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)

3A MATE

Product type 18

Deltamethrin

NA-APP Case Number in R4BP: BC-YA022158-47
NA-ADC Case Number in R4BP : BC-RB027612-53
NA-MIC Case Number in R4BP : BC-HW031605-20

Evaluating Competent Authority: France

Date: June 2016

Amended November 2017

Contents

1 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

1.1 Applicant

Company Name:	LA CELLIOSE S.A. Division ARTILIN
Address:	Chemin de la Verrerie BP 58
City:	Pierre Bénite
Postal Code:	69492
Country:	France
Telephone:	+33 (0) 553 875 165
Fax:	+33 (0) 553 676 676
E-mail address:	

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr Tieulières Bruno
Function:	QHSE manager
Address:	Rue de la Verrerie
City:	Pierre Bénite
Postal Code:	69310
Country:	France
Telephone:	+ 33 (0) 478 02 32 45
Fax:	+ 33 (0) 478 02 32 32
E-mail address:	bruno.tieulieres@celliose.com

1.2 Current authorisation holder

Company Name:	LA CELLIOSE S.A. Division ARTILIN
Address:	Rue de la Verrerie
City:	Pierre Bénite
Postal Code:	69310
Country:	France
Telephone:	+33 (0) 553 875 165
Fax:	+33 (0) 553 676 676
E-mail address:	
Letter of appointment for the applicant to	no

represent the authorisation holder provided (yes/no):	

1.3 Proposed authorisation holder

Company Name:	LA CELLIOSE S.A. Division ARTILIN
Address:	Chemin de la Verrerie BP 58
City:	Pierre Bénite
Postal Code:	69492
Country:	France
Telephone:	+33 (0) 553 875 165
Fax:	+33 (0) 553 676 676
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	no

1.4 Information about the product application

Application received:	2013.11.18.
Application reported complete:	2014.01.23.
Type of application:	New Authorisation
Further information:	The assessment is base on the IUCLID dossier with UUID : IUC5-9cb61f5a-cb34-4df3-afa4-62612285d6e5

Application received:	2016.11.17
Application reported complete:	2016.11.30
Type of application:	Administrative change
Further information:	Change of the name of the authroisation horlder

Application received:	2017.04.12
Application reported complete:	2017.06.01
Type of application:	Minor change
Further information:	Change of the duration of efficacy of the product

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	3A MATE
Manufacturer's development code number(s), if appropriate:	21012
Product type:	PT18
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Deltamethrin 0.74%
Formulation type:	water-based, film-forming composition
Ready to use product (yes/no):	yes
Is the product the very same (identity and content) to another product already authorised under the regime of Directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to Directive 98/8/EC (yes/no):	no

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Insecticide and acaricide for indoor use (walls and ceilings).
Target organisms / stages:	Scientific name: *Dermatophagoides pteronyssinus*, common name: house dust mite, development stage: all. Scientific name: *Blattella germanica*, common name: german cockroach, development stage: adults. Scientific name: *Blatta orientalis*, common name: oriental cockroach, development stage: adults. Scientific name: *Aedes aegypti,* common name: mosquito, development stage: adults. Scientific name: *Aedes albopictus*, common name: mosquito, development stage: adults. Scientific name: *Culex pipiens*, common name: mosquito, development stage: adults. Scientific name: *Anopheles gambiae,* common name: mosquito,

	development stage: adults. Scientific name: *Musca domestica*, common name: house fly, development stage: adults. Scientific name: *Stomoxys calcitrans*, common name: stable fly, development stage: adults.
Category of users:	Professional users only.
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	The product is for indoor use on walls and ceilings. It can be used in industrial and commercial premises, in private and public areas and in equestrian centres and kennels. The product is not to be used in other breeding premises and on breeding and transportation equipment for domestic animals. Painting 3A MATE can be applied on every construction material (cement, plaster, wood, concrete…), with a suitable sub-coat, and on existing adhesive matt paint. 3A MATE must be applied with a paintbrush or a roller. Do not spray. The recommended application rate is 1L of ready-to-use 3A MATE to paint 14 m², *i.e.* 71.4 mL per m². One application is sufficient to provide control for 3 years.
Potential for release into the environment (yes/no):	No
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	
Use Restrictions:	The product is not to be used in other breeding premises and on breeding and transportation equipment for domestic animals. Do not spray.

For full details of the intended uses claimed by the applicant, please see annex 0a.

1.5.3 Information on active substance

Active substance chemical name:	Deltamethrin (S)-α-cyano-3-phenoxybenzyl (1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate
CAS No:	52918-63-5
EC No:	258-256-6
Purity (minimum, g/kg or g/l):	98.5 %
Inclusion directive:	Commission Directive 2011/81/EU
Date of inclusion:	2013 October 1st
Is the active substance equivalent to the active substance listed in Annex I to Directive 98/8/EC (yes/no):	Yes

Manufacturer of active substance(s) used in the biocidal product:	
Company Name:	**Bayer CropScience Limited** Bayer House, Central
Address:	Avenue Hiranandani Gardens
City:	Powai
Postal Code:	Mumbai – 400076
Country:	India
Contact:	
Telephone:	
Location of manufacturing site	
Company Name:	**Bayer Vapi Private Limited**
Address:	Plot 306/3, 2 Phase, GIDC
City:	Gujarat
Postal Code:	Vapi – 396195
Country:	India
Contact:	

1.5.4 Information on the substance(s) of concern

The product contains no substance of concern.

The product contains preservatives currently in the review program of active substances for PT6 or already approved for this type of product. The product also contains a preservative currently in the review program of active substances for PT7. The data related to these preservatives shall be taken into account in the evaluation after their approvals at European level, at product's renewal stage.

1.6 Documentation

1.6.1 Data submitted in relation to product application

Identity, physicochemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product 3A MATE were provided by La Celliose.
La Celliose S.A. has access to physico-chemical properties studies and analytical methods on the active substance with a Letter of Access of Bayer.

Efficacy data

- Laboratory study according to CEB N°135[1] method with the product 3A MATE, (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Blattella germanica* (German cockroach), *Blatta orientalis* (Oriental cockroach), *Culex pipiens* (mosquito), *Aedes aegypti* (mosquito), *Aedes albopictus* (mosquito), *Anopheles gambiae* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite).
- Laboratory study according to internal method with the product 3A MATE, (0.74 % w/w deltamethrin) on *Stomoxys calcitrans* (stable fly).

[1] CEB n°135 method: « Efficacy trial method for acaricide / insecticide products intended for surface treatment of storage facilities, processing and marketing if industrial animal or vegetal products»

- Laboratory study according to CEB N°135 method with the product 3A MATE, (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Blattella germanica* (German cockroach), *Aedes aegypti* (mosquito), *Anopheles stephensi* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite).
- Simulated use test conducted in laboratory according to internal method with the product 3A MATE, (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Stomoxys calcitrans* (stable fly), *Blattella germanica* (German cockroach), *Blatta orientalis* (Oriental cockroach), *Culex pipiens* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite).

- **NA-MIC – 2017** : Semi-field study with the product 3A MATE, (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Culex pipiens* (mosquito), *Aedes aegypti* (mosquito), *Anopheles gambiae* (mosquito), and *Dermatophagoides pteronyssinus* (house dust mite).

Toxicology data

Studies on the product were submitted: acute oral and dermal studies, dermal and ocular irritation studies, skin sensitisation assays and dermal absorption.

Residue data

No specific residue data were submitted in the context of this dossier. The product 3A MATE is intended to be applied indoor by professional users on wall and ceiling (domestic, industrial or public buildings and animal houses: equestrian centers and kennels) in areas where food and feed, food ustensiles or food processing surfaces will not become into contact with or be contamined by it. 3A MATE will not get in contact with food, therefore residues in food are not expected.

Ecotoxicology data

No data submitted.

1.6.2 Access to documentation

BAYER SAS, Environmental Science granted a letter of access to the active substance dossier (part A) to La Celliose S.A. for the product 3A MATE.

Please refer to Annex 2 for the complete list of studies for which access has been granted.

2 SUMMARY OF THE PRODUCT ASSESSMENT

2.1 Identity related issues

The source of the active substance used in the biocidal product 3A MATE is a deltamethrin technical concentrate (purity = 98.50%).

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the active substance deltamethrin

Class of danger	Hazard statement

Acute tox. cat 3*	H331	Toxic if inhaled
Acute tox. cat 3*	H301	Toxic if swallowed.
Aquatic acute cat. 1	H400	Very toxic to aquatic life.
Aquatic chronic cat. 1	H410	Very toxic to aquatic life with long lasting effects.
Pas de limites spécifiques de classification		

2.2.2 Classification of the biocidal product 3A MATE

Class of danger	**Hazard statement**	
Aquatic acute cat. 1	H400	Very toxic to aquatic life.
Aquatic chronic cat. 1	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements	P273	Avoid release to the environment.
	P391	Collect spillage.
	P501	Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

The product contains more than 2% w/w of crystalline silica with a diameter inferior to 10µm. The IARC has classified the crystalline silica as carcinogenic to human by inhalation.
Considering that the silica will be trapped on the paint and that the required application is by brushing, the exposure by inhalation is not expected.

2.2.3 Labelling of the biocidal product

Pictograms:	
Signal words:	Warning
Hazard statements:	H410: Very toxic to aquatic life with long lasting effects (M=10 000)

The mention ”EUH 208 Contains isothiazolinones (2-octyl-2H-isothiazol-3-one, 1,2-benzisothiazol-3(2H)-one and reaction mass 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)). May produce an allergic reaction” has to be reported in labelling.

2.2.4 Packaging of the biocidal product

The packaging of the biocidal product as deposited by the notifier is:

For professional users:

3A MATE is supplied in 2.5L and 10L tin pails with crimp lids.
The tin pails are varnished internally with an epoxy-phenolic varnish (dry weight: 13 - 16 g/m²).

2.3 Physico/chemical properties and analytical methods

2.3.1 Active ingredient

2.3.1.1 Identity, origin of active ingredient

The source of the active substance used in the biocidal product 3A MATE is the source used for annex I inclusion:

Manufacturer of the active substance:
Name: **Bayer CropScience Limited**
Address: Bayer House, Central Avenue
Hiranandani Gardens, Powai
Mumbai – 400076
India

Plant location:
Name: Bayer Vapi Private Limited
Address: Plot 306/3, 2 Phase, GIDC
Vapi – 396195
Gujarat
India

2.3.1.2 Physico-chemical properties

Physico-chemical properties of the active substance deltamethrin have already been evaluated at EU level and are presented in the CAR of Bayer (2011). The notifier La Celliose S.A. has a letter of access to these data.

2.3.1.3 Analytical method for determination of active ingredient and impurities in the technical active ingredient

Analytical method(s) for the determination of pure active substances deltamethrin in the technical active substances as manufactured has already been performed and validated at EU level in the CAR of Bayer (2011). The notifier La Celliose S.A. has a letter of access to these data.

Summary:

	Principle of method
Technical active substance as manufactured:	HPLC-UV and chiral HPLC-UV
Impurities in technical active substance:	-

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

Analytical methods for the determination of residues of the active substance deltamethrin in the different matrices have already been performed and validated at EU level in the CAR of Bayer (2011). The notifier La Celliose S.A. has a letter of access to these data. See annex 2 of this document.

Summary:

Soil (principle of method and LOQ)	LC-MS/MS using 1 transition **LOQ 0.1 µg/kg**
Air (principle of method and LOQ)	GC-ECD for quantification and GC-MS for confirmation **LOQ 0.27 µg/m^3**
Water (principle of method and LOQ)	Drinking water GC-ECD for quantification and confirmation **LOQ 0.05 µg/L** LC-MS/MS using 1 transition **LOQ 5.9 ng/L** GC-ECD for quantification and GC-MS/MS for confirmation **LOQ 3 ng/L** Surface water GC-ECD for quantification and GC-MS/MS for confirmation **LOQ 3 ng/L**
Body fluids and tissues (principle of method and LOQ)	Tissues GC-ECD for quantification and confirmation **LOQ 0.02 mg/kg** for milk, eggs, meat, fat, liver and kidney Fluids GC-MS for quantification and confirmation **LOQ 200 µg/l** for whole blood GC-MS multi-method for pyrethroids for quantification **LOQ 20 ng/L** for whole blood
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required as the intended uses will not result in significant residues when the label instruction is followed. However two methods are provided which can be used in case of suspected contamination: GC-ECD for quantification **LOQ 0.02 mg/kg** for rice, flour, bread, meat, candy, butter, banana cream pie and lettuce LC-MS/MS **LOQ 0.01 mg/kg** for edible materials **LOQ 0.05 mg/kg** for non-edible materials for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD for quantification and confirmation **LOQ 0.02 mg/kg** for milk, eggs, meat, fat, liver and kidney

2.3.2 Biocidal product

2.3.2.1 Identity, composition of the biocidal product, packaging.

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex 1 of directive 98/8/EC.

Name	3A MATE	
Manufacturer's development code number	Development code: 21012	
Ingredient of preparation	Function	Content (% w/w)
Deltamethrin (CAS No.52918-63-5)	Active substance	0.74
Formulants	Details on the composition of the product are included in the Confidential part (Doc. C1 and C2)	
Physical state of preparation	Homogeneous semi-pasty liquid	
Nature of the preparation	PA (Paste): water-based, film-forming composition	

The composition of the product is confidential and is presented in a confidential annex. The product contains 0.74 % w/w of pure active substance deltamethrin.

Manufacturers of the biocidal product:

Name of manufacturer	~~LA CELLIOSE SA, division ARTILIN~~ CIN CELLIOSE
Address of manufacturer	Chemin de la Verrerie BP 58 69492 Pierre Bénite France
Location of manufacturing sites	10 boulevard du Poitou 49300 Cholet France

Name of manufacturer	~~LA CELLIOSE SA, division ARTILIN~~ CIN CELLIOSE
Address of manufacturer	Chemin de la Verrerie BP 58 69492 Pierre Bénite France
Location of manufacturing sites	31 avenue Robert Schumann 69360 Saint Symphorien d'Ozon France

Name of manufacturer	CIN Valentine, SAU
Address of manufacturer	Riera Seca, número 1 Poligono Industrial Can Millans 08110 Montcada i Reixac Barcelona Espana

Location of manufacturing sites	Riera Seca, número 1 Poligono Industrial Can Millans 08110 Montcada i Reixac Barcelona Espana

Name of manufacturer	**CIN - Corporação Industrial do Norte, SA**
Address of manufacturer	Avenida D. Mendo nº831 Apartado 1008 4471-909 Maia Portugal
Location of manufacturing sites	Avenida D. Mendo nº831 Apartado 1008 4471-909 Maia Portugal

2.3.2.2 Physico-chemical properties

The tested product is 3A MATE.
Deltamethrin's content in tested product is:

- 0.72 % w/w in the Batch 4036741

The biocidal product is ready-to-use painting to treat 14 m² with 1L of product.

Properties	Method	Purity/ Specification	Results	Reference	Acceptable Yes/no
B3 – Physical, chemical and technical properties					
B3.1 Appearance					
B3.1.1 – Physical state and nature **B3.1.2 – Colour** **B3.1.3 – Odour**	Visual examination Organoleptic determination	Batch 4036741	White, semi-pasty homogeneous product with no deposit and no phase partition	B3.1 – Legay S. 2013a Report No.402/12/1210F/cd-e, FCBA GLP	**Acceptable**
		-	Characteristic	B3.6 – See Document "III-B12_ANNEX1_SDS_3A MATE" No GLP	**Acceptable**
B3.2 Acidity/alkalinity					
pH 1% dilution	CIPAC MT 75.3	Batch 4036741	Pure test item : pH value 8.3 at 23°C pH value 7.8 at 21°C after 24months at 20°C	B3.1 – Legay S. 2013a Report No.402/12/1210F/cd-e, FCBA GLP Legay S. 2015 Report No.402/12/1210F/hij-e	**Acceptable**
B3.3 Relative density and bulk, tap density					
Relative density	EC Method A3 OECD No. 109 method	Batch 4036741	Pycnometric method: D = 1404 kg/m^3 (1.404 g/L) at 22°C	B3.2 – Legay S. 2013b Report No.402/12/1210F/efg-e, FCBA GLP	**Acceptable**

<table>
<tr><td colspan="6">B3.4 Storage stability, stability and shelf-life</td></tr>
<tr><td colspan="6">B3.4.1 Storage stability tests</td></tr>
<tr><td>B3.4.1.1 – Accelerated storage study (2 weeks at 54°C)</td><td>CIPAC MT 46.3
Visual examination
HPLC/UV method for deltamethrin
CIPAC MT 75.3</td><td>Batch 4036741</td><td>
<table>
<tr><th></th><th>Initial</th><th>After storage 14 days at 54 ±2 °C in glass flask</th></tr>
<tr><td>Appearance</td><td colspan="2">White, semi-pasty homogeneous product with no deposit and no phase partition</td></tr>
<tr><td>A.s. content
deltamethrin</td><td>0.72 % w/w</td><td>0.71 % w/w
(- 1.4 %)</td></tr>
<tr><td>pH
pure test item</td><td>8.3 at 23°C</td><td>7.8 at 22°C</td></tr>
</table>
</td><td>B3.1 – Legay S. 2013a
Report No.402/12/1210F/cd-e, FCBA
GLP</td><td>Acceptable

The product was considered stable after 14 days at 54°C in glass flask.

