV, Part B. That corresponds to 78.8 % and 47.72% of houses treated the same day by the ENCLEAN PAE Product, respectively. It is therefore not realistic to take these two values (3152 and 1909 treated houses) into account for the environmental evaluation.

According to the city scenario: leaching from paints, plasters and fillers applied in urban areas (2015), a number of houses treated daily ($N_{house,\ application}$) depends on the service life of the product. $N_{house,\ application}$ is calculated by the formula below and the result will be rounded up:

[3] Le parc de logements en France au 1er janvier 2014, INSEE Références, 2014 (http://www.insee.fr/fr/themes/document.asp?ref_id=if16) as consulted the 17th November 2016.

[4] OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18. EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES, IOMC, 2008

$$n_{house,application} = \frac{n_{house,city}}{service\ life \times 365}$$

Where:

- $N_{house,\ city}$ = number of houses in a city (4000);
- Service life = service life of the preserved products (0.5 year, the ENCLEAN PAE product is applied twice per year);
- 365 = number of days in a year.

To conclude, emissions from indirect environmental exposure was calculated considering 22 treated houses per day connected to the same STP.

Table 16 PECstp

Usage scenario		**Local release to waste water (kg/d)**	**Local concentration in untreated wastewater Clocalinf (mg.l^{-1})**	**STP-effluent concentration (mg.l^{-1}) (PECSTP)**
Emission due to application	One treated house (per day)	7.30E-02	3.65E-02	4.58E-03
	3152 treated houses (per day)	2.30E+02	1.15E+02	1.44E+01
	57 treated houses (per day)	4.16	2.08	2.61E-01
	1909 treated houses (refined with a simultaneity factor)	4.18	2.09	2.62E-01
Emission due to rinse (worst case)	One treated house (per day)	1.28E-01	6.40E-2	8.04E-03
	3152 treated houses (per day)	4.03E+02	2.02E+02	2.53E+01
	57 treated houses (per day)	7.30	3.65	4.58E-01
	1909treated houses (refined with a simultaneity factor)	7.33	3.67	4.60E-01

FR-CA box 27: *FR Opinion*

Application and rinsing are performed the same day; consequently emissions to STP can be added.

PEC stp - (house scenario – application and rinsing by a rainfall event)

Usage scenario		**Local release to waste water (kg/d)**	**Local concentration in untreated wastewater Clocal $_{inf}$ (mg.l^{-1})**	**STP-effluent concentration (mg.l^{-1}) (PEC$_{STP}$)**
22 treated houses (per day)	Application	1.95	9.74E-01	1.23E-01
	Application + rinsing	6.49	3.25	4.09E-01

Using the effluent concentration estimated and the default dilution parameters, the surface water and sediment concentrations can be calculated as below:

Table 17 PECsw

Usage scenario		**Local concentration in surface water Clocal$_{water}$ (mg.l^{-1}) (PEC$_{sw}$)**	**Local concentration sediment (mg.kg $_{wwt}^{-1}$) PEC$_{sed}$**
Emission due to application	One treated house (per day)	4.58E-04	8.29E-04
	3152 treated houses (per day)	4.59E-03	8.31E-03
	57 treated houses (per day)	2.61E-02	4.73E-02
	1909 treated houses (refined with a simultaneity factor)	2.62E-02	4.75E-02
Emission due to rinse (worst case) 100% wash-off	One treated house (per day)	8.04E-04	1.46E-03
	3152 treated houses (per day)	2.53	4.58
	57 treated houses (per day)	4.58E-02	8.29E-02
	1909 treated houses (refined with a simultaneity factor)	4.60E-02	8.32E-02

FR-CA box 28: *FR Opinion*

PEC surface water *via* STP (house scenario – application and rinsing by a rainfall event)

Usage scenario		**Local concentration in surface water C local $_{water}$ (mg.l^{-1}) (PEC $_{sw}$)**
22 treated houses (per day)	Application	1.23E-02
	Application + rinsing	4.09E-02

PEC surface water – Direct release (Bridge scenario - application and rinsing by a rainfall event)

Usage scenario	**Local concentration in surface water C local $_{water}$ (mg.l^{-1}) (PEC $_{sw}$)**
Application	3.28E-03
Application and rinsing by a rainfall event	1.09E-02

2.2.12.1.1.11 PEC IN SOIL AND GROUNDWATER

The use of the biocidal product leads to a soil exposure.
For "House in the countryside" and "Fence" scenario, direct emissions of Nonanoic Acid to soil are considered. A summary of results obtained previously is presented below;
In a first Tier, PEC $_{soil}$ due to direct releases to soil (Runoff and spray drift) were calculated without considering degradation of the substance in accordance with ESD PT10 and ESD PT8.

Table 18 Tier 1, PEC $_{soil}$ for direct soil exposure

Usage scenario		**Receiving Compartment**	**Concentration in local soil (kg.kg$_{wwt}^{-1}$)**	**Concentration in local soil (mg.kg$_{dwt}^{-1}$)**
Application	House in the countryside	Soil distant to treated surface	1.00E-07	1.13E-01
		Soil adjacent to treated surface	2.20E-06	2.49E+00
	Fence	Soil distant to treated surface	5.2E-09	5.82E-03

		Soil adjacent to treated surface	2.12E-05	2.40
Service life (rinse) 100% wash-off	House in the countryside	Soil distant to treated surface	2.76E-07	3.12E-01
		Soil adjacent to treated surface	7.10E-05	9.02
	Fence	Soil distant to treated surface	1.24E-08	1.40E-02
		Soil adjacent to treated surface	7.69E-05	8.69

FR-CA box 29: *FR Opinion*

Application and rinsing (by a rainfall event) are performed the same day; consequently emissions to soil can be added. Fence scenario is covered by House scenario.

Tier 1, PEC $_{soil}$ for direct soil exposure (house scenario)

Usage scenario	**Receiving Compartment**	**Initial concentration in local soil ($mg.kg_{wwt}^{-1}$)**
Emission due to application	Soil distant to treated surface	1.22E-01
	Soil adjacent to treated surface	2.67
Emission due to rinsing	Soil distant to treated surface	2.13E-01
	Soil adjacent to treated surface	7.01
Emission due to application + rinsing	Soil distant to treated surface	3.34E-01
	Soil adjacent to treated surface	9.68

In a second Tier, PEC $_{soil}$ were calculated taking degradation processes into account. A degradation rate of k = 0.231 d^{-1} was applied to initial concentrations in soil, based on a half-life of nonanoic acid in soil of 3 days. In accordance with the guidance on the Biocidal Products Regulation Volume IV[5], concentrations in soil were averaged over 30 days in order to evaluate risk to terrestrial ecosystems.
The following equation was used to calculate concentrations in soil averaged over 30 days, taking degradation processes into account:

[5] Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), V.1 April 2015, ECHA

Concentration in receiving soils due over 30 days:

$$C\ local\ soil_{(30\ days)} = C\ local\ soil_{(initial)} * Exp\ (-k/30)$$

Table 19 Tier 2, PEC $_{soil}$ for direct soil exposure

Usage scenario		Receiving Compartment	Concentration in local soil (mg/kgdwt)
Application	House in the countryside	Soil distant to treated surface	1.0E-04
		Soil adjacent to treated surface	2.43E-03
	Fence	Soil distant to treated surface	4.10E-05
		Soil adjacent to treated surface	8.99E-04
Service life (rinse) 100% wash-off	House in the countryside	Soil distant to treated surface	1.13E-04
		Soil adjacent to treated surface	3.26E-03
	Fence	Soil distant to treated surface	1.40E-02
		Soil adjacent to treated surface	8.69

FR-CA box 30: *FR Opinion*

According to the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013), a worst case scenario taking into account degradation processes has been carried out. The calculations below demonstrate the degradation of this amount of the active substance as a function of time (days) aiming to present the number of days it will take to reach the PNEC soil meeting an acceptable risk.

A half-life of nonanoic acid in soil of 2.1 days is used to estimate PEC soil with degradation processes. This results to a degradation rate of k=0.33 d^{-1}.

$$Clocal\ soil_{(30\ days)} = Clocal\ soil_{(initial)} * Exp(-k*t)$$

Tier 2, PEC $_{soil}$ for direct soil exposure (application + rinsing)

Usage scenario	Receiving Compartment	Concentration in local soil (mg.kg_{wwt}^{-1})		
		0 day	7 days	14 days
Emission due to application	Soil distant to treated surface	1.22E-01	1.21E-02	1.20E-03
	Soil adjacent to treated surface	2.67	2.65E-01	2.63E-02
Emission due to rinsing	Soil distant to treated surface	2.13E-01	2.11E-02	2.09E-03

	Soil adjacent to treated surface	7.01	6.96E-01	6.90E-02
Emission due to application + rinsing	Soil distant to treated surface	3.34E-01	3.32E-02	3.29E-03
	Soil adjacent to treated surface	9.86	9.61E-01	9.53E-02

Due to degradation and according to the half-life of 2.1 days, concentrations of Nonanoic acid in soil after 15 days is below the PNEC $_{soil}$ of 0.0990 mg.kg$_{wwt}^{-1}$, if 100% of the product leaches from 1 treated house in 1 day into the soil adjacent to the house.

- For "House in a City" scenario where emissions are directed to sewage systems, indirect emissions via sludge loadings on soil must be determined. Therefore, PECs in soil were calculated using EU TGD models as it has been done previously for STP, surface water and sediment assessment.

Table 20 PEC $_{soil}$ considering indirect exposure

Usage scenario			**Local PEC in agricultural soil averaged over 30 days (PEC_{soil}) (mg.kg$_{dwt}^{-1}$)**	**Local PEC in agricultural soil averaged over 180 days (PEC_{soil}) (mg.kg$_{dwt}^{-1}$)**	**Local PEC in grassland averaged over180 days (PEC_{soil}) (mg.kg$_{dwt}^{-1}$)**
PT10 House in a city	Application	One treated house (per day)	4.63E-04	1.35E-04	4.61E-05
		3152 treated houses (per day)	1.46	4.25E-01	1.45E-01
		57 treated houses (per day)	2.64E-2	7.70E-03	2.63E-03
		1909 treated houses (refined with a simultaneity factor)	2.65E-02	7.73E-03	2.64E-03
	Service-life (rinse)	One treated house (per day)	8.11E-04	2.36E-04	8.08E-05

	100 % wash-off	3152 treated houses (per day)	2.56	7.46E-01	2.55E-01
		57 treated houses (per day)	4.63E-02	1.35E-02	4.61E-03
		1909 treated houses (refined with a simultaneity factor)	4.65E-02	1.36E-02	4.63E-03

FR-CA box 31: *FR Opinion*

It has been considered that 22 houses are treated on a single day by ENCLEAN PAE product. Application and rinsing (by a rainfall event) are performed the same day; consequently emissions to soil can be added.