The HPLC-UV method, used for the determination of deltamethrin content was validated in this report (part 2.3.2.3).</td></tr>
<tr><td>B3.4.1.2 – Ambient shelf life study</td><td>GIFAP No. 17</td><td>Batch 4036741</td><td>The study to determine the stability of 3A Mate in its commercial packaging after 2 years at 20 ± 2°C according to GIFAP Monograph No.17
<table>
<tr><th></th><th>Initial</th><th>12months at 20°C</th><th>After 24months at 20°C</th></tr>
<tr><td>Appearance</td><td colspan="3">White, semi-pasty homogeneous product with no deposit and no phase partition No potential signs of corrosion or degradation of packaging</td></tr>
<tr><td>A.s. content
deltamethrin</td><td>0.72 % w/w</td><td>0.71%w/w</td><td>0.70%w/w</td></tr>
</table>
</td><td>B3.3 – Legay S. 2013c
Report No.402/12/1210F/hij, FCBA
GLP

B3.4 – Da Costa C. 2013
No GLP

B3.7 – Legay S. 2014
Report No.402/12/1210F/hij/T12M-e, FCBA

Legay S. 2015
Report No.402/12/1210F/hij-e</td><td>Acceptable
.</td></tr>
<tr><td>B3.4.1.3 – Low temperatures stability test (liquids)</td><td>CIPAC MT 39.3</td><td>Batch 4036741</td><td>At the start of the test, the test item was a white, semi-pasty homogeneous product with no deposit and no phase partition.
After 7 days of cooling at 0 ±2 °C, no change of appearance, no deposit and no partition phase were observed.
After the undisturbed period and inverting the cones, no change of appearance, no deposit and no partition phase were observed.</td><td>B3.2 – Legay S. 2013b
Report No.402/12/1210F/efg-e, FCBA
GLP</td><td>Acceptable

The product was considered stable after 7 days at 0°C.</td></tr>
<tr><td colspan="6">B3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product</td></tr>
<tr><td>B3.4.2.1 – Light</td><td>-</td><td>-</td><td rowspan="3">No required as the biocidal product is packaged in opaque tin pails which are barrier to the light.
The test item is considered to be stable after 14 days at 54 ± 2°C (please refer to 3.4.1.1). With crimp lids, the tin pails are leak-tight
Experience on the product has proved that no reactivity is expected towards container material. A long term storage study with the product in commercial packaging is still on-going, started on 2013/08/01 (please refer to 3.4.1.2).</td><td>-</td><td>Acceptable</td></tr>
<tr><td>B3.4.2.2 – Temperature and humidity</td><td>-</td><td>-</td><td>-</td><td>Acceptable</td></tr>
<tr><td>B3.4.2.3 – Reactivity towards container material</td><td>-</td><td>-</td><td>-</td><td>Acceptable</td></tr>
<tr><td colspan="6">B3.5 Technical characteristics of the biocidal product</td></tr>
<tr><td>B3.5.1 – Wettability</td><td>-</td><td>-</td><td>Not applicable. The product is liquid formulated as a PA (Paste).</td><td>-</td><td>Acceptable</td></tr>
</table>

B3.5.2 – Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.3 – Wet sieve analysis and dry sieve test	-	-	Not applicable. The product is liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.4 – Emulsifiability, re-emulsifiability and emulsion stability	-	-	**I** Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.5 – Disintegration tima	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.6 – Particle size distribution, content of dust/ fines attrition, friability	-	-	Not applicable. The product is liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.7 – Persistent foaming	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.8 – Flowability/ Pourability/ Dustability	-	-	Not applicable. The product is liquid formulated as a PA (Paste).	-	**Acceptable**
B3.5.9 – Burning rate – smoke generators	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste) and is not intended to be applied as a smoke.	-	**Acceptable**
B3.5.10 – Burning completeness – smoke generators	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste) and is not intended to be applied as a smoke.	-	**Acceptable**
B3.5.11 – Composition of smoke – smoke generator	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste) and is not intended to be applied as a smoke.	-	**Acceptable**
B3.5.12 – Spraying pattern - aerosols	-	-	Not applicable. The product is a ready-to-use liquid formulated as a PA (Paste) and is not intended to be applied by spray with propellant gas under pressure.	-	**Acceptable**
B3.5.13 – Other technical characteristics	-	-	-	-	**Acceptable**
B3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised					
B3.6.1 – Physical compatibility	-	-	Not applicable. The product is a ready-to-use product and is not designed to be used in conjunction with any other products or active substances except sixteen selected dyes (see confidential document C4). However, the addition of one or several selected dyes does not impact the physico-chemical hazards of 3A MATE (see confidential document C4). Hence no data on the physical compatibility of 3A MATE with other biocidal products, chemicals or active substances is required.	-	**Acceptable**
B3.6.1 – Chemical compatibility	-	-	Not applicable. The product is a ready-to-use product and is not designed to be used in conjunction with any other products or active substances except sixteen selected dyes (see confidential document		**Acceptable**

			C4). However, the addition of one or several selected dyes does not impact the physico-chemical hazards of 3A MATE (see confidential document C4). Hence no data on the physical compatibility of 3A MATE with other biocidal products, chemicals or active substances is required.		
B3.7 Degree of dissolution and dilution stability					
Dilution stability	-	-	Not applicable. The product is a ready-to-use product and contains more than 25% w/w of water.	-	**Acceptable**
B3.8 Surface tension					
Surface tension	EC Method A5 OECD No. 115	Batch 4036741	According to OECD 115 test guideline, the measurement of the surface tension by ring tensiometer method is restricted to aqueous solutions with a dynamic viscosity ≤ 200 mPa*s. As the product has viscosity > 200 mPa*s (43605 mPa*s), the measurement was performed with the plate tensiometer method instead of the ring tensiometer. The mean surface tension of the test item (neat product) was: 22.73 mN/m at 20°C.	B3.3 – Legay S. 2013c Report No.402/12/1210F/cd-e, FCBA GLP B3.5 – Legay S. 2013d Report No.COA-402/12/1210F/hij-e, FCBA GLP	**Acceptable** The product is considered as surface-active.
B3.9 Viscosity					
Viscosity	OECD No. 114	Batch 4036741	<u>At 20°C</u>: 43605 mPa*s (shear rate: 2.5 rpm) <u>After storage 12 months at 20°C:</u> <u>At 20°C</u>: From 225500 to 17120 mPa*s from 0.5 to 30 rpm (shear rate) From 16960 to 202800 mPa*s from 30 to 0.5 rpm (shear rate <u>At 40°C</u>: From 208800 to 9336 mPa*s from 0.5 to 50 rpm (shear rate) From 9336 to 201600 mPa*s from 50 to 0.5 rpm (shear rate <u>After storage 24 months at 20°C:</u> <u>At 20°C</u>: From 225600 to 9624 mPa*s from 0.5 to 50 rpm (shear rate) <u>At 40°C</u>: From 181200 to 7584mPa*s from 0.5 to 50 rpm (shear rate)	B3.3 – Legay S. 2013c Report No.402/12/1210F/cd-e, FCBA GLP B3.5 – Legay S. 2013d Report No.COA-402/12/1210F/hij-e, FCBA GLP B3.7 – Legay S. 2014 Report No.402/12/1210F/hij/T12M-e, FCBA Legay S. 2015 Report No.402/12/1210F/hij-e	**Acceptable** **The product is non-newtonian liquid.**
B4 – Physical hazards and respective characteristics					
B4.1 – Explosives	DETERMINATION OF EXOTHERMIC REACTIONS BY DSC	Batch 4036741	<u>The explosive properties of 3A MATE were determined by DSC:</u> In the temperature range used from 20°C to 500°C, no exothermic reaction was observed. The test item presents an endothermic peak during the first heating. Maximum peak temperature of reaction: 119°C Beginning of peak temperature: 52°C End temperature: 144°C Value of the enthalpy of reaction: 794 J/g According to D.S.C., the test item shall not be classified as explosive and the test on explosive properties with EC A14 method should not be performed.	B4.1 – Raphalen E. 2013 Report No.402/12/1210F/n-e, FCBA No GLP	**Acceptable** The product is not expected to have explosive properties.
B4.2 – Flammable gases	-	-	Not applicable as the product is formulated as a PA (Paste).	-	**Acceptable**
B4.3 – Flammable aerosols	-	-	Not applicable as the product is formulated as a PA (Paste).	-	**Acceptable**
B4.4 – Oxidising gases	-	-	Not applicable as the product is formulated as a PA (Paste).	-	**Acceptable**
B4.5 – Gases under pressure	-	-	Not applicable as the product is formulated as a PA (Paste).	-	**Acceptable**
B4.6 – Flammable liquids	EC Method A9	Batch 4036741	<u>Pensky-Martens apparatus</u>: The flash point of the test item was > 99°C.	B3.2 – Legay S. 2013b Report No.402/12/1210F/efg-e, FCBA GLP	**Acceptable** The product is not highly flammable.
B4.7 – Flammable solids	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**

B4.8 – Self-reactive substances and mixtures	-	-	Not required as the product is not explosive according to DSC and not flammable according to EC method A.9.	-	**Acceptable**
B4.9 – Pyrophoric liquids	-	-	Not required as experience in manufacture and handling of 3A MATE shows that the product does not ignite spontaneously on coming into contact with air at normal temperature.	-	**Acceptable**
B4.10 – Pyrophoric solids	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**
B4.11 – Self heating substances and mixtures	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**
B4.12 – Substances and mixtures which in contact with water emit flammable	-	-	Not required as 3A MATE contains more than 25% w/w of water and forms a stable mixture.	-	**Acceptable**
B4.13 – Oxidising liquids	EC Method A21	Batch 4036741	The test mixtures produced no pressure rise times (12.8s) well above the 3.95 s average for the 65% aqueous nitric/cellulose reference mixtures. The test item was not considered to have oxidizing properties in experimental conditions.	B4.2 – Demangel B. 2013a Report No.13-912030-001, Défitraces GLP	**Acceptable** The formulation is not expected to have oxidising properties.
B4.14 – Oxidising solids	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**
B4.15 – Organic peroxides	-	-	Not required as the product not contains organic peroxide.	-	**Acceptable**
B4.16 – Corrosive to metals	-	-	Not required as the product has not a low or high pH value	-	**Acceptable**
B4.17 Additionnal physical indications of hazard					
B4.17.1 – Auto-ignition temperatures of products (liquids and gases)	EC Method A15	Batch 4036741	The mean self ignition temperature of the test item was: 347 ± 5 °C (corrected temperature).	B4.3 – Demangel B. 2013b Report No.13-912030-002, Défitraces GLP	**Acceptable** The product is not expected to have self-ignition properties at ambient temperature.
B4.17.2 – Relative self-ignition temperature for solids	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**
B4.17.3 – Dust explosion hzard	-	-	Not applicable as the product is a liquid formulated as a PA (Paste).	-	**Acceptable**

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

An analytical method for the determination of the active substance deltamethrine in the formulation 3A MATE has been developed. The following analytical method for the determination of the active substance in the formulation performed on 3A MATE has not previously been reviewed and is provided in support of this assessment.

Report:	**B5.1 – Legay S., 2013e**
Title:	Validation of analytical method according to SANCO 3030/99 rev.4 and chemical analysis of active substance declared in the test item 3A MATE, Report
Document No:	No.402/12/1210F/ab-e, FCBA
GLP	Yes

Principle of the method

The product was weighted in order to obtain a concentration near 50 mg/L in deltamethrin pure with dilution in acetonitrile. For 3A MATE, 0.33g of product was diluted with acetonitrile to 50mL. An aliquot was filtered (0.45µM Nylon filter) before analysis. Deltamethrin was analyzed by liquid chromatography using an UV detector (210nm).

Specificity

Specificity was studied by carrying out twice an analysis of the matrix without any active substances (blank matrix). The specificity was assessed by checking for any interference in HPLC-UV at the selected wavelength at the retention time of deltamethrin (identified with the analytical reference item).

No interference at the selected wavelength (210 nm) was detected at the retention time of deltamethrin in HPLC-UV in blank formulation samples diluted in acetonitrile. No interference from other substances present in the preparation contributes more than 3% to the total peak area measured for the active substance deltamethrin.

Representative chromatograms of standard solution, formulation blank and formulation blank spiked with 50 mg/L of deltamethrin were provided.

Linearity

For the calibration of deltamethrin, two calibrations curves based on one injection per dilution was generated. The results were used to calculate the calibration curves to verify the linearity of detector response.

The analytical system gave a linear response (n=5) between 40 mg/L and 60 mg/L of deltamethrin. The linear correlation coefficient for the calibration range was found to be > 0.99.

Equation of the calibration line :

First series: $Y = 4.29*10^4 X + 1.86*10^4$

$r = 0.999652$

$r^2 = 0.999305$

Second series: $Y = 4.41*10^4 X + 1.78*10^4$

$r = 0.999909$

$r^2 = 0.999818$

Accuracy

Precision and accuracy were studied by spiking 2*6 matrix samples with known amounts of deltamethrin reference item to the "target value" (after dilution of the sample in order to be close to 100% of the calibration curve).
The recovery rates were calculated by comparison between the theoretical "target value" and the measured concentration of the 12 spiked matrix samples.
The matrix was spiked at the following active substance concentration: 50 mg/L for deltamethrin.
Precision is expressed by a relative standard of repeatability RSD_r (%) and a relative standard of intermediate precision RSD_R (%).
The recovery rates are detailed in the table below:

	Fortification Level (mg/L)	Number of Analyses	Mean Recovery (%)	RSD_r (%)	RSD_R (%)
Accuracy	50	12	102.3	0.63	0.71

Repeatability

Precision and accuracy were studied by spiking 2*6 matrix samples with known amounts of deltamethrin reference item to the "target value" (after dilution of the sample in order to be close to the 100 % of the calibration curve). Recovery rates were calculated:
RSD_r = 0.63 %
RSD_R = 0.71 %

Relative standard deviation of repeatability (RSD_r) were calculated with the modified equation of Horwitz:
$RSD_r = 0.67 * 2^{(1 - 0.5 \log C)}$
C = nominal concentration in deltamethrin = 0.0074 (0.74% w/w)
RSD_r = 2.80%

Relative standard deviation of intermediate precision (RSD_R) were calculated with the equation of Horwitz:
$RSD_R = 2^{(1 - 0.5 \log C)}$
C = nominal concentration in deltamethrin = 0.0074 (0.74% w/w)
RSD_R = 4.19%

RSD are below Horwitz values.

Conclusion

Specificity, linearity, precision and recovery were provided and found acceptable for deltamethrin.

Analytical methods using HPLC/UV (Legay S., 2013e, Report No.402/12/1210F/ab-e, FCBA) for the determination of deltamethrin in the formulation (3A MATE) as manufactured has been performed and validated in accordance to guidance of Regulation (EU) No 528/2012.

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

Analytical methods for deltamethrin residues in soil, air, water (including drinking water) and sediment, animal and human body fluids and tissues and deltamethrin residues in food/feed of plant and animal origin are available in Assessment Report Deltamethrin Product-type 18 (insecticides), May 2011.
A Letter of Access from Bayer has been provided.

2.4 Risk assessment for Physico-chemical properties

The biocidal product 3A MATE is a white, semi-pasty and homogeneous product with a characteristic odour. The product has no explosive properties, nor oxidising properties. It is not highly flammable (flash point is > 99°C) and not auto-flammable at ambient temperature (self-ignition temperature is 347°C). The pH of the product (pure test item) is about 8.3 at 23°C and the density of the product is 1.404 g/L. The product is considered as surface-active (mean surface tension of the pure test item is 22.7 mN/m) and a viscosity of 43605 mPa*s at 20°C.

After the accelerated storage procedure (14 days at 54 ± 2°C), no significant change of the product was observed, regarding the deltamethrin content, the aspect of the product and the pH. 3A MATE is considered stable after the accelerated storage during 14 days at 54 ± 2°C in glass flask.

No significant change of the product was observed, regarding the deltamethrin content, the aspect of the product and the pH after the accelerated and ambient storage studies. 3A MATE is considered stable and the the shelf-life is expected to be at least 2 years.
After storage of the product for 7 days at 0 ± 2°C, no change was observed in the test item appearance (no deposit, no phase partition and no change of colour). The product is considered to be stable after 7 days at 0°C.

Risk mitigation measures linked to risk assessment for physico-chemical properties

None.

Disposal considerations

None.

2.5 Effectiveness against target organisms

2.5.1 Function

Main Group 03: Pest Control
Product Type 18: Insecticides, acaricides and products to control other arthropods.

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

According to the uses claimed by the applicant, 3A MATE is intended to be used to control several arthropods, including insects and mites. The application codes are the followings:

Codes	Scientific names	Common terms and specific targets
I.1.4.3	Pyroglyphidae	House dust mites (*Dermatophagoides pteronyssinus*)
I.3.4.1	Blattellidae	Blattellid cockroaches, *e.g.* German cockroach (*Blattella germanica*)
I.3.4.2	Blattidae	Blattid cockroaches, *e.g.* Oriental cockroach (*Blatta orientalis*)
I.3.12.1	Culicidae	Mosquitoes (*Culex spp*. *Aedes spp*., *Anopheles spp*.)
I.3.12.6	Muscidae	House fly (*Musca domestica*) and stable fly (*Stomoxys calcitrans*)

The products and organisms to be protected are materials (VII.3 Material protection) and humans (VII.2 Health protection).

3A MATE is presented as a ready-for-use paint, in 2.5 or 10 L tin pails. It is restricted to professional users.

The product is for indoor use on walls and ceilings. This finishing paint can be used in industrial and commercial premises, private and public areas, and in some animal housings (equestrian centers and kennels). The product is not intended to be used in other breeding premises.

3A MATE can be applied on every construction material (cement, plaster, wood, concrete…), with a suitable sub-coat, and on existing adhesive matt paint.

3A MATE must be applied with a paintbrush or a roller, not by spraying.

Since the product is formulated as a ready-for-use product, no dilution or other preparations are necessary.

The application rates recommended by the applicant are the following:

100 g of the product per m² i.e. 1 L of the product for 14 m².

The product 3 A MATE was initially authorised for use against mosquitoes, flies and house dust mites for a residual efficacy of 6 months.
The proposed change concerns the duration of efficacy, increased up to 24 months after application.
The target organisms and application rates are unchanged.
The products, organisms or objects to be protected are industrial and commercial premises, private and public areas, and in some animal housings (equestrian centers and kennels).

2.5.3 Effects on target organisms and efficacy

The submitted studies to demonstrate efficacy of the product 3A MATE according to the uses and doses claimed, are described below. These studies were carried out with the product 3A MATE (0.74 % w/w deltamethrin).

1) **Laboratory study n°1577/0213R, conducted with the product 3A MATE, (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Blattella germanica* (German cockroach), *Blatta orientalis* (Oriental cockroach), *Culex pipiens* (mosquito), *Aedes aegypti* (mosquito), *Aedes albopictus* (mosquito), *Anopheles gambiae* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite) according to CEB N°135 method.**

The product was painted at the dose of 100 mg of product per m² (2 layers) on pre-painted (2 layers of pre-coating) plywood panels. After a drying time of 48 hours, the arthropods were placed in contact with this surface for an exposure time of 4 hours. The persistence was measured by performing the same test after 6 months, 1, 2 and 3 years of storage of treated panels. Four replicates were made for each test condition (surface*treatment*storage*arthropod).
Observations 48 hours after the end of the treatment, after 6 months and 1 year of storage, showed a complete mortality of the arthropods at the end of the 4-hour exposure period.

After 2 years of storage, the mortality of the arthropods was total within 24h for cockroaches and mites, and within 8h for the house fly and the mosquitoes.

The untreated controls demonstrated the validity of the test, with less than 5 % of mortality. The product 3A MATE showed total efficacy against all tested arthropods within 24 hours. This efficacy lasted for at least 2 years after application. Further tests will be done after 36 months of storage (i.e. the 16th February 2016).

It has to be noted that the exposure time of 4 hours seems not really representative of the time the arthropods might be in contact with a treated surface under natural conditions.

2) Laboratory study n°13/270, 2013/09/09 conducted with the product 3A MATE (0.74 % w/w deltamethrin) on *Stomoxys calcitrans* (stable fly, adults), according to an internal method.

The product was painted at the dose of 100 mg of product per m² (1 layer) on pre-painted (1 layer of pre-coating + 1 layer of non-insecticidal paint) plywood panels. The stable flies (*Stomoxys calcitrans*) were confined onto the panels within an upturned plastic pint size container for an exposure time of 4 hours. Assessments of knockdown and mortality were carried out at 5, 15 and 30 minutes and 1, 2 and 24 hours, post initial exposure to treatments. The persistence was measured by performing the same test after 1 month, 1, 2 and 3 years of storage of treated panels. Four replicates were conducted for each test condition (surface*treatment*storage).

For the first assessment, 1 month after treatment, the untreated controls showed 30% mortality after 24 hours, so this first test is not valid.

For the second assessment, after 1 year of storage, the untreated controls demonstrated the validity of the test, with < 10 % of mortality. One year after treatment, 100% of the flies were affected (knock down and dead) after 1 hour of exposure. Results after 2 and 3 years of storage are not available.

3) Laboratory study n°1239-VMAMM01/1107R, conducted with the product 3A MATE (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Blattella germanica* (German cockroach), *Aedes aegypti* (mosquito), *Anopheles stephensi* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite) according to CEB N°135 method.

The product was painted at the dose of 100 mg of product per m² on pre-painted wood panels. The arthropods were placed in contact with this surface for an exposure time of 8 hours. The persistence was measured by performing the same test after 1, 3, 6, 9, 12, 15, 24 and 36 months of storage of treated panels. Three replicates were made for each test condition (surface*treatment*storage*arthropod).

The untreated controls demonstrated the validity of the test, with < 10 % mortality of the arthropods. Until 24 months after application, the mortality of the arthropods was total after a maximum exposure time of 3 hours.
After 36 months, 4 hours of exposure were necessary to kill all the flies, mosquitoes and mites. For the cockroaches, they died during the post-monitoring phase and 100% were dead 24 hours after an 8 hours exposure.
The product 3A MATE showed total efficacy against all tested arthropods within 24 hours. This efficacy lasted for at least 3 years after application.

It has to be noted that the exposure time of 8 hours seems not really representative of the time the arthropods might be in contact with a treated surface under natural conditions.

4) Semi-field tests n°1889/0115R, conducted with the product 3A MATE (0.74 % w/w deltamethrin) on *Musca domestica* (house fly), *Stomoxys calcitrans* (stable fly), *Blattella germanica* (German cockroach), *Blatta orientalis* (Oriental cockroach), *Culex pipiens* (mosquito), and *Dermatophagoides pteronyssinus* (House dust mite), according to an internal method.

The product was painted at the dose of 100 mg of product per m² on pre-painted wood panels. The panels were disposed in a test chamber (12 m² floor). The panels were set vertically on two adjacent walls (one panel is 3 m wide x 2 m high and the other panel is 2 m wide x 2 m high) in each test chamber. The treated surface represented half of the test chamber (50 % of the wall area). To simulate what happens in practice, a few cardboards are set into the test chamber to be harbourages and water + food sources, on non-treated areas. The insects were introduced 48h after the second layer of paint and were able to reach water and food sources without being in contact with the insecticide and they have the choice not to be in contact with the product. Due to the very small size of the house dust mites, a special area of 0.1 m² (30 cm x 33.3 cm) on the floor + 0.1 m² (30 cm x 33.3 cm) on a treated wall was limited using Teflon to avoid escapes. The dust mites were released on the untreated part (floor) - some special food (dust + yeast) was also set on this untreated part. The efficacy was assessed on "freshly" treated panels (48h after the second layer) and after 6 months of storage.Four replicates were made for each species.

The untreated controls demonstrated the validity of the test, with < 10 % mortality of the arthropods. The product 3A MATE showed total efficacy 24 hours after the beginning of the exposure period 6 months after application.

It shall be also noted that these semi-field tests were performed directly and 6 months after application and that results after 1, 2 and 3 years of storage are not available.

Conclusion

- Considering the requirements of the TNsG on PT18, the data submitted and intended to prove the efficacy of the product 3A MATE are insufficient to validate the use against flies in animal housings (equestrian centers and kennels) and cockroaches. Indeed, according to the requirements of the TNsG on product evaluation for PT18/19 :

  - efficacy against cockroaches (*B. Germanica* and *B. orientalis*) is not proved as no field test has been provided for these target organisms. Furthermore, exposure time (4 and 8 hours) in the laboratory tests is not really representative of the time the insects might be in contact with a treated surface under natural conditions. Finally, the simulated use test is ongoing and only results until 6 months were submitted.
  - efficacy against flies (*M. domestica* and *S. calcitrans*) in animal housings is not proved as no field test has been provided for these target organisms. Furthermore, exposure time (4 and 8 hours) in the laboratory tests is not really representative of the time the insects might be in contact with a treated surface under natural conditions. Finally, the simulated use test is ongoing and only results until 6 months were submitted.

- According to TNsG on PT18 (13.2.2.2.2 & 13.2.3.) for products intended to be used as general surface treatment in houses against flies (*M. domestica* and *S. calcitrans*), simulated-use test (e.g. in test chamber) is sufficient, while field studies are not mandatory. The submitted data permit to valid the efficacy of the product 3A MATE against flies for surface treatment in houses only.

- Considering the requirements of the TNsG on PT18, the data submitted and intended to prove the efficacy of the product 3A MATE against house dust mites and mosquitoes permits to valid these uses for only a residual activity of 6 months and under the condition that field or semi-field data on Aedes and Anopheles mosquitoes is submitted within one year. Indeed, according to the requirements of the TNsG on product evaluation for PT18/19 :

- efficacy against mosquitoes (*Culex, Anopheles* and *Aedes* genus) is not sufficiently proved as only a semi-field test on Culex genus has been provided. Furthermore, exposure time (4 and 8 hours) in the laboratory tests is not really representative of the time the insects might be in contact with a treated surface under natural conditions, these results are not sufficient to valid the Aedes and the Anopheles genus. Finally, the simulated use test is ongoing and only results on freshly and 6 month-aged painted surfaces were submitted
- efficacy against house dust mites (*D. pteronyssinus*) is only proved for a duration of 6 months as the simulated use test is ongoing and only results on freshly and 6 month-aged painted surfaces were submitted.

Target Organismes	**Rate**	**Method of application**	**Time delay of the biocidal product**	**Duration of the effect**
House dust mites, larves and adults (*Dermatophagoides pteronyssinus*) Mosquito, adults (*Culex, Aedes* and *Anopheles* genus) Flies, adults (*Musca domestica* and *Stomoxys calcitrans*)	100 g of the product per m² i.e. 1 L of the product for 14 m².	Surface treatment : painting using a paintbrush or a roller The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.	After a few hours	6 months

Based on these efficacy data, the product 3A MATE (0.74% w/w deltamethrin), formulated as a paint, applied at a rate of 100 g of the product per m², showed an efficacy over a 6 months period against house dust mites (*Dermatophagoides pteronyssinus,* larves and adults), flies (*M. domestica* and *S. calcitrans*) in houses only, and mosquitoes (*Culex*, *Anopheles* and *Aedes* genus*,* adults, under the condition that field or semi-field data on *Aedes* and *Anopheles* genus is submitted within one year after authorisation.

In laboratory tests, the effect began a few hours after application.

NA-MIC -2017:

Results of residual efficacy after storage of 24 months were submitted. Furthermore, it includes also results against *Aedes spp.* and *Anopheles spp.* requested in the frame of post authorisation requirement.
According to the efficacy data submitted, the requirements and criteria of TNsG PT 18 (2012) are fulfilled, and efficacy of the product 3A MATE was proved up to 24 months against flies (*Musca domestica* and *Stomoxys calcitrans*, adults), mosquitoes genus *Culex, Aedes*, and *Anopheles* (adults) and house dust mites *Dermatophagoides pteronyssinus* (adults).

All efficacy studies are presented in annex 9.

2.5.4 Mode of action including time delay

Deltamethrin is a pyrethroid insecticide which acts on insects by contact and ingestion. It expresses a strong knock-down effect.
Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes after insecticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve

membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyper-excitability.

After drying of the paint, the effect begins around a few hours after contact of the product in the laboratory trials submitted by the applicant.

2.5.5 Occurrence of resistance – resistance management / Unacceptable Effect

Deltamethrin is a pyrethroid insecticide. Deltamethrin products are widely used for various applications: veterinary medicine, crop protection, indoors and outdoors biocide, and against numerous arthropods target organisms. Resistance to deltamethrin has already been reported in several insects[2], including important nuisance insects of breeding premises.

Resistant populations of house flies (*Musca domestica*) have been identified in the whole world (Asia, Europe, and America). Several mechanisms are involved in resistance to pyrethroids in house fly. This includes detoxification of the active substances, knockdown resistance (also called "kdr"), correlated with decrease nerve sensitivity, and decrease in the rate of penetration of the products. These mechanisms can co-exist in a resistant strain[3]. Cross-resistance also exists in resistant strains, among pyrethroids, but also other insecticide types (chlorpyrifos and imidacloprid).

A recent French study with two populations of stable fly (*Stomoxys calcitrans*) concluded that the population from the "conventional" farm, with cattle and stable walls frequently treated with deltamethrin, was resistant to the five tested pyrethroids, including deltamethrin[4].

Concerning *Culex pipiens* (or *C. quinquefasciatus*[5], very close species), deltamethrin resistant populations have been identified in many part of the world, including North and West Africa and Asia[6]. Resistant populations have not been identified in Europe yet.

Populations of *Aedes aegypti*[7] resistant to pyrethroids have been identified, mainly in South America, West Indies and South East Asia. *Aedes albopictus*[8] resistant populations have been identified in South East Asia. Populations of *Anopheles gambiae*[91011] resistant to pyrethroids have been identified in West Africa, and in other parts of this continent. Concerning *Culex pipiens*, deltamethrin resistant populations have been identified in many parts of the world, including North and West Africa and China.

Populations of fleas (*Ctenocephalides felis)* resistant to deltamethrin have not been identified in Europe yet. Resistance to insecticide is difficult to identify in fleas, because of important intra-population variability[12].

Concerning poultry red mites (*Dermanyssus gallinae*), populations resistant to permethrin, another pyrethroids active substance, have been identified in France and other European countries. However, resistance to deltamethrin is not reported in the scientific literature[13].

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[9] Chandre F., Darrier F., Manga L., Akogbeto M., Faye O., Mouchet J., Guillet P., Status of pyrethroid resistance in Anopheles gambiae sensu lato, Bulletin of the World Health Organization, 1999, 77 (3).

[10] Diabate A., Baldet T., Chandre F., Akogbeto M, Guiguemde T. R., Darriet F., Brengues C., Guillet P., Hemingway J., Small G. J., Hougard J-M., The role of agricultural use of insecticides in resistance to pyrethroids in *Anopheles gambiae* S.L. in Burkina Faso, *Am. J. Trop. Med. Hyg.,* 67(6), 2002, pp. 617–622

[11] Kerah-Hinzoumbé C., Péka M., Nwane P., Donan-Gouni I., Etang J., Samè-Ekobo A., Simard F., Insecticide resistance in *Anopheles gambiae* from south-western Chad, Central Africa, *Malaria Journal* 2008, **7**:192.

[12] Bossard RL, Hinkle NC, Rust MK. Review of insecticide resisitance in cat fleas (Siphonatera : Pulicidae). J. Med. Entomol. 35(4):415-422 (1998)

[13] Marangi M, Cafiero MA, Capelli G, Camarda A, Sparagano OAE, Giangaspero A. Evaluation of the poultry red mite, *Dermanyssus gallinae* 'Acari:Dermanyssidae) susceptibility to some acaricides in field populations from Italy. Exp Appl Acarol (2009) 48:11-18.

Concerning cockroaches, several mechanisms are also involved in resistance to pyrethroids[14]. Resistant populations of German cockroaches have been identified in the entire world (Asia, Europe, and America). The Oriental cockroach has developed little resistance.

Concerning the house dust mite *Dermatophagoides pteronyssinus*, no scientific literature mentioning populations resistant to deltamethrin has been found.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.5.6 Evaluation of the Label Claims

French competent authorities (FR CA) concludes that the submitted data are permits only to valid the efficacy of the product 3A MATE on house dust mites, flies (in houses only) and mosquitoes for a residual activity of 6 months and under the condition that a semi-field or a field test on Aedes and Anopheles mosquitoes is submitted within one year after the product authorisation.

The application rate validated is the following:
100 g of the product per m² i.e. 1 L of the product for 14 m².
The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.

NA-MIC -2017:

French competent authorities (FR CA) concludes that the submitted data permit to validate the efficacy of the product 3A MATE on flies, house dust mites and mosquitoes for a residual activity of 24 months.

Furthermore, the semi field or field test against *Anopheles* and *Aedes* genus requested in post AMM was sumitted and assessed in the frame of this minor change dossier. Therefore the required information linked to efficacy assessment is fulfilled.

2.5.7 Summary of efficacy assessment

The efficacy level of the product 3A MATE (0.74% w/w deltamethrin) is satisfactory for the uses proposed in 2.5.3.

Conditions of use linked to efficacy assessment

[14] Wei Y., Appel A.G., Moar W. J, Liu N., Pyrethroid resistance and cross resistance in the german cockroach, *Blattella germanica* (L), Pest manag Sci 57 :1055-1059, (2001).

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- The users should inform if the treatment is ineffective and report straightforward to the registration holder

Recommendations to be taken into account by the authorisation holder

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

Required information linked to efficacy assessment

- A semi-field or a field test demonstrating the efficacy of 3A MATE against *Anopheles* and *Aedes* genus will need to be provided in post-authorisation, within one year.
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.

2.6 Description of the intended use(s)

The product 3A MATE is a finishing paint with insecticide/acaricide properties containing 0.75% (w/w) deltamethrin as active substance. The product is intended to control mosquitoes and house dust mites. It will be used by professionals only.

Table 3.1-1: Summary of intended uses

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
Main Group 03; Pest Control PT18: insecticides, acaricides and products to control other arthropods	Professional uses	
	Insecticide for use by professionals against mosquitoes, flies (in houses only) and house dust mites infestation	0.75% w/w (10.5 g/L based on a relative density = 1.404)
	Non-professional uses	
	Not applicable	Not applicable

Method of application

The product 3A MATE is an insecticide and acaricide finishing paint presented in buckets of 2.5 and 10 L. The paint product can be applied with a brush or a roller. The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.

The recommended dose of application is 1L for 14 m², corresponding to 0.0714 L/m² or 0.0971 kg of product/m², i.e. 752 mg of a.s. / m².

The product is to be used by professionals only.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.

The following corresponds to the summary of the effect assessment available in the assessment report of Deltamethrin.

Absorption, distribution, metabolism and excretion

The rate of oral absorption of deltamethrin was approximately 75%, this based on urinary and biliary excretion data in rats. Deltamethrin was rapidly absorbed when orally administered to rats (the majority of the radioactivity was eliminated within 24 hrs after dosing, 19-47% with the urine; 32-55% in faeces) and distributed to most tissues. Residues in tissues and carcass were low. The highest residues were found in fat. There was no indication of accumulation, although the residue of deltamethrin in adipose tissue eliminated with a half-life of >24 hrs.
Deltamethrin was rapidly excreted in both urine and faeces. 7 days postdose, 31% to 56% of the oral dose was excreted with the urine and 36% to 59% in faeces. No 14CO2 was formed according to data from the open literature. Deltamethrin was rapidly and extensively metabolised in rats. The main route of metabolism was via cleavage of the ester bond with or without hydroxylation at the 4' position of the alcohol moiety. The acid moiety and alcohol moiety were further transformed and excreted in urine in free forms and as conjugated metabolites. Unchanged deltamethrin was the major compound in faeces.
No studies were located regarding absorption rate following inhalation exposure to animals. Consequently a default absorption value by inhalation was considered in the risk assessment.