A fraction to sludge of 0.6% and a half-life of nonanoic acid in soil of 2.1 days have been considered according to Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013).

PEC $_{soil}$ for indirect soil exposure

Usage scenario	**Local PEC in agricultural soil averaged over 30 days (PEC $_{soil}$) ($mg.kg_{wwt}^{-1}$)**	**Local PEC in agricultural soil averaged over 180 days (PEC $_{soil}$) ($mg.kg_{wwt}^{-1}$)**
Emission due to application - 22 treated houses (per day)	2.15E-03	3.59E-04
Emission due to application + rinsing (by a rainfall event) - 22 treated houses (per day)	7.18E-03	1.20E-03

According to the OECD ESD on wood preservatives (Appendix 4, p. 178)[6] for substances with low Kocs or high DT_{50}s in soil there is a concern for groundwater and an assessment must be made.

Therefore, potential environmental emissions of nonanoic acid to groundwater have been assessed above, based on available guidances.

Simulations were conducted using two modelling softwares: FOCUS PELMO (v5.5.3) and FOCUS PEARL (4.4.4) and following the FOCUS working group recommendations (FOCUS, 2000[7], 2009[8] and 2011[9]).

[6] Groundwater exposure assessment for wood preservatives Factors to consider

[7] SANCO/321/2000 rev.2: FOCUS groudwater scenarios in the EU review of active substances.-

[8] FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp

[9] FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater assessments, Version 2.0, January 2011.

As realistic worst-case, an overall vulnerability corresponding to the 90th percentile of predicted concentration in groundwater is defined. This is approximated by combining a 80th percentile value for soil and a 80th percentile value for weather. The softwares and the different scenario properties are described in the FOCUS document (FOCUS, 2000).
Location of the scenarios and the main properties are shown in the table below.

Figure 9.6-1 Location of the 9 groundwater scenarios (excerpt from FOCUS, 2009)

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Table 21 Properties of the 9 groundwater scenarios

Location	Mean Annual Temp. (°C)	Annual Rainfall (mm)	Topsoil	Org. matter (%)
Châteaudun	11.3	648 + I*	Silty clay loam	2.4
Hamburg	9.0	786	Sandy loam	2.6
Jokioinen	4.1	650	Loamy sand	7.0
Kremsmünster	8.6	899	loam/silt loam	3.6
Okehampton	10.2	1038	loam	3.8
Piacenza	13.2	857 + I*	Loam	2.2
Porto	14.8	1150+ I*	loam	2.5
Sevilla	17.9	493+ I*	Silt loam	1.6
Thiva	16.2	500 + I*	loam	1.3

* I: Irrigation

Groundwater assessment has been performed for a realistic worst-case scenario according to the guidance document "Groundwater exposure assessment for wood preservatives Factors to consider". This worst-case scenario is defined by applications of a biocidal product on 35 houses per hectare, corresponding to a total treated area of 4375 m ² per hectare. According to the guidance document, the assessment is based on ten applications a year of an intended rate of biocidal product split by ten.

Use conditions claimed by the Applicant are presented below:

Conditions	Values	Unit
Concentration on ENCLEAN PAE product	500	$g_{as}.l^{-1}$
Volume of ENCLEAN PAE product used for 100 m² area to be treated	0.18	l
Volume of diluted product for 100 m² area to be treated	5	l
Surface to be treated	100	m²
Concentration in diluted product (ready to use)	18	$g_{as}.l^{-1}$
Application rate of substance	0.9	$g_{as}.m^{-2}$

According to the worst-case scenario defined previously with a total treated area of 4375 $m^2.ha^{-1}$, the application rate in kilograms per hectare taken into account for ground

water assessment is about 3.39375 kg $_{as}$.ha^{-1} per year (Application rate (g.m^{-2}) x Area (m².ha^{-1}) .1000^{-1}).

In order to weight over time the exposition of Nonanoic Acid, the single application of 3.39375 kg as /ha per year is split into 10 applications about 0.3937 kg as /ha per year.

Parameters used for the groundwater assessment are presented below:

Input	**Values**
Molecular weight (g.mol^{-1})	158.2
Vapour pressure (Pa, at 20°C)	0.9
Octanol-water partition coefficient (as log)	2.4
Water solubility (mg.l^{-1} at 25°C)	202.7
$K_{oc\ (soil)}$ (L/kg)	47.3
DT_{50}soil (at 20°C) (d)	3
Freundlich exponent (-)	0.9
Split application rate (kg.ha^{-1})	0.39375
Nb applications (year^{-1})	10
Crop	Grass

Chosen dates for split applications are presented below:

	Date of split applications
1st Application	15/01
2nd Application	15/03
3rd Application	15/04
4th Application	15/05
5th Application	15/06
6th Application	15/07
7th Application	15/08
8th Application	15/09
9th Application	15/11
10th Application	15/12

Nine realistic worst-case scenarios have been defined, which collectively represent agricultural use in the EU.