Dermal absorption

Dermal penetration studies have been conducted in vitro in rats with deltamethrin as an oil/water emulsion (EW) and as an emulsifiable concentrate (EC) in rat and human skin and in an in vivo study in rats. The results of these studies indicated that dermal absorption was somewhat lower for the EW 15 than for the EC 25. The Decis EC 25 formulation may be considered to be a worst case with regard to K-Othrine formulations. The main difference which is relevant to skin absorption is the solvent (water in K-Othrine SC formulations versus light aromatic solvent in Decis EC 25). The content of aromatic solvent is expected to enhance the degree of dermal absorption in comparison with K-Othrine formulations. For the solid formulations of deltamethrin a lower dermal absorption is expected since water and certain solvents favour.
Using data obtained in the dermal absorption studies on Decis EC 25 formulation, the dermal absorption of deltamethrin in man was estimated to 1.19% for the concentrate and 1.89% for the a.s. when diluted in the spray solution. The value of 2% (maximum dermal absorption) was used in the risk assessment.

Acute toxicity, irritation and corrosivity, sensitisation

Deltamethrin was considered of high acute toxicity by the oral and inhalation route (LD_{50} rat: 87 mg/kg bw; LC_{50} rat: 0.6 mg/L), while the acute dermal toxicity of deltamethrin was low (LD_{50} rat: >2000 mg/kg bw). Clinical signs of systemic toxicity, poor condition and neurotoxicity were observed in rats after oral and inhalation administration. Skin and eye irritation and pathological changes (enlarged inguinal and mandibular lymph nodes, and pulmonary congestion) were noted in addition after administration via the inhalation route. No clinical signs were noted in rats after dermal application.
The vehicle has a great influence on the LD_{50}. Sesame oil as vehicle shows less toxicity than polyethylene glycol. Aqueous suspensions are significantly less toxic than formulations in oils.
Deltamethrin was not irritating according to skin- and eye irritation studies in rabbits, and no sensitising potential was found in tests according to GPMT (Guinea Pig Maximisation Test) or Buehler.

Repeated dose toxicity (short-term toxicity)

The short-term oral toxicity of deltamethrin was investigated in rats (90-day studies) and dogs (90-day studies; one-year study). In both species, the nervous system was the main target organ. Reduced bodyweight gain was also noted in both species.
The lowest relevant NOAEL for short-term toxicity was 1 mg/kg bw/day obtained in the 90-day (gelatine capsules, vehicle: PEG 200) and 1-year oral (gelatine capsules, vehicle: none) toxicity studies in dogs based on clinical signs of neurotoxicity noted in both sexes at the dose level of ≥ 2.5 mg/kg bw/day.
In addition, the repeated dose toxicity was investigated in rats after dermal exposure (21-day toxicity study in rats) where dermal irritation was noted, and inhalation exposure (14-day toxicity study in rats) where clinical signs (irritative and neurotoxic) and reduced bodyweight gain were noted. Scratching was noted in all treated groups in the inhalation toxicity study. This effect was considered to be related to the irritant nature of deltamethrin but may also be due to the neurotoxic nature of the substance (an indirect consequence of parasthesia).

Genotoxicity

The genotoxic potential of deltamethrin was investigated in a battery of tests in vitro (assays for gene mutations, chromosomal aberrations and DNA effects). All tests were negative.
Based on the weight of evidence from this full in vitro package and the results of the carcinogenicity studies, it was concluded that deltamethrin is not mutagenic.

Chronic toxicity (long-term toxicity) and carcinogenicity

The long term toxicity of deltamethrin was studied in rats and mice. No evidence of carcinogenic potential of deltamethrin was found in the rat or the mouse. In both species the nervous system was the target organ. The liver was another target organ in the rat.
Lowest relevant NOAEL for long-term toxicity was 1 mg/kg bw/day obtained in the 2-year chronic toxicity/carcinogenicity (feeding) study in the rat based on liver effects (histopathological changes) noted at the dose level of 5 mg/kg bw/day and above. In addition clinical signs of neurotoxicity were noted at higher doses.

Reproductive toxicity

Reproductive toxicity of deltamethrin was investigated in a two-generation study in rats. Developmental toxicity was investigated in rats, mice and rabbits. The mouse study was considered acceptable but of restricted quality due to low number of pregnant animals used in each test groups.
No effect on mating performance or fertility was noted in the rat two-generation (feeding) study. Clinical signs (indicating neurotoxic effects), reduced body growth and histopathological changes (gastric erosions) were noted in adult rats. In offsprings reduced pup body weights, increased pup deaths (F1 generation) and reduced lactation index (F1 generation) were noted at maternal toxic doses.
No developmental toxicity was noted in rats or rabbits at maternal toxic doses. Increased incidence of supernumerary ribs was noted in the offspring of mouse at doses with maternal toxicity.
Lowest relevant developmental LOAEL was 3 mg/kg bw/day based on a statistically significant increase in the occurrence of supernumerary ribs noted in mice at ≥ 3 mg/kg bw/day.

Neurotoxicity

The neurotoxicity of deltamethrin was investigated in standard toxicity studies with the rat (acute neurotoxicity study; subchronic neurotoxicity study; developmental neurotoxicity (DNT) study) and in experimental (non GLP) studies in rats and mice. No studies on acute delayed neurotoxicity were submitted (not required).
The NOAEL for acute neurotoxicity in adult CD-rats was 5 mg/kg bw, while the NOAEL for subchronic neurotoxicity in adult CD rats was 4 mg/kg bw/day. In both studies the NOAEL was based on signs of neurotoxicity noted at 15 mg/kg bw/day and above, and mortalities and reduced bodyweight gain noted at higher dose levels.
The NOAEL for developmental neurotoxicity in Wistar rats was 6.78 mg/kg bw/day based on reduced bodyweight gain, increased incidence of vocalizations with handling (males only) and delayed balanopreputial separation noted in offsprings at a dose with maternal toxicity (16.1 mg/kg bw/day).
The DNT study follows the OECD guideline no. 426 in that way that some exposure to the pups was demonstrated in the pilot study. However, the view of RMS is that there might be some uncertainty in the DNT study protocol in those cases where direct dosing of pups has not been considered and the exposure level in offspring is not clear. No blood analyses were taken and the offspring dose level might be very low. The effects noted in the pups of the high dose group (decreased body weight and body weight gain, delayed sexual maturation in males) are not sufficient evidence to support exposure to the pups during the brain growth spurt period since these effects in the offspring could be due to maternal toxicity or exposure in utero.

Furthermore, there is a concern for the lack of data for the most sensitive strain. Comparing data from standard neurotoxicity studies the Wistar rat used in the DNT study seems to be a less sensitive strain with regard to neurotoxicity of deltamethrin. There were no clinical signs of neurotoxicity reported for adult Wistar rats administered deltamethrin via the diet at doses up to 16.1 mg/kg bw/day (noted in the DNT study), whereas clinical signs of neurotoxicity were evident in the CD rat at a dose level of 14 mg/kg bw/day (noted in the 13-week neurotoxicity study). The choice of strain used in the deltamethrin DNT study might therefore be questioned.
Due to the uncertainties mentioned above the RMS originally proposed (draft CAR) to use an extra safety factor of 3 in the risk assessment of deltamethrin. The Technical Meeting I in 2010 reached an agreement that where uncertainties are perceived by the RMS of a pyrethroid on the DNT studies (especially negative studies), these uncertainties should be formally expressed in the CAR. The TM also agreed that the currently available evidence does not support the use of an extra assessment factor to cover for the perceived uncertainties on DNT in the dossier of deltamethrin.
During the Technical Meeting II in 2010, it was decided to use the document on survey of DNT studies for pyrethroids prepared by the Netherlands as basis for the assessment of this category of substances. The conclusions of this survey were:
- Possible DNT effects induced by pyrethroids are covered by the AELs set on neurotoxicity in the acute neurotoxicity and medium-term studies since DNT effects from acceptable OECD TG 426 performed studies are taking place at higher LOAELs than other neurotoxicological effects.
- The DNT effects are also covered by the AELs set for long-term exposure (based on neurotoxic or other critical endpoints).
- As neurotoxic effects are critical effects after acute or medium-term exposure and the available data indicate that DNT effects are induced at higher LOAELs, it is unlikely that, in the absence of DNT studies, the potential DNT effects are not covered by AELs set on neurotoxic effects observed in acute and medium-term studies. It was concluded that additional DNT studies according to OECD TG 426, if such a study is not present, is not necessary.
The RMS respects the decision of TM although the view of RMS is still that there might be some uncertainty in the DNT study protocol and the most sensitive strain has not been used in the DNT study.

Medical data

Medical data from manufacturing, formulating and packaging plants indicate that transitory skin sensations were the most prevalent finding (paraesthesia, transient local burning, tingling, pickling sensations, itching, numbness of the facial skin – erythema in some cases). Cases of intoxications (mostly occupational due to inappropriate handling of products) have been reported. Two cases of occupational acute deltamethrin poisoning died of convulsions and another died of pulmonary oedema. No late sequeala of pyrethroid poisoning have been described in the scientific literature. There is no specific antidote for pyrethroids. Any treatment can only be symptomatic.
Other test(s) related to the exposure of humans. The trans-deltamethrin isomer has been tested for oral acute toxicity and mutagenicity (Ames test). The results of these studies showed that the acute oral toxicity of the trans-deltamethrin does not exceed the acute oral toxicity of the parent compound cis deltamethrin and no genotoxicity potential was found according to the Ames test.
In a study where food commodities (covered and uncovered) were exposed to an environment in which a deltamethrin based product was applied as a general surface treatment showed that the use of deltamethrin products will not contaminate food stuffs when spray is applied downwards. Spraying overhead or direct transfer of residues from treated spaces was not investigated in this study. However, no exposure of food stuffs is expected during and after crack and crevice treatment of food handling areas with the deltamethrin product when label instructions are followed.

Biocidal products

The acute toxicity of K-Othrine SC 26.25, SC 7.5 and DP 0.05 by oral, dermal and inhalation exposure is low. The acute toxicity of K-Othrine WG 250 by oral and dermal route is low, whereas the acute toxicity by inhalation route is moderately; therefore K-Othrine WG 250 should be classified as “Harmful” and assigned the risk phrase R20 (“Harmful by inhalation”).
The products are not irritating to skin or eyes, and are not sensitising to skin.

Tolerable exposure

The reference values, (acute/medium term and long term AELs) derived for deltamethrin were obtained from studies in dogs since the data submitted demonstrated that the dog was the most sensitive species to the

toxicity of deltamethrin. In addition a safety factor of 100 was applied taking into account a factor for inter- and intraspecies differences of 100 (10 x 10).

Acceptable daily intake (ADI)

Setting of an ADI is not considered necessary since no exposure of foodstuffs should occur during and after treatment of food handling areas with deltamethrin when product label instructions are followed.

Acute reference dose (ARfD)

Setting of an ARfD is not considered necessary since no exposure of foodstuffs should occur when product label instructions are followed, and risk of contamination of drinking water is not considered.
Acceptable exposure levels (AELs)

AEL (acute): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in a 13-week dog study after taking an oral absorption of 75% and a safety factor of 100 into account. In the study neurotoxic effects occurred early after dosing.

AEL (medium-term): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 13-week and 1-year dog studies after taking an oral absorption of 75% and a safety factor of 100 into account.

AEL (long-term): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study after taking an oral absorption of 75% and a safety factor of 100 into account.

Maximum acceptable concentration in drinking water

According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1µg/l for substances considered separately.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains no substance of concern.

2.7.1.3 Toxicology of the biocidal product

Toxicological data have been submitted on the product 3A MATE.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

2.7.1.3.1 Percutaneous absorption

The ability of deltamethrin to penetrate the skin was examined in vitro with the 3A MATE formulation containing 14C-deltamethrin at 0.74% w/w in pure substance and 0.75% w/w technical substance.
The product, applied at a target rate of 10 mg/cm^2, was in contact with dermatomed human skin (4 donors, 2 cells per donor) mounted on static cells during 8 hours (mimicking a normal working day); the experiment was then ended after an exposure time of 24 hours.

For each experiment and each cell, a recovery balance was calculated. The individual total recoveries were between 92.9% and 104.8% leading to a mean recovery of 101.2%.
Following exposure, a radioactivity below limit of quantification was recovered in the receptor fluid. This LOQ in dpm (100 dpm) or Ci ($4.5*10^{-11}$ Ci) is considered far below the amount of radioactivity applied on the skin ($0.38 * 10^{-3}$ Ci). The amount of active substance in the receptor fluid is therefore considered as negligible.

It was considered that absorption is essentially complete at the end of the study (> 75% of total absorption occurring within half of the study duration). Therefore, strips 3 to 7 were considered as non-absorbable material and were excluded from absorption calculation. The first 2 tape strips can be also excluded considering that they will not become bioavailable due to desquamation.
Therefore, the dermal absorption corresponds only to the product remaining in the skin.
The mean in vitro dermal absorption in the 3A MATE formulation was 0.03 ± 0.02% for deltamethrin.
According to the EFSA guidance on dermal absorption (2012)[9], as the standard deviation is larger than 25% of the mean of the absorption, the standard deviation is added to the mean value.

Therefore, the in vitro dermal absorption in the 3A MATE formulation is 0.05% for deltamethrin.

2.7.1.3.2 Acute toxicity

2.7.1.3.2.1 Oral

The test item 3A MATE was administered to a group of 6 female Sprague Dawley rats at the single dose of 2000 mg/kg body weight.
No mortality occurred during the study.
A decrease in spontaneous activity (1/6) was noted during the first hours of the test. The animal recovered a normal behaviour at 24 hours post-dose.
The body weight evolution of the animals remained normal throughout the study.
The macroscopic examination of the animals at the end of the study did not reveal treatment related changes.

In conclusion, an oral toxicity test (OECD 423) has been carried out on rats with 3A MATE resulting in a LD50 > 2000 mg/kg b.w. for females.

3A MATE has a low acute toxicity by oral route and is not classified for acute oral toxicity.

2.7.1.3.2.2 Dermal

The test item 3A MATE was applied onto the intact skin of 10 Sprague Dawley rats (5 males and 5 females) at the single dose of 2000 mg/kg body weight.
No mortality occurred during the study.
Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.
Depilation was noted on the treated area of all animals from 24 hours post-dose and was totally reversible on day 5.
The body weight evolution of the animals remained normal throughout the study.
The macroscopic examination of the animals at the end of the study did not reveal treatment-related changes.
In conclusion, an acute dermal toxicity test has been carried out on rats with 3A MATE resulting in a LD50 for males and females higher than 2000 mg/kg b.w.

3A MATE has a low acute toxicity by dermal route and is not classified for acute dermal toxicity.

2.7.1.3.2.3 Inhalation

In order to avoid unnecessary animal experiment, no acute inhalation study was conducted on the product 3A MATE according to the following arguments:

1- Considering TNsG recommendations, for studies 8.5.1 to 8.5.3 (formerly 6.1.1 to 6.1.3) biocidal products other than gases shall be administered *via* at least two routes, one of which should be the oral route. The choice of the second route will depend upon the nature of the product and the likely route of human exposure.
As the preparation is neither a gas nor a volatile liquid, nor a powder, no study is deemed necessary.

2- The active substance deltamethrin has a very low vapour pressure ($1.24*10^{-8}$ Pa at 25°C) and is present at very low concentration (< 1%) in the preparation. Therefore, it can be considered that exposure by inhalation is not a relevant route of human exposure.

3- In line with Directive 98/8/EC and with the new Regulation (EU) No.528/2012, acute inhalation testing does not need to be conducted since valid data are available on each of the components to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No. 1272/2008 (CLP). Synergistic effects between any of the components are not expected.
Accordingly acute inhalation of the product is extrapolated from data on the active substance and co-formulants.

In the formulated product 3A MATE, 3 of the components are toxicologically relevant for acute inhalation.

Nevertheless, a classification is not justified since the preparation contains less than the threshold value of substance classified.

Therefore the proposed classification of 3A MATE for acute inhalation toxicity is according to the criteria of Annex I to Regulation (EC) No.1272/2008: not classified.

To conclude the product 3A MATE does not require classification for acute toxicity by any route.

2.7.1.3.3 Irritation and corrosivity

2.7.1.3.3.1 Skin

The test item 3A MATE was applied, as supplied, at the dose of 0.5 mL, under semi-occlusive dressing during 4 hours on an undamaged skin area of three New Zealand rabbits.

A very slight erythema associated with a very slight oedema was noted on the treated area in all animals, 1 hour after the patch removal. The erythematous reactions were totally reversible between days 1 and 7. The oedematous reactions were totally reversible on day 1.

3A MATE is not a skin irritant in the study and is not classified.

2.7.1.3.3.2 Eye

The test item 3A MATE was instilled as supplied, into the eye of three New Zealand rabbits at the dose of 0.1 mL.

The conjunctivae reactions observed during the study have been slight to moderate and totally reversible: a slight to moderate redness noted 1 hour after the test item instillation and totally reversible between days 1 and 2 associated with a slight chemosis noted 1 hour after the test item instillation and totally reversible on day 1.

3A MATE is not an eye irritant in the study and is not classified.

2.7.1.3.4 Sensitisation

The aim of the study was to evaluate the possible allergenic activity of the test item after intradermal and topical administration in guinea pigs.
After induction (intradermic injection at 20% and topical application at 100%) of 10 Guinea Pigs of treated group with the test item 3A MATE and a 10-day rest phase, the challenge phase, under occlusive dressing for 24 hours, consisted to a single topical application of the test item diluted at 20% and 10% in distilled water.
No cutaneous reaction attributable to allergy was recorded in animals from the treated group after the challenge phase, on the treated area with the test item at 20% and 10%.
No cutaneous intolerance reaction was recorded in animals from the negative control group after the challenge phase, on the treated area with the test item at 20% and 10%.

3A MATE is not a skin sensitising in the study and is not classified.
However, the mention ”EUH 208 Contains isothiazolinones (2-octyl-2H-isothiazol-3-one, 1,2-benzisothiazol-3(2H)-one and reaction mass 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)). May produce an allergic reaction” has to be reported in labelling.

2.7.1.3.5 Other studies

No other study was performed on the biocidal product.

2.7.2 Human exposure assessment

The product 3A MATE is a finishing paint with insecticide/acaricide properties containing 0.75% (w/w) deltamethrin as active substance. The product is intended to control flying and crawling insects. It will be used indoor and by professionals only.
The product 3A MATE is a paint presented in buckets of 2.5 and 10 L. The paint product can be applied indoor with a brush or a roller.
The human exposure difference between application by brushing and use of a roller is considered as negligible. Therefore no separate exposure assessment will be performed.
The recommended dose of application is 1L for 14 m², corresponding to 71.43 mL/m² or 0,075 mg of a.s. / cm².
There are two main phases for the professional exposure:

- Application: application of the paint with a brush or a roller
- Post-application: cleaning and maintenance of the equipment

Adults and children may be secondarily exposed to deltamethrin when re-entering rooms where the product 3A MATE has been applied.

2.7.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Not appropriate	Primary exposure	Secondary exposure	Not relevant
Dermal	Not appropriate	Primary exposure	Secondary exposure	Not relevant
Oral	Not appropriate	Not relevant	Secondary exposure	Not relevant

2.7.2.2 Direct exposure as a result of use of the active substance in biocidal product

2.7.2.2.1 Exposure of professional users

In Annex 6„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.

There are two main phases for the professional exposure:

- Application: application of the paint with a brush or a roller
- Post-application: cleaning and maintenance of the equipment

No user survey study and no data related to the exposure of the biocidal product are available.

Therefore, exposure was determined using data available in TNsG, user guidance and HEEG opinion.

Application phase

No model for professional brush application is described. Consequently, in a worst case situation the Consumer product painting model 1, available in TNsG part 2[15], and reviewed in User Guidance was used.
Exposure by inhalation and dermal routes are expected. The following parameter have been used used to determine exposure.

Parameters for the calculation of exposure:

Parameter	Value	Unit	Source
Content of active substance in product	0.75%	%	
Density	1.4	kg/L	
Dermal absorption	0.05%	%	See dermal absorption paragraph
Inhalation absorption	100%	%	Default value
Task duration	360	min	Use pattern data base TNsG 2007
Body weight	60	kg	HEEG opinion 17: Default human factor values for use in exposure assessments for biocidal products endorsed at TM II 2013
Inhalation exposure	1.25	m3/h	HEEG opinion 17: Default human factor values for use in exposure assessments for biocidal products endorsed at TM II 2013
Indicative value			
Hand and forearms exposure	150	mg/min	Consumer product painting model 1 TNsG 2002 part 2, reviewed by user guidance
Body exposure	35.7	mg/min	Consumer product painting model 1 TNsG 2002 part 2, reviewed by user guidance
Inhalation exposure	3.1	mg/m^3	Consumer product painting model 1 TNsG 2002 part 2, reviewed by user guidance

Cleaning phase

To attempt to estimate the potential exposure to the skin of hands during the activity of cleaning of a brush, the exposure assessment of professionals is performed according to the General Exposure Calculator proposed by the HEEG opinion document[16]. Within this model, dermal exposure is considered as the only relevant route, and both inhalation and oral exposures are considered to be negligible.
Exposure calculations are performed using the following parameters.

Parameter	Value	Unit
Content of active substance in product	0.75%	%
Density	1.4	kg/L
Dermal absorption	0.05%	%
Body weight	60	kg

[15] Technical Notes for Guidance - Human Exposure to Biocidal Products - Guidance on Exposure Estimation (European Commission, 2002, part 2)
[16] HEEG opinion on Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (Endorsed at TM III 2010, Ispra, 07/07/2011).

The results are presented in the following table:

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
Task – time frame:	**Application – 360 minutes daily**		
Tier 1: Without PPE	2.91E-03	4.18E-03	7.08E-03
Task – time frame:	**Cleaning of brush**		
Tier 1: Without PPE	Not relevant	1.15E-05	1.15E-05

The combined exposure assessment of the professionals using the paint 3A MATE is summarized below:

Task – time frame:	**Combined exposure: application and cleaning of brush**		
Tier 1: Without PPE	2.91E-03	4.19E-03	7.1E-03

2.7.2.2.2 Exposure of non-professional users

The product 3A MATE is a finishing paint with insecticide/acaricide properties intended to be used by professionals only. Therefore the assessment of non-professional exposure is not relevant

2.7.2.3 Indirect exposure as a result of use of the active substance in biocidal product

Adults and children may be incidentally exposed to deltamethrin when re-entering rooms where the product 3A MATE has been applied. As the vapour pressure of deltamethrin is low (1.24*10-8 Pa, 25°C), inhalation exposure can be considered as negligible. Therefore, the main secondary exposure is considered via the dermal route, through contact with a treated area (wet or dried), and via the oral route with subsequent hand-to-mouth contact.
As a worst-case scenario the risk of indirect exposure is estimated for a toddler of 10 kg.

There is no relevant scenario for exposure of a child to product applied in the form of brush- or roll-painting. Therefore scenario has to be set up using the following parameter:

Parameter	Value	Unit	Source
Application rate for paint	71.43	mL/m^2	
Content of active substance in product	0.75%	%	
Density	1.404	kg/L	
Transfer coefficient from dried wall to hand	3	%	TNsG 2002 part 2 Transfer coefficient-dislodgeable residues
Transfer coefficient from freshly painted wall to	50	%	Ad-hoc follow-up for PT21 product The transfer of the paint from the wall to

Parameter	Value	Unit	Source
hand			the toddler hands is unlikely to be 100% as the paint it is sticky. It would probably stick equally as well to the wall as to the skin of the hands. Therefore, it is reasonable to assume that 50% of the touched paint will transfer to the hand and 50% will remain sticking to the wall.
Area of hands (palm only on both hands)	115	cm^2	HEEG opinion: default human factor values for use in exposure assessments for biocidal products endorsed at TM II 2013 The area of hands (palms and back of both hands) of toddler (1-2 years) is 230.4 cm^2
Proportion of palms of hands in contact with dried paint	40	%	Agreed by WG ad hoc follow-up Brouwer et al. (1999) found that following single-hand press contact onto powder-loaded glass plate, about 40% of the palm of the hand was exposed following 12 contacts.
Proportion of palms of hands in contact with freshly painted surface	100%		Recommendation n°5 of Ad hoc WG on human exposure: Non-professional use of antifouling paints: exposure assessment for a toddler. The hands might be pressed into the paint and smeared around.
Transfer coefficient from hands to mouth (dried paint)	50	%	Agreed by WG ad hoc follow-up Default assumption from the pest Control fact sheet. The dry paint does not result in a layer on the skin and may go unnoticed by the toddler when mouthing its hands/fingers
Transfer coefficient from hands to mouth (freshly painted)	10	%	Recommendation n°5 of Ad hoc WG on human exposure: Non-professional use of antifouling paints: exposure assessment for a toddler. A toddler is unlikely to lick all of the wet paint from its two hands but is more likely that two fingers from one hand could be sucked. Two fingers from one hand constitutes about 10 % of the total palm area of both hands (i.e. default of 115.2 cm2 for surface area of both palms x 10% = 11.52 cm2). In the absence of data to the contrary, it is assumed all wet paint entering the mouth is ingested to become a systemic dose.
Dermal absorption	0.05%	%	See dermal absorption paragraph
Oral absorption	75%	%	Active substance data
Toddler body weight	10	Kg	HEEG opinion: default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013

Remark: the applicant provided a study to determine the dislodgeable residue factor. However, this study was realised with residue dislodgeabled from a treated foamed polystrene. The extrapolation between the treated foamed polystrene and a painted surface was judged not acceptable. Consequently, the proposed value was not used to determine exposure.

Using the previous parameters, the systemic exposures of a toddler who touches a dried or freshly painted surface and puts his hands to mouth are:

Scenario	Exposure
Systemic exposure – toddler touching freshly painted surface	3.3 E-02 mg /kg/d
Systemic exposure – toddler touching dried painted surface	3.90 E-03 mg /kg/d

Exposure to companion animals

The product is applied indoors and in some animal houses. Exposure by ingestion (animals licking treated surfaces) is therefore considered.

On the basis of the studies assessed in the CAR, the following reference value was determined:

- Dogs: for human, an AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study, taking into account an oral absorption of 75% and a safety factor of 100. A specific AEL for dogs can be derived considering an intrainter-species assessment factor of 1, leading to an AEL for dog of 0.075 mg/kg bw/d.

An AEL for the cat has been proposed by applicant, extrapolating data between permethrin and deltamethrin. However, as it was based only on hypothesis and extrapolation, the AEL proposed by applicant (although it is well justified) is not accepted. Consequently, no specific AEL for the cat has been proposed.

Exposure by ingestion (animals licking dried painted surfaces)

A reverse scenario is proposed to determine the maximum treated surface area that a dog has to lick to reach the AEL.
The following parameters have been considered:

- Concentration of active substance: 0.75%;
- Application rate: 71.43 mL product/m^2;
- Density value: 1.404;
- Oral absorption value: 75%;
- Transfer coefficient : 3%;
- Body weight: 5 kg ;
- AEL_{dog} = 0.075 mg/kg bw/d .

A surface area of 221 cm^2/day has to be licked to reach the AEL.
This reverse calculation is depending of the body weight. In this context, assessment was realized for a dog of 5 kg. However, the more body weight is high, the more the surface that dog could lick is high.

2.7.2.4 Indirect exposure via residues in food

No specific residue data were submitted in the context of this dossier. The product 3A MATE is intended to be applied indoor by professional users on wall and ceiling (domestic, industrial or public buildings and animal houses: equestrian centers and kennels) in areas where food and feed, food ustensiles or food processing surfaces will not become into contact with or be contamined by it, and therefore does not leave residues in commodities for human or animal consumption.

In this purpose, the following precautionary statement should be indicated on the labels:

Do not apply in vicinity of food and feed or utensil and surfaces in contact with food and feed

2.7.3 Risk assessment for human health

The estimated exposures for the professional users are compared to the systemic AEL of deltamethrine set in the Assessment Report (0.0075 mg/kg bw/day for short, medium and long-term exposures).

2.7.3.1 Risk for direct exposure

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for Professional users (%AEL<100%).

Summary of risk characterisation for professionals

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Application – 360 minutes daily				
Tier 1 Without EPI	7.5 E-03	7.08E-03	94	Acceptable
Cleaning of brush				
Tier 1 Without EPI	7.5 E-03	1.15E-05	0.15	Acceptable
Combined exposure: application and cleaninf of brush				
Tier 1 Without EPI	7.5 E-03	7.1E-03	95	Acceptable

The risk is considered as acceptable for professional without PPE.

2.7.3.1.1 Non-professional users

The product is for professional use only.

2.7.3.2 Risk for indirect exposure

Based on the risk assessment of the active substance, unacceptable risk for a toddler who touches a freshly painted surface has been observed. No unacceptable risk has been identified for a toddler who touches dried painted surface.

Summary of risk characterisation for general public

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Contact with freshly paint and contact hand-mouth	7.5 E-03	3.3 E-02	435	Unacceptable
Contact with dried paint and contact hand-mouth	7.5 E-03	3.9 E-03	52	Acceptable

In this context, risk mitigation to avoid contact with freshly painted surface is necessary.

Risk to companion animals

Veterinary pharmacovigilance available data in France cannot be used to determine hypersensitivity of a species to deltamethrin.

However, it could be noted that the most adverse effects have been reported for cats and equines (29 cases for cats and 17 for horses since 2002). The main clinical symptoms are:

- For cats: hypersalivation, vomiting, ataxia, tremors, and (likely related to overdosing) death;
- For horses: hyperthermia, itch and agitation.

Furthermore, bibliographic data reveal that cats are particularly sensitive to pyrethroids, due to a lack of glucuronide conjugation enzymes and other not yet elucidated reason(s)[17,18,19]. Although sensitivity to permethrin is more documented, without any further data, it is recommended that the product 3A MATE is not used to treat premises were cats are housed, as well as other species that may display a particular sensitivity to deltamethrin.

Oral exposure

A surface area of 221 cm^2/day for dog has to be licked to reach the AEL.
This reverse calculation is depending of the body weight. In this context, assessment was realized for a dog of 5 kg. However, the more body weight is high, the more the surface that dog could lick is high.

In conclusion, secondary exposure to companion animals with treated surfaces cannot be precisely assessed. However, considering the presented estimations, this exposure cannot be considered negligible. In order to limit this exposure, the implementation of the following risk mitigation measures is essential.

Risk mitigation measures linked to risk assessment for animals

- Do not use in premises where cats are housed, or where other animals with particular sensitivity to deltamethrin are housed.
- Do not use at the same time as a veterinary antiparasitic treatment containing a pyrethroid.
- Apply only during a fallowing period in animal shelters/housings (empty premises).
- Do not apply on surfaces likely to be licked by animals.
- Wait complete drying of the treated surfaces after the end of the treatment, before allowing animals to re-enter.

2.7.3.3 Risk for consumers via residues in food

Based on the intended use and the proposed restriction, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers.
The product shall not be applied on surfaces likely to be in direct contact with food, feed or drinks Regarding consumer health protection, there are no objections against the intended uses.

2.7.3.4 Summary of risks characterisation of the product for human health

Risks related to the use of 3A MATE by professionals are considered acceptable, in accordance with the proposed conditions of use.

Risk mitigation measures linked to risk assessment for human health

- Avoid contact with freshly painted surface.

[17] Gfeller, R.G., Messonnier, S.P., 2004. *Handbook of Small Animal Toxicology and Poisonings, second ed*. Mosby, St. Louis, MO, USA.
[18] Anadón A., Martínez-Larrañaga M.R., Martínez M.A., 2008. *Use and abuse of pyrethrins and synthetic pyrethroids in veterinary medicine*. The Veterinary Journal 182 (2009) 7–20.
[19] Beugnet F., Franc M., 2012. *Insecticide and acaricide molecules and/or combinations to prevent pet infestation by ectoparasites*. Trends in Parasitology, July 2012, Vol. 28, No. 7.

- The product shall not be applied on surfaces likely to be in direct contact with food, feed or drinks

2.8 Risk assessment for the environment

The summary of information on the active substance properties is carried out with the data from the Competent Authority Report (CAR) of deltamethrin. (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, deltamethrin CAS 52918-63-5, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Sweden, May 2011).

2.8.1 Fate and distribution in the environment of the active substance deltamethrin

2.8.1.1 Degradation

2.8.1.1.1 Abiotic degradation

2.8.1.1.1.1 Hydrolysis in function of pH

For the active substance deltamethrin, no significant hydrolysis was observed at pH 5 and 7. At pH 9, however, the hydrolysis was significant with a half-life of 2.5 days at 25°C (7 days at 12°C). At pH 8, half-life was 31 days at 23°C (75 days at 12°C).

2.8.1.1.1.2 Photolysis in water

Direct photochemical reactions do not occur at a rate that makes this a significant route of degradation of deltamethrin under natural conditions in water.

2.8.1.1.1.3 Photolysis in soil

In soil, direct and indirect photochemical reactions may contribute to the degradation of deltamethrin, but other routes of transformation account for the major loss of parent compound.

2.8.1.1.1.4 Photodegradation in air

The photo-oxidative degradation of deltamethrin in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.91 (AOPWIN). Half-life for reaction with OH-radicals was calculated to 16 hours.

2.8.1.1.2 Biotic degradation

2.8.1.1.2.1 Aquatic compartment

- Ready biodegradation / inherent biodegradation

Deltamethrin is not readily biodegradable under OECD 301F Test (degradation of 0% after 28 days).

- Degradation in water/sediment system

A higher tier water/sediment simulation study in two different water/sediment systems has been conducted and provides information on aerobic aquatic degradation of deltamethrin. 60% of the applied radioactivity was found in the sediments immediately after application. The total system degradation DT_{50} of deltamethrin in two different water/sediment systems was estimated to 85 and 267 days at 12°C, and the dissipation DT_{50} in sediment to 104 and 253 days at 12°C. The difference in degradation rate between the two systems probably reflects difference in amount of fine-textured material and amount of organic matter.

2.8.1.1.2.2 Degradation in STP

No study on the degradation of the active substance in STP has been submitted in the CAR of deltamethrin.

2.8.1.1.2.3 Terrestrial compartment

- Aerobic degradation

Four laboratory studies on degradation in soils have been submitted in the CAR of deltamethrin, and one further study presented calculations of rate of degradation for the relevant metabolite Br_2CA (> 10%) based on data from the four laboratory studies. In one additional study the rate of degradation for deltamethrin and its relevant metabolite were re-calculated using more appropriate approaches than in the original studies.
Deltamethrin is relatively rapidly degraded in soil, with a geometric mean DT_{50} value of 48 days at 12°C. The main metabolite of deltamethrin was Br_2CA. It was detected in available studies, up to 23% of applied radioactivity after about 2 weeks of incubation. No other metabolites were detected at levels of > 10% of applied radioactivity. When normalised to 12°C, the geometric mean of DT_{50} value for Br_2CA was 5.6 days.

- Anaerobic degradation

No study on the anaerobic degradation of deltamethrin in soil has been submitted in the CAR.

2.8.1.2 Distribution

Deltamethrin is very strongly adsorbed to soil and other organic matter, with an arithmetic mean Koc value of 408 250 $L.kg^{-1}$. The relevant metabolite is more mobile with an arithmetic mean Koc value of 25.6 $L.Kg^{-1}$.

2.8.1.3 Accumulation

The bioaccumulation of ^{14}C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*). The BCF_{fish} values obtained were 310, 2800 and 1400 $L.Kg^{-1}$ for edible, non-edible and whole body tissue, respectively. After the 14-day depuration period 70, 75 and 76% of the ^{14}C-residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue.

No experimental data are available for terrestrial bioconcentration. Therefore, the terrestrial BCF have been estimated using a linear Quantitative Structure Activity Relationship (QSAR) model and the log P_{ow} of deltamethrin of 4.6 at 25°C. The $BCF_{earthworm}$ was 483 $L.kg^{-1}$ (according to TGDII Equation 82d).

2.8.1.4 Behaviour in air

Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3} $Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals.

2.8.2 Effects on environmental organisms for active substance deltamethrin

No new ecotoxicological information on the active substance deltamethrin has been submitted in the product dossier compared to the CAR.