Results for the two FOCUS models are presented in tables below.

Scenario	**80th Percentile PECGW at 1 m Soil Depth (μg.l^{-1})**	
	PELMO 5.5.4	**PEARL4.4.4**
Châteaudun	<0.001	<0.001
Hamburg	<0.001	0.010
Jokioinen	<0.001	0.001
Kremsmünster	<0.001	<0.001
Okehamtpon	0.001	0.014
Piacenza	0.001	0.020
Porto	0.002	0.063
Sevilla	<0.001	0.003
Thiva	<0.001	<0.001

For both simulations, PECs gw are all below the threshold of 0.1 μg.l^{-1}.

FR-CA box 32: *FR Opinion*

A groundwater assessment via FOCUS PEARL was conducted for direct release to soil. Concerning the groundwater assessment after sewage sludge application, an assessment was not carried out as the application rate for arable land (1.80E-06 kg/ha) or grassland (3.60E-07 kg/ha) was substantially lower than the one calculated for the direct release to the soil (0.861 kg/ha).

In a worst-case approach, groundwater assessment has been revised considering the inputs parameters from the Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013). Application dose has been estimated in taking into account the amount used for 35 houses spread over 12 annual applications per year.

Note that in the ESD PT 8, 16 houses for 2 applications per year is considered, which is covered by the current assessment.

Input parameter PEARL 4.4.4	**Unit**	**Value**	**Reference**
Product name : ENCLEAN PAE			

Substance name : Nonanoic acid			
Physicochemical parameters			
Molecular weight	$g.mol^{-1}$	158.2	AR
Water solubility (20 °C, pH 5)	$mg.l^{-1}$	415	AR
Molar enthalpy of dissolution	$kJ.mol^{-1}$	27	Default
Saturated vapour pressure (20°C)	Pa	0.9	AR
Molar enthalpy of vaporisation	$kJ.mol^{-1}$	95	Default
Diffusion coefficient in water (20 °C)	$m^2.d^{-1}$	4.3E-05	Default
Diffusion coefficient in air (20 °C)	$m^2.d^{-1}$	0.43	Default
Degradation parameters			
Half-life (, pF2) (12°C)	d	2.1	AR
Arrhenius activation energy	$kJ.mol^{-1}$	65.4	Default
Exponent of moisture correction function	-	0.7	Default
Sorption parameters			
K_{oc} value	$l.kg^{-1}$	63.1	AR
K_{om}value (20°C)	$ml.g^{-1}$	36.6	AR
Freundlich exponent 1/n	-	1	Default
Method of subroutine description	-	pH independent	-
Crop related parameters			
Crop uptake factor	-	0	Default
Application Schemes			
Dosage	$kg.ha^{-1}$	0.861	
	D = (1.093 $g_{as}.m^{-2}$ *270 m^2 *35 houses) / 12 = 0.732		
Application type	-	To the soil surface	/
Repeat interval for years	-	1	
Date	-	15/01	The product can be applied anytime in the year.
		15/02	
		15/03	
		15/04	
		15/05	
		15/06	
		15/07	
		15/08	
		15/09	
		15/10	
		15/11	
		15/12	
Crops Application			
Crop(s)	-	**Grassland**	
Selected Locations		CHATEAUDUN	
		HAMBURG	
		JOIKIONEN	

	KREMSMUENSTER
	OKEHAMPTON
	PIACENZA
	PORTO
	SEVILLA
	THIVA

Results

Scenario	**80th Percentile PECGW at 1 m Soil Depth (μg.l^{-1})**
	PEARL4.4.4
Châteaudun	<0.001
Hamburg	<0.001
Jokioinen	<0.001
Kremsmünster	<0.001
Okehamtpon	<0.001
Piacenza	<0.001
Porto	<0.001
Sevilla	<0.001
Thiva	<0.001

2.2.12.1.1.12 PEC IN AIR

The vapour pressure of Nonanoic acid at ambient temperature 0.9 Pa (20°C) and Henry's law constant is 0.33 Pa.m^3.mol^{-1} at 20°C (with a water solubility of 0.2027 g/L). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

Usage scenario	**Concentration in air during emission episode (mg/m^3)**
PT10: House in a city	1) 2.78E-9 2) 7.50E-9

FR-CA box 33: *FR Opinion*

Not relevant. As stated in the Assessment Report of nonanoic acid, with an half life in air of 39.4h, an accumulation of nanoic acid is not to be expected in the atmosphere.