2.8.2.1 Aquatic compartment (including water, sediment and STP)

2.8.2.1.1 Aquatic organisms

The table below summarises all the data available for the active substance deltamethrin. The metabolite Br_2CA is considered not relevant for the aquatic compartment. Nevertheless a PNEC was derived in the CAR. Moreover it has been demonstrated in the CAR that the risk assessment for the metabolite, Br_2CA was covered by the risk assessment for deltamethrin.

Table 2.8.2-1: Existing endpoints for aquatic organisms

Test item	Species	Guideline	Endpoints	Toxicity [$\mu g.L^{-1}$]
Fish				
Deltamethrin	*Onchorhynchus mykiss*	OECD 203	LC_{50} – 96h Flow-through	0.26[1]

Test item	Species	Guideline	Endpoints	Toxicity [µg.L^{-1}]
			conditions	
	Pimephales promelas	US EPA 72-5	NOEC – 260d	0.017[1]
Br_2CA		QSAR calculation	LC_{50} (96h)	10 400
Invertebrates				
Deltamethrin	*Gammarus fasciatus*	US EPA	LC_{50} – 96h Flow-through conditions	0.0003[1]
	Daphnia magna	OECD 211	NOEC – 21d Flow-through conditions	0.0041[1]
	Chironomus riparius	BBA 1995	NOEC – 28d	0.0035[1]
Br_2CA		QSAR calculation	EC_{50} (48h)	84 900
Algae				
Deltamethrin	*Chlorella vulgaris*	Brazilian method D.4.1	EbC_{50} – 96h ErC_{50} – 96h NOErC Static conditions	>0.47E03[1] >0.47 E03[1] 0.47 E03
Br_2CA		QSAR calculation	EC_{50} (96h)	74 100
Higher tier studies				
Deltamethrin	*water flea*	Mesocosm guidance[3]	NOEC Mesocosm conditions	0.0048[2]

[1] measured concentrations
[2] nominal concentrations
[3] OECD 2004 "Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms)"

Additional endpoints: not relevant.

Justification of $PNEC_{water}$

Deltamethrin
According to the TGD for Risk Assessment (2003), and using the lowest chronic laboratory NOEC value (3.5 ng.L^{-1}) and an assessment factor of 5 (considering that the test organism had been identified as the most sensitive), the $PNEC_{water}$ is 0.7 ng L^{-1}.

Br_2CA
According to the TGD for Risk Assessment (2003), and using the lowest chronic laboratory NOEC value (10.4 mg.L^{-1}) and an assessment factor of 1 000 (considering that the test organism had been identified as the most sensitive), the $PNEC_{water}$ is 10.4 µg L^{-1}.

2.8.2.1.2 Sediment dwelling organisms

Justification of $PNEC_{sediment}$

Deltamethrin
The $PNEC_{sediment}$ is estimated from $PNEC_{water}$ in using the Equilibrium Partitioning Method (according to the TGD for Risk Assessment (2003)) with the mean Koc value for deltamethrin of 408 250 L.Kg^{-1}. The $PNEC_{sediment}$ is 6.2 µg kg $_{wwt}^{-1}$.

Br_2CA
Using the equilibrium partitioning method, a $PNEC_{sediment}$ of 1.39 x 10^{-2} mg.kg $_{wwt}^{-1}$ is obtained, for Br_2CA.

2.8.2.1.3 STP micro-organisms

The table below summarises the data available for the active substance deltamethrine.

Table 2.8.2-2: Existing endpoints for STP micro-organisms

Test item	Guideline	Species/ Inoculum	Exposure design	Exposure duration	Result [mg a.s.L^{-1}]		
					NOEC	EC_{50}	EC_{80}
Deltamethrin	OECD 209	Activated sludge	Respiration inhibition	3h		>300	-
Deltamethrin	OECD 209	Activated sludge	Respiration inhibition	3h	>0.3	**>0.3**	

Additional endpoints: not relevant

Justification of $PNEC_{STP\ microorganisms}$

Deltamethrin
According to the TGD for Risk Assessment (2003), and taking into account that deltamethrin had no significant effect at the highest tested concentration (NOEC ≥ 0.3 mg L^{-1}), an assessment factor of 10 can be applied. Thus, the $PNEC_{microorganisms}$ is 30 µg.L^{-1}.

Br_2CA
No data are available concerning the specific effect of the major metabolite on microorganisms. However, based on the QSAR modelling performed for other aquatic organisms, it can be concluded that Br_2CA is considerably less toxic than the parent substance. Therefore, it has been assumed that a $PNEC_{microorganisms}$ of 30 µg.L^{-1} for deltamethrin will be suitably protective for exposure to Br2CA.

2.8.2.2 Atmosphere

Significant exposure of the environment via air is not expected.

Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252 x 10^{-3} Pa.m^3.$mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals (DT_{50} reaction with OH-radicals = 16 hours). It is thus considered that it is not likely that significant volatilisation will occur after use of deltamethrin.

2.8.2.3 Terrestrial compartment

The table below summarises all the data available for the active substance deltamethrin and its relevant metabolite, BR_2CA.

Table 2.8.2-3: Toxicity so soil organisms

Test item	Guideline/Test method	Species inoculums	Endpoint / type of test	Exposure design duration	Results
ACUTE					
Deltamethrin	OCDE 207	*Eisenia fetida*	$LC50_{mortality}$	14d - Artificial soil	> 1290 mg/kg^{-1} $_{dw\ soil}$
CHRONIC					
Br_2CA	SECOFASE (1996)	*Hypoaspis aculeifer*	$NOEC_{mortality}$ Br_2CA mixed with LUFA 2.1 soil	14d	10 mg/kg^{-1} $_{dw\ soil}$
Deltamethrin	BBA VI 2-2	*Eisenia fetida*	$NOEC_{reproduction}$	56d - Artificial soil	0.78 mg/kg^{-1} $_{dw\ soil}$
	ISO 11267	*Folsomia candida*	$NOEC_{mortality}$	28d - Artificial soil	1.25 mg/kg^{-1} $_{dw\ soil}$
	Hypoaspis ring-test (SETAC, 2005)	*Hypoaspis aculeifer*	$NOEC_{mortality}$ and $NOEC_{reproduction}$	16d - Artificial soil	1.78 mg/kg^{-1} $_{dw\ soil}$
	BBA VI, 1-1	Microorganisms	NOEC- Effect on aerobic respiration in 2 soils	28/56-d	>0.50 mg/kg^{-1} $_{dw\ soil}$ equivalent to > 375 g/ha
	BBA VI, 1-1	Microorganisms	NOEC - Effect on N cycle in 2 soils	28d	>0.50 mg/kg^{-1} $_{dw\ soil}$ equivalent to > 375 g/ha

Additional endpoints: not relevant.

Justification of $PNEC_{soil}$

Deltamethrin

Due to the lack of effects in the tests on micro-organisms and chronic toxicity to earthworms, the PNEC is based on the NOEC from the reproduction test on springtails.

The results are converted to standard soil which is defined as a soil with an organic matter content of 3.4% using the following equation:

$NOEC_{standard} = NOEC_{exp} \times F_{om,\ soil\ standard} / F_{om,\ soil\ exp}$ (TGD, part II, Eq. 71)

With $NOEC_{exp} = 1.25\ mg.kg^{-1}$ dry soil

$F_{om,\ soil\ standard} = 3.4\ \%$

$F_{om,\ soil\ exp} = 5\ \%$

Then, $NOEC_{standard} = 0.85\ mg.kg^{-1}$ dry soil

An assessment factor of 10 can be applied. Thus, the following $PNEC_{soil}$ is derived:

$PNEC_{soil}$ = 85 µg.kg^{-1} dry soil (75 µg.kg^{-1} wet soil)

Br_2CA

An overall NOEC of 10 mg.kg^{-1} (dry weight soil) was found. According to the TGD for Risk Assessment (2003) an assessment factor of 100 is appropriate as a NOEC is available for a species representing one trophic level, The resulting $PNEC_{soil}$ for the major metabolite Br_2CA is 0.10 mg.kg^{-1} dry soil (0.14 mg.kg^{-1} wet soil).

2.8.2.4 Effects on honeybees

No data, the exposure of deltamethrin to honeybees is expected to be very limited.

2.8.2.5 Non compartment specific effect relevant to the food chain

The table below summarises the data available for the active substance deltamethrin:

Table 2.8.2-4: Toxicity to birds and mammals

Test item	Guideline/Test method	Species	Test/ Duration		Results
Birds					
Deltamethrin	US EPA FIFRA E 71-1	*Bobwhite quail (Colinus virginianus)*	Acute oral LD_{50}		>2250 mg.kg^{-1} $_{bw}$
	Conducted before an appropriate guideline	Mallard duck *(Anas platyrhynchos)*	Acute oral LD_{50}		> 4640 mg.kg^{-1} $_{bw}$
	US EPA 71-2 / OECD 205	*Bobwhite quail (Colinus virginianus)*	Dietary 5-day LC_{50}		> 5620 mg/kg^{-1} $_{diet}$
	US EPA 71-2 / OECD 205	Mallard duck *(Anas platyrhynchos)*	Dietary 5-day LC_{50}		8039 mg/kg^{-1} $_{diet}$
	US EPA 71-4; OECD 206	*Bobwhite quail (Colinus virginianus)*	Reproduction 22-week NOEC		> 450 mg/kg^{-1} $_{diet}$ (55 mg.kg^{-1} $_{bw}$ d^{-1})
	US EPA 71-4; OECD 206	Mallard duck *(Anas platyrhynchos)*	Reproduction 22-week NOEC		> 450 mg/kg^{-1} $_{diet}$ (70 mg.kg^{-1} $_{bw}$ d^{-1})
Mammals					
Deltamethrin	OECD 401	rat	LD_{50}	Oral	95 mg.kg^{-1} $_{bw}$ (males) 87 mg.kg^{-1} $_{bw}$ (females)
	OECD 416	rat	NOAEL	Oral	80 ppm

Justification of PNECoral,bird and PNECoral,mammal for secondary poisoning

The $PNEC_{bird}$ and the $PNEC_{mammals}$ calculations are based on a long-term toxicity / reproduction study with bird and on a 2 generation toxicity test on rat respectively. According to the TGD for Risk Assessment (2003), an assessment factor of 30 for bird and mammal can be applied. Thus, the following $PNEC_{oral}$l are derived:

$$\mathbf{PNEC_{oral,bird} = 15\ mg.kg^{-1}\ _{diet}}$$

$PNEC_{oral,mammal}$ = 2.67 $mg.kg^{-1}$ $_{diet}$

2.8.2.6 Summary of PNECs of the active substance deltamethrin

Compartment	Species	Endpoint	Safety factor	PNEC
Deltamethrin				
Surface water	*Chironomus riparius*	NOEC – 28d = 3.5 $n.gL^{-1}$	5	0.7 $ng.L^{-1}$
Sediment	6.2 $\mu g.kg^{-1}$ww sediment (equilibrium partitioning)			
Microorganisms (STP)	Activated sludge	NOEC ≥ 0.3 mg L^{-1}	10	30 $\mu g.L^{-1}$
Soil	*Folsomia candida*	NOECstandard = 0.85 $mg.kg^{-1}$ $_{dry\ soil}$	10	75 $\mu g.kg^{-1}$ wet soil
Bird	*Colinus virginianus* *Anas platyrhynchos*	NOEC > 450 mg/kg^{-1} $_{diet}$	30	15 $mg.kg^{-1}$ diet
Mammal	*Rat*	NOAEL = 80 ppm	30	2.67 $mg.kg^{-1}$ diet
Br2CA				
Surface water	**Fish**	**QSAR LC_{50} = 10.4 mg a.s. L^{-1}**	**1000**	**10.4 µg. L^{-1}**
Sediment	**13.9 $\mu g.kg^{-1}$ww sediment (equilibrium partitioning)**			
Microorganisms (STP)	**No Data**	**No Data**	**No Data**	**30 $\mu g.L^{-1}$**
Soil	***Hypoaspis aculeifer***	**NOEC = 10 $mg.kg^{-1}$**	**100**	**0.14 $mg.kg^{-1}$ wet soil**

2.8.2.7 PBT and ED Assessment

According to the PBT assessment in TGD, criteria for substance to be persistent (P) and very persistent (vP) are fulfilled when:

- T 1/2 in freshwater sediment > 120 days for P;
- T 1/2 in freshwater sediment > 180 days for vP.

Results of a simulation test on two different water/sediment systems show that deltamethrin partitions very rapidly to sediment. The degradation half-lives of deltamethrin in both systems were 85 and 267 days at 12°C (degradation in the whole water/sediment systems).

It can be concluded that in one system the DT_{50} normalised to 12°C exceeds the P- and the vP-criteria for freshwater sediment – while in the other system the DT_{50} normalised to 12°C does not exceed any of P / vP criteria. With one value below the criteria and one value above, it cannot be concluded whether deltamethrin should be classified as persistent in the sediment compartment or not.

Laboratory data from four different soils were available; the DT_{50}s ranged from 31 to 74 days (12°C). Hence, none of the half-lives for degradation in soil exceeds the P-criterion for soil (i.e. > 120 days). It is concluded that deltamethrin cannot be classified as persistent in the soil compartment.

Both environmental compartments for which there is adequate data available (i.e., sediment and soil) are considered to represent relevant environmental compartments since emissions may occur to both systems, via release from STP or application of sludge. Based on the data above **it can be concluded that deltamethrin potentially fulfils the criteria for persistence**.

According to the PBT assessment in TGD, a substance is considered to fulfil the B criterion when the bioconcentration factor (BCF) exceeds a value of 2 000 L/kg. In a BCF study done with *Lepomis macrochirus*, the steady-state BCF for uptake of deltamethrin estimated in whole fish was 1400 L/kg. Considering this result, **deltamethrin is not selected according to the B criterion**.

According to the PBT assessment in TGD, the toxicity criterion is fulfilled when the chronic NOEC for aquatic organism is less than 0.01 $mg.L^{-1}$ or when the substance is toxic to mammals and classified as Very Toxic or Toxic after oral dosing. Based on ecotoxicity freshwater data on water flea, NOEC = 4.8 $ng.L^{-1}$, **T criterion is fulfilled**.

As the B criterion is not fulfilled and only the T criterion is clearly fulfilled, deltamethrin is not classified as PBT.

2.8.3 Effects on environmental organisms for biocidal product 3A MATE

The applicant hasn't provided acute ecotoxicological data on the biocidal product 3A MATE. Therefore the risk assessment for the product is based on the data obtained from the active substance deltamethrin (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, deltamethrin CAS 52918-63-5, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Sweden, May 2011).

According to the identified risks from the risk calculation based on the active substance only, an additionnal assessment taking into account preservatives and others co-formulants was not deemed necessary. Therefore, FR CA considered that the effects of deltamethrin outweigh those of the non-active components of the product and that the effects assessment for the product 3A MATE can be extrapolated from the effects assessment of the active substance deltamethrin.

2.8.3.1 Aquatic compartment (including water, sediment and STP)

2.8.3.1.1 Aquatic organisms

No additional data. Refer to section 2.8.2.1

2.8.3.1.2 Sediment dwelling organisms

No additional data. Refer to section 2.8.2.1

2.8.3.1.3 STP micro-organisms

No additional data. Refer to section 2.8.2.1

2.8.3.2 Atmosphere

No additional data. Refer to section 2.8.2.2

2.8.3.3 Terrestrial compartment

No additional data. Refer to section 2.8.2.3.

2.8.3.4 Non compartment specific effect relevant to the food chain

No additional data. Refer to section 2.8.3.4.

2.8.3.5 Summary of PNECs

No additional data. Refer to section 2.8.3.5.

2.8.4 Environmental exposure assessment

2.8.4.1 Emissions to the environment

The product 3A MATE containing 0.75% (w/w) deltamethrin is an insecticide and acaricide finishing paint restricted to professional use. 3A MATE is presented as a ready-for-use paint, in 2.5 or 10 L tin pails. It is intended to control flying and crawling insects.

The product is applied indoors by brushing or rolling on walls and ceilings.

This finishing paint is intended to be used in individual and collective houses, offices and commercial premises, public areas including hospital and retirement home, and in some animal houses (equestrian centres and kennels). The product is not to be used in other breeding premises.

The product 3A MATE can be applied on every construction material (cement, plaster, wood, concrete…), with a suitable sub-coat, and on existing adhesive matt paint.

The recommended rate of application is 1L for 14 m², corresponding to 0.0714 L/m² or 100.3 g of product/m² (considering a product density of 1.404 g/mL), *i.e.* 752 mg of active substance/m². The efficacy against target insects should last at least 3 years after application.

Since the product is formulated as a ready-for-use product, no dilution or other preparations are necessary.

Emission to the environment: Professional use: application by brushing or rolling

The scenario "indoor spray application" proposed in the ESD for insecticides (PT18) [20] and the ESD for wood preservatives (PT8) [21] were used for the environmental exposure assessment.

Insecticides applied indoor will generally reach the treated surfaces, the floor, the applicator and the indoor air in the building. As a result, insecticides will not reach directly the environmental compartments (i.e. surface water, groundwater, soil and air). The cleaning of surfaces will lead to releases either to wastes (through dry cleaning methods like vacuuming) or to waste water (through wet cleaning methods). Therefore, the Sewage Treatment Plant (STP) is considered as the main receiving compartment where insecticides will be released through wet cleaning events. Then, the final environmental compartment will be surface water (through STP), the soil and the groundwater (from sludge application) and the outdoor air.

For a brushing or rolling application of the product 3A MATE, the following assumptions are made:

Mixing and loading step

The product is a ready-for-use product, therefore no emission is calculated for the preparation.

Application step

A surface area of a TGD standard house of 130 m^2 is considered with a height of walls of 2.5 m.