2.2.12.2 Risk characterisation

Regarding cases as exposed in section 2.4 of the present document, risk characterisation for indirect environmental exposure was calculated considering several number of potential treated houses connected to the same STP. The scenarios are described as below:

- One treated house per day connected to a STP

- *3152 treated houses per day connected to the same STP, based on 15 million of potentially concerned houses in France according to JADE's previsions without any refinement (60 million of French people, divided by 4 manufacturers that produce similar biocide product as ENCLEAN PAE). This number of houses has been compared to the total number of individual houses in France (INSEE, 2014[10]). The obtained fraction of potentially treated houses was then reported to the default number of 4000 houses connected to the same STP provided by ESD PT10 for city scenario. This simulation is considered as a worst case, as it considers that 100% (80% of French individual houses) the potentially concerned houses are treated the same day with ENCLEAN PAE product.*

- *57 treated houses per day connected to the same STP. Based on the maximum number of houses treated the same day leading to an acceptable risk for all environmental compartments without any refinement. A rate of 57 houses per STP corresponds to a number of 271 305.8 houses (based on the previous INSEE ref.) at a national scale (1% of French individual houses).*

- *1909 treated houses connected to the same STP. In order to provide a more realistic evaluation, a factor of simultaneity of treatments of houses with ENCLEAN PAE was taken into account as for a refinement. The number of 1909 houses corresponds to the maximum number of treated houses leading to acceptable risks for environmental compartments considering a factor of simultaneity of 0.03. This factor is provided by the ESD for PT18 "Emission Scenario Document For Insecticides, Acaricides and Products to control Arthropods for Household and Professional Uses"[11], 2008. It is used to estimate emission rates of an active substance to the sewage system per day following applications of outdoor insecticides. This factor is considered as sufficiently conservative as outdoor algaecides are intended to be used at a lower frequency than outdoor insecticides. A rate of 1909 houses per STP corresponds to a number of 9 086 362.8 houses at a national scale (48 % of French individual houses) which is a realistic worst case.*

[10] Le parc de logements en France au 1er janvier 2014, INSEE Références, 2014 (http://www.insee.fr/fr/themes/document.asp?ref_id=if16)

[11] OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18. EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES, IOMC, 2008

FR-CA box 34: *FR Opinion*

An emission from indirect environmental exposure was calculated considering 22 treated houses connected to the same STP (Please see BOX 24 for more explanation).

Aquatic compartment

Predicted Environmental Concentrations (PEC) for the aquatic compartment

Due to the highly conservative nature of the emission scenarios considered, the estimated PEC values are likely to be over estimates. Furthermore, as a worst-case situation, no removal or loss mechanisms are taken into account and due to the retentive properties of the active substance in the environment, it is considered that the majority of the emitted amounts will not actually make it from the point source to the STP location.

Assessment of risk for the aquatic compartment

The risk assessment is based on a comparison of the PNEC value for the aquatic compartment with the relevant PEC value. A PEC/PNEC ratio of less than one indicates that the risks are acceptable associated with the use of formulated products containing Nonanoic acid.

Table 22 Summary of the PECsw and PNECsw values together with the PEC/PNEC values

Used Scenario			**Worst-case PEC $_{sw}$ (mg.l^{-1})**	**PNEC $_{sw}$ (mg.l^{-1})**	**Worst-case PEC/PNEC ratio**
House scenario PT10	One treated house (per day)	Releases during application	4.58E-04	4.6E-2	9.96^{E}-03
		Releases during rinsing	8.04E-04		1.75^{E}-02
	3152 treated houses (per day)	*Releases during application*	*1.44*		*3.14^{E}+01*
		Releases during rinsing	*2.53*		*5.50^{E}+01*
	57 treated houses (per day)	*Releases during application*	*2.61E-02*		*5.68^{E}-01*
		Releases during rinsing	*4.58E-02*		*9.95^{E}-01*
	1909 treated houses (refined with a simultaneity factor)	*Releases during application*	*2.62E-02*		*5.70^{E}-01*
		Releases during rinsing	*4.60E-02*		*9.998^{E}-01*
Bridge over pond scenario PT8		Releases during application	2.70E-03		5.87E-02
		Releases during rinsing	9.01E-03		1.96E-01

As PNECsed was calculating, the PECsed/PNECSed ratio is increased by a factor of 10 in order to take uptake via ingestion of sediment into account. (BPR: Volume IV Part B Risk Assessment Version 1.0 April 2015.).

Table 23 Summary of the PECsed and PNECsed values together with the PEC/PNEC values

Used Scenario			Worst-case PEC $_{sed}$ (mg.Kg$_{wwt}^{-1}$)	PNEC $_{sed}$ (mg.Kg$_{wwt}^{-1}$)	Worst-case PEC/PNEC ratio x 10
House scenario PT10	One treated house (per day)	Releases during application	8.29E-04	0.0833	9.95E-03
		Releases during rinsing	1.46E-03		1.75E-02
	3152 treated houses (per day)	*Releases during application*	*2.61*		*3.14E+01*
		Releases during rinsing	*4.58*		*5.50E+01*
	57 treated houses (per day)	*Releases during application*	*4.73E-02*		*5.67E-01*
		Releases during rinsing	*8.29E-02*		*9.95E-01*
	1909 treated houses (refined with a simultaneity factor)	*Releases during application*	*4.75E-02*		*5.70E-01*
		Releases during rinsing	*8.32E-02*		*9.99E-01*
Bridge over pond scenario PT8		Releases during application	4.89E-03		5.87E-02
		Releases during rinsing	0.0163		1.96E-01

These PEC/PNEC ratios indicate that no unacceptable risks to sediment dwelling biota arise from the use of the formulations containing Nonanoic acid, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day.

Considering the claim of the applicant, the risk for aquatic organisms is acceptable.

FR-CA box 35: *FR Opinion*

PEC/PNEC values for surface water

Used Scenario	PEC/PNEC ratio

Indirect releases via the STP House scenario PT10 - 22 treated houses (per day)	Releases during application	2.16E-01
	Releases during application + rinsing	7.20E-01
Direct releases Bridge over pond scenario PT8	Releases during application	5.77E-02
	Releases during application + rinsing	1.92E-01

The sediment risk assessment is equal to the aquatic risk assessment as both PEC $_{sediment}$ and the PNEC $_{sediment}$ have been calculated by EPM from the PEC $_{local,water}$ and the PNEC $_{aquatic}$, respectively.

Conclusion: the risk for aquatic organisms is acceptable.

STP compartment

Predicted environmental concentrations (PEC)
Summary of the PEC_{STP} and $PNEC_{STP}$ values together with the PEC/PNEC values (Worst-case assumptions - STP compartment)

Table 24 Summary of the PECstp and PNECstp values together with the PEC/PNEC values

Used Scenario			**Worst-case PECSTP ($mg.l^{-1}$)**	**PNECSTP ($mg.l^{-1}$)**	**Worst-case PEC/PNEC ratio**
House scenario PT10	One treated house (per day)	Releases during application	4.58E-03	5.652	8.10E-04
		Releases during rinsing	8.04E-03		1.42E-03
	3152 treated houses (per day)	*Releases during application*	*1.44E+01*		*2.55*
		Releases during rinsing	*2.53E+01*		*4.48*
	57 treated houses (per day)	*Releases during application*	*2.62E-01*		*4.64E-02*
		Releases during rinsing	*4.60E-01*		*8.14E-02*
	1909 treated houses (refined with a simultaneity factor)	*Releases during application*	*4.58E-01*		*8.10E-02*
		Releases during rinsing	*8.03E-01*		*1.42E-01*

For all scenarios, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day, the risk is acceptable for STP micro-organisms. The sub-scenario was adjusted considering use claimed by the applicant.
According to the Risk Assessment TGD supporting Commission Directive 93/67/EEC for new notified substances, Commission Regulation (EC) No 1488/94 for existing substances and Directive 98/8/EC for biocidal products, this indicates that no unacceptable risks to sewage micro-organisms arise from the use of the formulations containing Nonanoic acid.

FR-CA box 36: *FR Opinion*

PEC/PNEC values for stp

Used Scenario		**PEC/PNEC ratio**
Indirect releases via the STP House scenario PT10 - 22 treated houses (per day)	Releases during application	2.17E-02
	Releases during application + rinsing	7.24E-02

Conclusion: the risk for STP organisms is acceptable.

Atmosphere

The vapour pressure of Nonanoic acid at ambient temperature is 0.9 Pa (20°C) and Henry's law constant is 0.33 $Pa.m^3.mol^{-1}$ at 20°C (with on a water solubility of 0.2027 g/L). Furthermore, the photochemical oxidative degradation half-life of Nonanoic acid air was estimated using the Atmospheric Oxidation Program v1.92 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). The estimated half-life of Nonanoic acid in air via hydroxyl reactions is calculated to 1.096 d. Therefore, Nonanoic acid is not expected to persist in air.

FR-CA box 37: *FR Opinion*

Not relevant.

Terrestrial compartment

According to usage patterns described, emissions of the active substance to soil are considered to occur via STP sludge loadings after STP treatment; therefore, PECs in soil and groundwater have been calculated.

Indirect Emissions to soil

PECsoil due indirect releases via sludge application were calculated for 1, 57 and 3152 houses considering releases to STP occurring the same day. PECsoil were also calculated for 1909 houses considering a simultaneity factor of 0.03.

Averaged over 30 days PECsoil due to indirect emission of substance to agricultural soil via sludge application and PEC/PNEC ratio are presented in table below:

Table 25 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Indirect releases to soil

Used Scenario				**PECsoil (30d) ($mg.Kg_{dwt}^{-1}$)**	**PNECsoil ($mg.Kg_{dwt}^{-1}$)**	**PEC/PNEC ratio**
PT10 House	**House in a city (agricultural soil)**	One treated house (per day)	Releases during application	4.63E-04	0.0931	4.97E-03
			Releases during rinsing (100%wash-off)	8.11E-04		8.71E-03
		3152 treated houses (per day)	*Releases during application*	*1.46*		*1.57E+01*
			Releases during rinsing (100%wash-off)	*2.56*		*2.75E+01*
		57 treated houses (per day)	*Releases during application*	*2.64E-02*		*2.83E-01*
			Releases during rinsing (100%wash-off)	*4.63E-02*		*4.97E-01*
		1909 treated houses (refined with a simultaneity factor)	*Releases during application*	*2.65E-02*		*2.85E-01*
			Releases during rinsing (100%wash-off)	*4.65E-02*		*4.99E-01*

Regarding the scenario "House in a city" use, except the unrealistic scenario, all scenario lead to an acceptable risk regarding indirect release to soil after treatment even with rinsing.

Direct Emissions to soil

Tier 1 PECsoil due to direct emissions to adjacent soil and associated PEC/PNEC ratios are presented in table below. In Tier one, PECsoils were calculated without taking degradation processes into account.

Table 26 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Direct releases to soil - T1, without degradation process.