Considering for the exposure assessment that only walls are painted, the application area is:

Type of building	TGD standard house	
Height of walls	2.5	m
Length of the house	17.5	m
Width of the house	7.5	m
$Application\ area = (height \times Length \times 2) + (height \times width \times 2)$		
Application area	125	m^2

[20] ESD n°18 "Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses", OECD n°18 (2008)
[21] ESD n°8 "Emission scenario document for wood preservatives", OECD n°2 (2013)

The following default values for the emission factors for an application by brush are proposed in ESD for PT8 with an exception for the fraction emitted to applicator. These values are relevant for paint application.

Fraction emitted to applicator	$F_{application, applicator}$	0.01
Fraction emitted to floor	$F_{application, floor}$	0.03
Fraction emitted to treated surfaces	$F_{application, treated}$	0.96

Cleaning step after the application phase

The cleaning of painting equipment (brushes or rollers) is not taken into account in the risk assessment as the use of an appropriate cleaning system for collecting rinse water and paint residues is mandatory according to the label. Moreover it is recommended to protect the soil during application with a plastic foil and to wear disposable protective clothing. Therefore, the cleaning step after the application phase results in no emission to wastewater.

These risk mitigation measures must be indicated on the label.

Cleaning step during the paint service-life

It is not a common practice to wash the walls and ceilings with water in the premises intended for 3A MATE application as individual and collective houses, offices and commercial premises, public areas, … Nevertheless, it could be usual in animal houses as equestrian centres and kennels. The application on a surface of 125 m^2 represents a best case for these types of premises.

It is considered that 100% of treated surface (125 m^2) are periodically cleaned by wet methods. Cleaning step will therefore lead to releases to waste water.

Considering the ESD for PT18:

- Cleaning events result only in emission to wastewater: surfaces are washable and the clothes of the applicator are washed, then $F_{waste} = 0$ and $F_{wastewater} = 1$.

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. According to the ESD for PT18 (Table 3.3.3-8) cleaning efficiency is 50% for surface spraying. For painted walls by brushing, cleaning efficiency must be adapted. With an efficacy of the paint of at least 3 years and a washing of walls every week in a realistic approach, a cleaning efficiency is estimated in considering that after 3 years the whole content of the deltamethrin in paint is released. Therefore a value of 0.64% (7 days /1095 days *100) for the cleaning efficiency is taken into account.

Total local emission to wastewater

In this scenario, local emissions are considered within one day and are expressed as the mass of substance emitted through a unique point source, the STP, into environmental compartment. Emission rate from only one house is used in a best case approach.

The parameters used in the calculation of emission rates are summarised in the following table:

Parameters for the calculation of environmental exposure:

Parameters	Symbol	Value	Unit
Product Information			
Product Name	(-)	3A MATE	(-)
Active substance	(-)	DELTAMETHRIN	(-)
Fraction of as in product	F_{as}	0.0075	(-)
Treatment Rate (product)	$Q_{product}$	100.3	$g_{product}.m^{-2}$
Treatment Rate (active substance)	Q_{as}	7.52E-01	$g_{as}.m^{-2}$
Mixing and loading step			
Ready-for-use product - no emission is calculated for the preparation.			
Indoor application step by brushing or rolling			

Type of building	(-)	House standard	(-)
Application area	$AREA_{treated}$	125	m^2
Number of applications per day	N_{app}	1	(-)
Fraction emitted to applicator	$F_{application, applicator}$	0.01	(-)
Fraction emitted to floor	$F_{application,floor}$	0.03	(-)
Fraction emitted to treated surfaces	$F_{application, treated surface}$	0.96	(-)
$E_{application,j} = Q_{as} \times AREA_{treated} \times N_{app} \times F_{application,j} \times 10^{-3}$			
Emission to the applicator	$E_{application, applicator}$	9.40E-04	kg
Emission to the floor	$E_{application, floor}$	2.82E-03	kg
Emission to treated surfaces	$E_{application, treated surface}$	9.03E-02	kg
Cleaning step			
Fraction emitted to waste water from applicator	$F_{ww,applicator}$	0	(-)
Fraction emitted to waste water from floor	$F_{ww, floor}$	0	(-)
Fraction emitted to waste water from treated surfaces	$F_{ww, treated surface}$	1	(-)
Cleaning efficiency	F_{CE}	0.0064	(-)
$E_{treated,ww} = E_{application,treated surfaces} \times F_{ww} \times F_{CE}$			
Emission to waste water from treated surfaces	$E_{treated, ww}$	5.77E-04	$kg.d^{-1}$
Number of houses by STP	$N_{house/STP}$	1	(-)
Local Emission to STP	$E_{local STP}$	5.77E-04	$kg.d^{-1}$

2.8.4.2 PEC calculations

2.8.4.2.1 Aquatic compartment (surface water, sediment, STP)

According to the CAR of deltamethrin, the following distribution characteristics in the STP (determined from the SimpleTreat 3.1 Model) and the following physicochemical parameters have been used. Moreover calculations have been adjusted to consider a SLUDGE RATE value of 710 $kg.d^{-1}$ instead of 790 $kg.d^{-1}$ integrated in the EUSES program.

Distribution in the STP and Physico-chemical parameters used for PEC calculations

Fate	% of residue
to air	0.0
to water	9.6
to sludge	90.4
degraded	0.0
Total	100.0
Physico-chemical parameter	**Value**
Organic carbon-water partition coefficient	408 250 $L\ kg^{-1}$
Henry's law constant	1.252×10^{-3} $Pa.m^3.mol^{-1}$

Deltamethrin concentrations in the STP effluent, in surface water and in sediment are calculated according to the GBPR (Guidance on the Biocidal Products Regulation - Volume IV Environment – Part B Risk assessment, active substances, 2015) equations.

Table 2.8.4-1: PECs in Aquatic compartment – Release via the STP - Emission from treated surface (cleaning)

Symbol	Parameter	Value	Unit	Reference
$E_{local,STP}$	Local Emission to STP	5.77E-04	[$kg.d^{-1}$]	Output
PEC_{STP}	PEC in the treated wastewater	2.77E-05	[$mg.L^{-1}$]	GBPR Eq. 33
$PEC_{local\ water}$	PEC in water during emission episode	1.72E-06	[$mg.L^{-1}$]	GBPR Eq. 45
$PEC_{local\ sed}$	PEC in sediment during emission episode	1.52E-02	[$mg.kg^{-1}_{wwt}$]	GBPR Eq. 50

No PEC was derived for the relevant metabolite Br_2CA in the aquatic compartment, since toxicity results show that the parent compound is more toxic and more persistent than this metabolite.

In order to estimate potential environmental exposure to the major metabolite Br_2CA associated with losses to the wastewater compartment during the service-life of the product 3A MATE, it is assumed that the metabolite is formed at the point of emission (*i.e.* in the STP effluent) at a quantity equivalent to 100% of the parent. PEC (Br_2CA) is therefore estimated equal to PEC (deltamethrin) adjusted to take into account the molecular weights of the compounds. The parent compound has a molecular mass of 505.2 g/mol, whilst the metabolite Br_2CA has a molecular mass of 298 g/mol. Therefore, the PECs calculated for deltamethrin have been adjusted by a factor of 0.59 (*i.e.* 298 / 505.2).

PEC_{STP} (Br_2CA) = PEC_{STP} (deltamethrin) * 0.59
PEC_{STP} (Br_2CA) = 2.77E-05 * 0.59 = 1.63E-05 $mg.L^{-1}$

$PEC_{surfacewater}$ (Br2CA) = $PEC_{surfacewater}$ (deltamethrin) * 0.59
$PEC_{surfacewater}$ (Br2CA) = 1.72E-06 * 0.59 = 1.01E-06 $mg.L^{-1}$

The PEC of the major metabolite Br_2CA in sediment is calculated based upon the $PEC_{surfacewater}$ value, according to the equilibrium partitioning method (equation 50 of the Technical Guidance Document, TGD, 2003):

$PEC_{sediment} = (K_{susp\text{-}water} / RHO_{susp}) * PEC_{surfacewater} * 1000$

Where:

$K_{susp\text{-}water}$: Suspended matter-water partitioning coefficient (1.54 m^3 / m^3).
$K_{susp\text{-}water}$ was calculated according to equations 23 and 24 of the TGD, based upon a K_{oc} value for Br_2CA of 25.61 L/kg, representing the arithmetic mean sorption value derived in an adsorption study on Br_2CA.
RHO_{susp}: Bulk density of suspended matter (1150 kg/m_3, according to TGD).

$PEC_{sediment}$ (Br_2CA) = (1.54 / 1150) * 1.01E-06 * 1000 = 1.36E-06 mg/kg_{wwt}

2.8.4.2.2 Atmospheric compartment

Significant exposure of the environment via air is not expected.

Due to its low vapour pressure (1.24×10^{-8} Pa at 25°C), deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3} $Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals (DT_{50} reaction with OH-radicals = 16.4 hours). It is thus considered that it is not likely that significant volatilisation will occur after use of deltamethrin.

2.8.4.2.3 Terrestrial compartment (soil and groundwater)

The concentrations in agricultural soil, following the spreading of contaminated STP sludge, are calculated according to the GBPR equations considering the emission rates to wastewater (E_{ww}). A degradation of

deltamethrin in soil (DT_{50} value of 48 days at 12°C) is taken into account. To estimate PECs in porewater for the relevant metabolite Br_2CA, a Koc value of 25.61 $L.Kg^{-1}$ and a DT_{50} in soil at 12°C of 5.6 days have been considered. Initial concentrations of Br_2CA in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weight of the compound, F=0.59).

According to the TGD, PECs groundwater were derived from the twa value of PECs soil over 180 days.

Table 2.8.4-2: PECs in Terrestrial compartment – Release via the STP - Emission from applicator

Symbol	Parameter	Value	Unit	Reference
$E_{local,STP}$	Local Emission to STP	5.77E-04	[$kg.d^{-1}$]	Output
$PEC_{local\ soil\ deltamethrin}$	$PEC_{soil\ 30d}$	8.81E-04	[$mg.kg^{-1}_{wwt}$]	GBPR Eq. 60
	$PEC_{soil\ 180d}$	3.87E-04		
$PEC_{local\ soil\ Br2CA}$	$PEC_{soil\ 30d}$	1.64E-04		
	$PEC_{soil\ 180d}$	2.80E-05	[$mg.kg^{-1}_{wwt}$]	
$PEC_{local\ soil\ porewater\ Deltamethrin}$	$PEC_{in\ porewater\ (agricultural.\ Soil)\ 180d}$	5.37E-05	[$\mu g.L^{-1}$]	GBPR Eq. 67
$PEC_{local\ soil\ porewater\ Br2CA}$		4.92E-02		

2.8.4.2.4 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

The product 3A MATE is an insecticide and acaricide finishing paint applied only indoors (on walls and ceilings) by brushing or rolling. Consequently primary poisoning (direct consumption of insecticide by non-target animals like birds, mammals or honeybees) and secondary poisoning (contaminated food) are not expected. On the other hand, an exposure via the waste water can be envisaged. The concentration of deltamethrin in contaminated food is calculated in order to address the risk of secondary poisoning to top predators via the aquatic food chain (i.e. fish-eating birds and mammals). Biomagnification may also occur via the terrestrial food chain and the risk concerning secondary poisoning for worm-eating birds and mammals is also assessed.

The PEC oral,fish value and the PEC oral,earthworm are presented in the Tables below.

Table 2.8.4-3: Overview on the calculated local PECoral fish and local PECoral earthworm – Release to waste water

Symbol	Parameter	Value	Unit	Reference
$PEC_{oral,\ predator}$	Predicted Environmental Concentration in food (fish)	1.20E-03	[$mg.kg^{-1}$]	TGD Eq. 76
$PEC_{oral,\ predator}$	Predicted Environmental Concentration in food (earthworm)	3.13E-05	[$mg.kg^{-1}$]	TGD Eq. 81

2.8.5 Risk characterisation for the environment

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC). The environmental risk characterization has been carried out for deltamethrin.

The only potential way of environmental contamination would be via the wet cleaning of painted surfaces which could be relevant for some premises as animal housings.

Table 2.8.5-1: PEC/PNEC ratio for the service-life of paint (cleaning of painted surfaces)

3A MATE	PEC	PEC/PNEC	Risks
Deltamethrin			
STP [$mg.L^{-1}$]	$PNEC_{STEP\ microorganisms}$ = 3.00E-02 $mg.L^{-1}$		
	2.77E-05	9.23E-04	Acceptable
Surface water [$mg.L^{-1}$]	$PNEC_{surface\ water}$ = 0.70 ng L^{-1}		
	1.72E-06	2.45E+00	**Unacceptable**
Sediment [$mg.kg_{wwt}^{-1}$]	$PNEC_{sediment}$ = 6.20 $\mu g.kg_{wwt\ sediment}^{-1}$		
	1.52E-02	2.46E+00	**Unacceptable**
Soil [$mg.kg_{wwt}^{-1}$]	$PNEC_{soil}$ = 0.075 $mg.kg_{wwt\ soil}^{-1}$		
	8.81E-04	1.17E-02	Acceptable
Groundwater	Threshold value = 0.1 $\mu g.L^{-1}$		
	< 0.1 $\mu g.L^{-1}$		Acceptable
Secondary Pois.	$PNEC_{oral\ mammal}$ 2.67 mg kg_{diet}^{-1}		
Terrestrial food chain [$mg\ kg_{diet}^{-1}$]	3.13E-05	1.17E-05	Acceptable
Aquatic food chain [$mg\ kg_{diet}^{-1}$]	1.20E-03	4.50E-04	Acceptable
Br_2CA			
STP [$mg.L^{-1}$]	$PNEC_{STEP\ microorganisms}$ = 3.00E-02 $mg.L^{-1}$		
	1.63E-05	5.45E-04	Acceptable
Surface water [$mg.L^{-1}$]	$PNEC_{surface\ water}$ = 10.4 µg L^{-1}		
	1.01E-06	9.74E-05	Acceptable
Sediment [$mg.kg_{wwt}^{-1}$]	$PNEC_{sediment}$ = 13.9 $\mu g.kg_{wwt\ sediment}^{-1}$		
	1.36E-06	9.76E-05	Acceptable
Soil [$mg.kg_{wwt}^{-1}$]	$PNEC_{soil}$ = 0.14 $mg.kg_{wwt\ soil}^{-1}$		
	1.64E-04	1.17E-03	Acceptable
Groundwater	Threshold value = 0.1 $\mu g.L^{-1}$		
	< 0.1 $\mu g.L^{-1}$		Acceptable

According to the risk mitigation measures proposed by the applicant for the use of 3A MATE, the application phase of the product will lead to no emissions to the environment and therefore to no unacceptable risk. Therefore the following risk mitigation measures will be mandatory:

- soil must be protected during application;
- painters must use a cleaning system for collecting rinse water and paint residues;
- painters must wear disposable protective clothing;

Considering the service-life of painted surfaces and the possibility to wash some surfaces with water (i.e. in animal housings), in the case of the exposure of STP, soil and groundwater, all calculated RCR values were < 1 for deltamethrin, indicating no unacceptable risk to these environmental compartments. **However, for surface water and sediment compartment, the RCR values for deltamethrin were > 1 and the risks are considered unacceptable,** especially as a best case has been assessment considering only one building per STP**.**

In most cases in individual and collective houses, offices and commercial premises, public areas, people never clean their wall entirely but only partially, where there is a mark on the wall for example, with a sponge whose surface is approximately 15 cm². Nevertheless, the following risk management measure is proposed:

- treated surfaces (walls and ceilings) should not be cleaned with wet cleaning methods.

If treated surfaces are not washed, the outdoor environment is therefore not exposed to deltamethrin and consequently, the risk can be considered as acceptable.

Therefore, it can be concluded that the use of the product 3A MATE when used in accordance with label recommendations, will not pose risk to the environment.

Risk mitigation measures linked to risk assessment for environment

- Do not wash the contaminated material under tap water.
- An appropriate plastic sheet must protect the ground during application
- The applicator must wear a disposable protective equipment (gloves and protective clothing)
- Treated surfaces (walls and ceiling) must not be cleaned with water. If occasional washing occurs, do not drain off the washing water in the sewage disposal systems.
- Use an independent recovery system for contaminated waters and aqueous sludge from paint during the equipment cleaning.
- Do not discharge unused products, aqueous sludge from paint and rinsing waters, on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

2.9 Risk assessment for companion and ornamental animals

See 2.7.3.2.

2.10 Measures to protect man, animals and the environment

See Summary of Product Characteristics (SPC)

3 PROPOSAL FOR DECISION

Conclusions of efficacy and risk assessment

Risk assessment for Physico-chemical properties

The biocidal product 3A MATE is a white, semi-pasty and homogeneous product with a characteristic odour. The product has no explosive properties, nor oxidising properties. It is not highly flammable (flash point is > 99°C) and not auto-flammable at ambient temperature (self-ignition temperature is 347°C). The pH of the product (pure test item) is about 8.3 at 23°C and the density of the product is 1.404 g/L. The product is considered as surface-active (mean surface tension of the pure test item is 22.7 mN/m) and a viscosity of 43605 mPa*s at 20°C.

After the accelerated storage procedure (14 days at 54 ± 2°C), no significant change of the product was observed, regarding the deltamethrin content, the aspect of the product and the pH. 3A MATE is considered stable after the accelerated storage during 14 days at 54 ± 2°C in glass flask.

No significant change of the product was observed, regarding the deltamethrin content, the aspect of the product and the pH after the accelerated and ambient storage studies. 3A MATE is considered stable and the the shelf-life is expected to be at least 2 years.
After storage of the product for 7 days at 0 ± 2°C, no change was observed in the test item appearance (no deposit, no phase partition and no change of colour). The product is considered to be stable after 7 days at 0°C.

Summary of efficacy assessment

The efficacy level of the product 3A MATE (0.74 % w/w deltamethrin) is satisfactory for the uses proposed in annex 0b.

NA-MIC: 2017:

In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18 (2012), the product 3 A MATE shows sufficient efficacy up to 24 months against flies (*Musca domestica* and *Stomoxys calcitrans*, adults), mosquitoes (*Culex, Aedes*, and *Anopheles*, adults) and house dust mites (*Dermatophagoides pteronyssinus*, larvae and adults).