Used Scenario	**PECsoil ($mg.Kg_{dwt}^{-1}$)**	**PNECsoil ($mg.Kg_{dwt}^{-1}$)**	**PEC/PNEC ratio**

House in the countryside (soil adjacent to the treated area application)	Releases during application	2.49	0.0931	26.7
	Releases during rinsing (100%wash-off)	9.02		96.9
Fence scenario PT8 (soil adjacent to the treated area)	Releases during application	0.92		9.89
	Releases during rinsing (100%wash-off)	3.34		35.83

As a first-tier approach, and without taking into account degradation process, Risk to soil following a direct release is always unacceptable. A tier 2 approach with a refinement is therefore necessary and degradation properties of nonanoic acid are considered.
Tier 2 PECsoil due to direct emissions to adjacent soil and associated PEC/PNEC ratios are presented in table below. In second Tier, PECsoils were calculated taking degradation processes into account and averaged over 30 days.

Table 27 Summary of the PECsoil and PNECsoil values together with the PEC/PNEC values - Direct releases to soil – T2 with degradation process as a refinement.

Used Scenario		**PECsoil (mg.Kg_{dwt}^{-1})**	**PNECsoil (mg.Kg_{dwt}^{-1})**	**PEC/PNEC ratio**
House in the countryside (soil adjacent to the treated area application)	Releases during application	2.43E-03	0.0931	2.61E-02
	Releases during rinsing (100%wash-off)	8.81E-03		9.46E-02
Fence scenario PT8 (soil adjacent to the treated area)	Releases during application	8.99E-04		9.65E-03
	Releases during rinsing (100%wash-off)	3.26E-03		3.50E-02

According to the Risk Assessment TGD supporting Commission Directive 93/67/EEC for new notified substances, Commission Regulation (EC) No 1488/94 for existing substances and Directive 98/8/EC for biocidal products, this indicates that no unacceptable risks to terrestrial organisms arise from the use of the formulations containing Nonanoic acid when considering application on urban houses, except for the unrealistic worst-case scenario which assumes a maximum of houses treated the same day.

All Tier 1 PEC/PNEC ratios for direct releases to soil are >1. In a higher tier, when taking degradation processes of nonanoic acid in soil into account, no unacceptable risks to terrestrial organisms.

No unacceptable risks to terrestrial organisms arise from the use of ENCLEAN PAE product on urban houses, except for the unrealistic worst-case scenario which assumes a maximum of

houses treated the same day, even with rinsing after treatment.

FR-CA box 38: *FR Opinion*

Indirect Emissions to soil - PEC/PNEC values

Used Scenario		PEC/PNEC ratio
House city scenario PT10 - 22 treated houses (per day)	Releases during application	2.18E-02
	Releases during application + rinsing	7.25E-02

Indirect emission to soil: the risk for soil organisms is acceptable.

Direct Emissions to soil - PEC/PNEC values - with degradation process as a refinement

Usage scenario	Receiving Compartment	PEC/PNEC ratio		
		0 day	**7 days**	**14 days**
Emission due to application	Soil distant to treated surface	**1.23**	11.22E-01	1.21E-02
	Soil adjacent to treated surface	**26.97**	**2.68**	2.66E-01
Emission due to rinsing	Soil distant to treated surface	**2.15**	2.13E-01	2.11E-02
	Soil adjacent to treated surface	**70.81**	**7.03**	6.97E-01
Emission due to application + rinsing	Soil distant to treated surface	**3.37**	3.35E-01	3.32E-02
	Soil adjacent to treated surface	**99.60**	**9.71**	9.63E-01

Direct emission to soil: PEC/PNEC ratio is acceptable on day 14 after application. According to Assessment Report of the active substance (see Assessment Report of Nonanoic acid, PT2, July 2013), 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.

Moreover, nonanoic acid is readily biodegradable and has a DT50soil 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. Consequently the following risk mitigation measures and instruction of use are recommended, in order to avoid any possible harm:

- During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment.
- Products can only be used if the weather forecasts show no rain for the day of application.
- Do not clean the surface after treatment.

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 to be acceptable.

Therefore, 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 possibly if the proposed RMM above are ignored. Furthermore, in the CAR of nonanoic acid, a risk is pointed out in the adjacent soil, up to 15 days (included) after the product application. As the risk for the adjacent soil is acceptable after 14 days, the ENCLEAN PAE product is compliant with the conditions of approval of the substance.
Moreover, regarding the environmental profile of the a.s. (readily biodegradability, low potential of bioaccumulation, half-time life in soil and air...), the risk for soil organisms can be considered acceptable.

Nevertheless, we underline the importance to clearly distinguish nonanoic acid from other products with algicide 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 RMM.**Conclusion**: In accordance with the conclusions of Nonanoic acid CAR, the risk for soil organisms can be considered acceptable.

Primary and secondary poisoning

FR-CA box 39: *FR Opinion*

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.

Conclusion: 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.

Overall conclusion on the risk assessment for the environment of the product

FR-CA box 40: *FR Opinion*

Phase	STP	Surface water		Sediment		Soil		Groundwater		Sec. Poisoning
		Direct Release	*Via* STP	Direct Release	*Via* STP	Direct Release	*Via* STP	Direct Release	*Via* STP	*Via* STP
ENCLEAN PAE product										
Application	Non acceptable risks without RMMs									
Rinsing										

Following risk mitigation measures shall be established in order to protect the environment:

- Products can only be used if the weather forecasts show no rain for the day of application.
- During the application, the ground and plants adjacent to the treated area shall be protected to avoid emission to the environment

2.2.13 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.14 Assessment of a combination of biocidal products

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Member State Data Protection Claimed (Y/N)	Owner
[redacted]	[redacted]	Determination of the Accelerated Storage Stability of VVH 86087 Report number 82929204	Y	JADE
[redacted]	[redacted]	Determination of the Low Temperature Stability of VVH 86087 Report number 82928204	Y	JADE
[redacted]	[redacted]	Oxidising properties Study report 2013045203	Y	JADE
[redacted]	[redacted]	Explosive properties Study report 20130452.01	Y	JADE
[redacted]	[redacted]	Auto-ignition temperature Study report 20130452.02	Y	JADE
[redacted]	[redacted]	Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087 Project 83241101	Y	JADE
[redacted]	[redacted]	Determination of Free Acidity / Alkalinity of Enclean Prêt à l'emploi S16-01013	Y	JADE
[redacted]	[redacted]	Relative Density of Enclean Prêt à l'emploi S16-01010	Y	JADE
[redacted]	[redacted]	Surface Tension of Enclean Prêt-à-l'emploi S16-01006	Y	JADE
[redacted]	[redacted]	Viscosity of Enclean Prêt à l'emploi S16-01003	Y	JADE
[redacted]	[redacted]	Ready to use (RTU): Method Validation	Y	Belchim
[redacted]	[redacted]	Enclean: Persistent Foaming Study Number: BT88JV	Y	Belchim Crop Protection NV
[redacted]	[redacted]	Determination of the Accelerated Storage Stability of VVH 86087 Report number 82929204	Y	JADE
[redacted]	[redacted]	Determination of the Low Temperature Stability of VVH 86087 Report number 82928204	Y	JADE

[redacted]	[redacted]	Determination of the Relative Density of VVH 86087 Report number 82921182	Y	JADE
[redacted]	[redacted]	Determination of the Surface Tension of an aqueous solution of VVH 86087 Report number 82927184	Y	JADE
[redacted]	[redacted]	Determination of the Viscosity of VVH 86087 Report number 82926196	Y	JADE
[redacted]	[redacted]	Oxidising properties Study report 2013045203	Y	JADE
[redacted]	[redacted]	Explosive properties Study report 20130452.01	Y	JADE
[redacted]	[redacted]	Auto-ignition temperature Study report 20130452.02	Y	JADE
[redacted]	[redacted]	Validation of an Analytical Method for the Determination of Nonanoic Acid in Formulation VVH 86087 Project 83241101	Y	JADE

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)**	**Date of first submission**
[redacted]	[redacted]	Determination of efficacy of biocide BCP1011H against Algae on impermeable surfaces, R042-17H, not published, Philippe REYNENS, 17 May 2017	Yes	Jade	2017.06.07
[redacted]	[redacted]	Determination of efficacy of biocide BCP1011H against Algae on impermeable surfaces, H17NNNNN, not published, McConnell Kirsty, 26 April 2017	Yes	Jade	2017.06.07
[redacted]	[redacted]	Determination of efficacy of biocide BCP1011H against Algae on impermeable surfaces (painted plaster wall), Trial no. H17NNNNN01-SE01, Andrius Hansen Kemezys, 28 April 2017	Yes	Jade	2017.06.07

Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
				Yes	No	Yes	No	Yes	No
[redacted]	[redacted]	VVH 86086 EVALUATION OF ACUTE ORAL TOXICITY IN RATS - ACUTE TOXIC CLASS METHOD	JADE		x	x		x	
[redacted]	[redacted]	VVH 86086 EVALUATION OF ACUTE DERMAL TOXICITY IN RATS	JADE		x	x		x	
[redacted]	[redacted]	VVH 86087 ASSESSMENT OF ACUTE DERMAL IRRITATION	JADE		x	x		x	
[redacted]	[redacted]	VVH 86087 ASSESSMENT OF ACUTE EYE IRRITATION	JADE		x	x		x	
[redacted]	[redacted]	VVH 86086 ASSESSMENT OF SENSITISING PROPERTIES ON ALBINO GUINEA PIGS Maximisation test according to MAGNUSSON	JADE		x	x		x	

		AND KLIGMAN							
[redacted]	[redacted]	Pelargonic acid 21.7 g/L ready-to-use (AL) : sprayability testing during shelf-life storage stability (3 years) Report n°24749	BELCHIM		X	X		x	
[redacted]	[redacted]	Pelargonic acid 21.7 g/L ready-to-use (AL) : Physico-chemical properties and storage stability in HDPE and PET packagings Report n°24716	BELCHIM		X	X		x	
[redacted]	[redacted]	Determination of the Particle size distribution for "BCP1011H Enclean Prêt à l'emploi" and Calculation of Mass Median Aerodynamic Diameter (MMAD) Report Mo6531	BELCHIM		X	X		x	
[redacted]	[redacted]	Determination of the Particle size distribution and Calculation of Mass Median Aerodynamic Diameter (MMAD) for 'BCP1011H"	BELCHIM		X	X		x	

		Report Mo7305							

3.2 Output tables from exposure assessment tools

Not applicable

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

The product ENCLEAN PAE is intended to be used on building as disinfectant and algaecide. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[12]

3.6 Confidential annex

Please refer to the Confidential annex file.

3.7 Other

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