Summary of risks characterisation of the product for human health

Risks related to the use of 3A MATE by professionals are considered acceptable, in accordance with the proposed conditions of use.

Summary of risks characterisation of the product for the environment

The use of the product 3A MATE when used in accordance with label recommendations, will not pose risk to the environment.

Summary of risks assessment for the companion and ornamental animals

Secondary exposure to companion animals with treated surfaces cannot be precisely assessed. However, considering the presented, estimations, this exposure cannot be considered negligible, especially exposure by oral route. In order to limit this exposure, the implementation of the following risk mitigation measures is essential to limit this exposure.

Risk mitigation measures and conditions of use

Conditions of use linked to efficacy assessment

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- The users should inform if the treatment is ineffective and report straightforward to the registration holder

Risk mitigation measures linked to risk assessment for human health

- Avoid contact with freshly painted surface.
- The product shall not be applied on surfaces likely to be in direct contact with food, feed or drinks

Risk mitigation measures linked to risk assessment for environment

- Do not wash the contaminated material under tap water.
- An appropriate plastic sheet must protect the ground during application
- The applicator must wear a disposable protective equipment (gloves and protective clothing)
- Treated surfaces (walls and ceiling) must not be cleaned with water. If occasional washing occurs, do not drain off the washing water in the sewage disposal systems.
- Use an independent recovery system for contaminated waters and aqueous sludge from paint during the equipment cleaning.
- Do not discharge unused products, aqueous sludge from paint and rinsing waters, on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

Risk mitigation measures linked to risk assessment for animals

- Do not use in premises where cats are housed, or where other animals with particular sensitivity to deltamethrin are housed.
- Do not use at the same time as a veterinary antiparasitic treatment containing a pyrethroid.
- Apply only during a fallowing period in animal shelters/housings (empty premises).
- Do not apply on surfaces likely to be licked by animals.
- Wait complete drying of the treated surfaces after the end of the treatment, before allowing animals to re-enter.

Recommendations to be taken into account by the authorisation holder

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

Information required post-authorisation

Required information linked to efficacy assessment

- ~~A semi-field or a field test demonstrating the efficacy of 3A MATE against *Anopheles* and *Aedes* genus will need to be provided in post-authorisation, within one year.~~
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.

4 APPENDICES

Annex 0a: Practical use claimed by the applicant

Target Organismes	Rate	Method of application	Time delay of the biocidal product	Duration of the effect
House dust mites, larves and adults (*Dermatophagoides pteronyssinus*) Mosquito, adults (*Culex, Aedes* and *Anopheles* genus) Flies, adults (*Musca domestica, Stomoxys calcitrans*) Coackroaches, nymphs and adults (*Blattellidae, Blattidae*)	100 g of the product per m² *i.e.* 1 L of the product for 14 m².	Professional users only. The product is for indoor use on walls and ceilings. It can be used in industrial and commercial premises, in private and public areas and in equestrian centres and kennels. Ready-to-use paint. Surface treatment : painting using a paintbrush or a roller The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.	-	3 years

Annex 0b: Proposed uses for the authorization of 3A MATE

This table reflects the results of the risk assessment. In case of differences between the uses suggested by Anses to be authorised and the uses contained in the decision taken by the French ministry, only the original and signed decision has a legal value.

Target Organismes	Rate	Method of application	Time delay of the biocidal product	Duration of the effect
House dust mites, larves and adults (*Dermatophagoides pteronyssinus*) Mosquito, adults (*Culex, Aedes* and *Anopheles* genus) Flies, adults (*Musca domestica* and *Stomoxys calcitrans*)	100 g of the product per m² *i.e.* 1 L of the product for 14 m².	Professional users only. The product is for indoor use on walls and ceilings. It can be used in: - industrial and commercial premises, - private and public areas - equestrian centres and kennels (except against flies). Ready-to-use paint. Surface treatment : painting using a paintbrush or a roller The product must be applied with a suitable sub-coat, and on existing adhesive matt paint.	After a few hours	~~6 months~~ 24 months

Annex 1: Summary of product characteristics

See separated file.

Annex 2: List of studies reviewed

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access	Data protection claimed
Section 3							
B3.1.1 B3.1.2 B3.2 B3.4.1.1	B3.1	S. Legay	2013a	Stability testing at 54°C during 14 days according to CIPAC MT 46.3 and pH measurement according to CIPAC MT 75.3 on the test item 3A MATE, Report No.402/12/1210F/cd-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
B3.3 B3.4.1.3 B4.6	B3.2	S. Legay	2013b	Stability testing at 0°C during 7 days according to CIPAC MT 39.3, flash point according to EC A9 and density measurement according to OECD 109/ EC A3 on the test item 3A MATE, Report No.402/12/1210F/efg-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
B3.4.1.2 B3.8 B3.9	B3.3	S. Legay	2013c	Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife), surface tension according to OECD 115/ EC A5 and viscosity measurements according to OECD 114 on the test item 3A MATE, Study plan No.12/1210F/hij, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
B3.4.1.2	B3.4	C. Da Costa	2013	Memorandum - Certificat de Qualité – seau tulipe 188x147 et 188x157,	La Celliose S.A., Division Artilin	No	Yes

				Colep Navarra GLP			
B3.8 B3.9	B3.5	S. Legay	2013d	Certificate of analysis 3A MATE, batch No.4036741, No.COA-402/12/1210F/hij-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
B3.1.3	B3.6	-	2013	Document III-B Section B12_ANNEX1 Safety Data Sheet 3A MATE (september 2013)	La Celliose S.A., Division Artilin	No	No
B3.4.1.2	B3.7	S. Legay	2014	Certificate of analysis 3A MATE, No.COA-402/12/1210F/hij/T12M-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
Section 4							
B4.1	B4.1	E. Raphalen	2013	Differential Scanning Calorimetry (DSC) measurement on the test item 3A MATE, Report No.402/12/1210F/n-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
B4.13	B4.2	B. Demangel	2013a	Oxidising properties of liquids test on 3A MATE in compliance with Commission Regulation (EC) No.440/2008 A21 method (2008), Report No.13-912030-001, Défitraces GLP	La Celliose S.A., Division Artilin	No	Yes
B4.17.1	B4.3	B. Demangel	2013b	Auto-ignition temperature of liquids test on 3A MATE in compliance with Commission Regulation (EC) No.440/2008 - EC A15 method (2008), Report No.13-912030-002, Défitraces GLP	La Celliose S.A., Division Artilin	No	Yes
Section 5							

B5.1	B5.1	S. Legay	2013e	Validation of analytical method according to SANCO 3030/99 rev.4 and chemical analysis of active substance declared in the test item 3A MATE, Report No.402/12/1210F/ab-e, FCBA GLP	La Celliose S.A., Division Artilin	No	Yes
Section 9							
B9.2.1	B9.2.1	Dr. Ute Hammesfahr	2013	Toxicity of 3A MATE to Activated Sludge in a Respiration Inhibition Test (Limit Study)	La Celliose S.A., Division Artilin	No	Yes
NA-MIC							
		Serrano B.	2017	Simulated use trial of the efficacy of an insecticidal paint intended to control household pests (cockroaches, flies, mosquitoes and dust mites) T.E.C Laboratory N°1889/0115			

Annex 3: Analytical methods residues – active substance

<Deltamethrin>

Date: xx.xx.xxxx

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	-	deltamethrin	No exposure expected
food of animal origin	0.02 mg/kg	deltamethrin	Confirmatory method is required
soil	0.1 µg/kg	deltamethrin	Confirmatory method is required
drinking water	3 ng/L	deltamethrin	Confirmatory method is required
surface water	3 ng/L	deltamethrin	Confirmatory method is required
air	2.25 µg/m^3	deltamethrin	-
body fluids / tissues	20 ng/L	deltamethrin	Confirmatory method is required

Methods suitable for the determination of residues (monitoring methods)

Matrix	Method	Limit of quantification	Reference
Soil	LC-MS/MS	0.1 µg/kg***	***Brumhard, B. (2005a)***
Air	GC-ECD	0.27 µg/m^3	***Class, T. (2001a)***
Water	GC-ECD	3 ng/L***	***Class, T. (2001b)***
	LC-MS/MS	5 ng/L*	***Brumhard, B. (2005b)***
	GC-ECD	50 ng/L*	***Martens, R. (1999)***
Blood	GC-MS multi-method for pyrethroids	20 ng/L***	***Ramesh, A. & Ravi, P.E. (2004)***
	GC-MS	200 µg/L**	***Frenzel, T. et al (1998)*** ***Frenzel, T. et al (2000)*** ***Brennecke, R. (1998)***
Muscle, fat, liver/kidney, eggs	GC-ECD	0.02 mg/kg***	***Martens, R. (2000)***
Milk	GC-ECD	0.02 mg/L***	***Martens, R. (2000)***
Plants	GC-ECD	0.02 mg/kg for rice, flour, bread, meat, candy, butter, banana cream pie and lettuce	***Silvoy, J.J. (1993a)***
	LC-MS/MS	0.02 mg/kg for edible material for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini	***Zimmer D. & Philipowski C. (2004)***
		0.05 mg/kg for non-edible materials for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini	

* The LOQ is not low enough to cover the concentration having an effect on the most sensitive aquatic organisms (NOEC: 4.8 ng/L, from mesocosm study; see Doc II-A section 4).
** The LOQ (200 µg/l) is not in compliance with the general requirement in Regulation (EU) No 528/2012 (i.e. 50 µg/l).
*** Confirmatory methods is required to update this dossier

Annex 4 : Toxicology and metabolism –active substance

<Active Substance>

Threshold Limits and other Values for Human Health Risk Assessment

Date: xx.xx.xxxx

Summary			
	Value	Study	SF
AEL long-term	0.0075 mg/kg bw/d	13-week dog study	100
AEL medium-term	0.0075 mg/kg bw/d	13-week and 1-year dog studies	100
AEL acute	0.0075 mg/kg bw/d	1-year dog study	100

Inhalative absorption	100%
Oral absorption	75%
Dermal absorption	2%

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	T, R23/25 No specific limit concentrations
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute tox. 3* - H301 Acute tox. 3* - H331 No specific limit concentrations

Annex 5 : Toxicology – biocidal product

<3A MATE>

Date: xx.xx.xxxx

General information

Formulation Type	Paste: water based, film-forming composition
Active substance(s) (incl. content)	0.75% (w/w)
Category	

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 423)	>2000mg/kg bw/d
Rat LD50 dermal (OECD 402)	>2000mg/kg bw/d
Rat LC50 inhalation (OECD 403)	None
Skin irritation (OECD 404)	No
Eye irritation (OECD 405)	No
Skin sensitisation (OECD 429; LLNA)	No*

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	None
Toxicological data on active substance(s) (not tested with the preparation)	None
Toxicological data on non-active substance(s) (not tested with the preparation)	None
Further toxicological information	None

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	None
Regulation 1272/2008/EC	None

* However, the mention ”EUH 208 Contains isothiazolinones (2-octyl-2H-isothiazol-3-one, 1,2-benzisothiazol-3(2H)-one and reaction mass 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)). May produce an allergic reaction” has to be reported in labelling.

Annex 6 : Safety for professional operators

<3A MATE>

Date: xx.xx.xxxx

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

	Component	CAS	Total Dermal Total [mg/kg/d]	Inhalation Exposure mg a.i. / kg bw /day	Model
Application – 360 minutes daily					
Tier 1	Deltamethrine	52918-63-5	4.18E-03	2.91E-03	Consumer product painting model 1, available in TNsG part 2 , and reviewed in User Guidance
Cleaning of brush					
Tier 1	Deltamethrine	52918-63-5	1.15E-05	Not relevant	General Exposure Calculator proposed by the HEEG opinion document for cleaning of brush
Combined exposure: application and cleaninf of brush					
Tier 1	Deltamethrine	52918-63-5	4.19E-03	2.91E-03	

Risk assessment

Component	CAS	AEL [mg/kg /d]	Absorption [%]		Total syst exposure [mg/kg bw/d]	% AEL	Risk
			inhal ation	derm al			
Application – 360 minutes daily							
Deltamethrine	52918-63-5	0.0075	100	0.05	7.08E-03	94	Acceptable
Cleaning of brush							
Deltamethrine	52918-63-5	0.0075	100	0.05	**1.15E-05**	0.15	Acceptable
Combined exposure: application and cleaninf of brush							
Deltamethrine	52918-63-5	0.0075	100	0.05	**7.1E-03**	95	Acceptable

Secondary exposure

	Component	CAS	Total Dermal Total [mg/kg/d]	Inhalation Exposure mg a.i. / kg bw /day	Oral exposure [mg/kg/d]
Application – 360 minutes daily					
Contact with freshly paint and contact hand-mouth	Deltamethrine	52918-63-5	1.9E-04	negligible	3.2 E-02
Contact with dried paint and contact hand-mouth	Deltamethrine	52918-63-5	2.59E-06	negligible	3.89E-03

Risk assessment

	Component	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]	% AEL	Risk
			oral	dermal			
Chronic exposure							
Systemic exposure - Contact with freshly paint and contact hand-mouth	Deltamethrine	0.0075	75	0.05%	3.3 E-02	435	Unacceptable
Systemic exposure – toddler touching dried treated surface	Deltamethrine	0.0075	75	0.05%	3.9E-03	52	Acceptable

Annex 7 : Safety for non-professional operators and the general public

<3A MATE>

The product is for professional use only.

Annex 8 : Residue behaviour

Deltamethrin

Date: 30.04.2014

Intended Use (critical application)
Active substance(s): Detamethrine (0.74% w/w)
Formulation of biocidal product: PA (paste) density: 1.404
Place of treatment:
indoor use by professionnal : finishing paint on wall and ceiling (industrial and commercial premises, household and private areas, public areas, animal houses: equestrian centers and kennels)
Insecticide and acaricide
1 application for 3 years with1 L / 14 m^2 (accordingly 752 mg s.a./m^2)
considering 0.5% s.a is dislogeable only 3.6 mg s.a./m^2 is available
Application with paintbrush or a roller (no spray)

The intended use descriptions of the deltamethrine-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used only for inside building in areas where food and feed, food ustensiles or food processing surfaces will not become into contact with or be contamined by it. No further data are required concerning the residue behaviour.

Annex 9: Efficacy of the active substance from its use in the biocidal product (*)

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
3A MATE Deltamethrin 0.74%	*Blattella germanica* *Blatta orientalis* *Musca domestica* *Aedes aegypti* *Aedes albopictus* *Culex pipiens* *Anopheles gambiae* *Dermatophagoides pteronyssinus* 25 adult insects in each replicate, or 300 adult and nymph mites.	Laboratory test. Insects and mites **exposed during 4 hours** to the product applied on a plywood panel. Monitoring of the arthropods during the exposure period and the following 24 hours. The efficacy was assessed on "freshly" treated panels and after 6 months, 1 and 2 years of storage, and the test will continue with assessments after 3 years of storage. Product applied on plywood panels after 2 layers of a pre-coating paint. Two layers of the paint, to obtain approximately **100 g of the product per m²**.	Panels of 15 cm * 15 cm. 4 replicates for each test condition: test product or untreated control * target organism * storage duration. Storage in a chamber at a temperature of 23°C + 2°C and a relative humidity of 65% + 5%. Ambient conditions in testing chamber during the period of testing, *i.e.* temperature between 19.8°C and 21.5°C, relative humidity between 63% and 78%, and with light of 1200 lux.	Knock-down and mortality of the arthropods during the exposure period and the following 24 hours. At the first three assessments, 48 hours after the end of the treatment, after 6 months and 1 year of storage, the mortality of the arthropods was total at the end of the 4-hour exposure period. After 2 years of storage, the mortality of the arthropods was total within 24h for cockroaches and mites, and within 8h for the house fly and the mosquitos. Further tests will be done after 36 months of storage.	Serrano B. (2013)	2

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
3A MATE Deltamethrin 0.74%	*Stomoxys calcitrans* Mixed sex adults, 2 to 5 days old, 10 adults per replicate.	Laboratory test. Insects **exposed during 4 hours** to the product applied on a plywood panel. Monitoring of the arthropods during the exposure period and the following 24 hours. The efficacy was assessed on panels treated since 1 month and after 1 year of storage. The test will continue with assessments after 2 and 3 years of storage. Product applied on plywood panels after **one layer of a pre-coating paint and one layer of a non-insecticidal paint**. **One layer of the paint**, to obtain approximately **100 g of the product per m²**.	Panels of 15 cm * 15 cm. 4 replicates for each test condition: test product or untreated control * storage duration. Storage of the panels under ambient conditions at a temperature of 25°C + 2°C and a relative humidity of 50% + 30%. Ambient conditions in testing chamber during the period of testing, *i.e.* temperature between 23.4°C and 23.9°C, relative humidity between 44.5% and 60.1%.	Knock-down and mortality of the flies during the exposure period and the following 24 hours. For the first assessment after 1 month, the untreated controls showed 30% mortality after 24 hours, so this first test is not valid. For the second assessment after 1 year of storage, the untreated controls demonstrated the validity of the test, with good survival of the flies. At the second assessment, 1 year after treatment, the knock-down of the flies was total after 1 hour of exposure, and mortality was complete 24 hours after beginning of the exposure. Further tests will be done after 2 and 3 years of storage.	Gibson D. (2013)	2

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
3A MATE Deltamethrin 0.74%	*Blattella germanica* *Musca domestica* *Aedes aegypti* *Anopheles stephensi* *Dermatophagoides pteronyssinus.* 25 adult insects in each replicate, or 300 adult and nymph mites.	Laboratory test. Insects and mites **exposed during 8 hours** to the product applied on a plywood panel. Monitoring of the arthropods during the exposure period and the following 72 hours. Product applied on wood panels, after a pre-coating paint, to obtain approximately **100 g of the product per m²**. The efficacy was assessed after 1, 3, 6, 9, 12, 15, 24 and 36 months of storage of the treated panels.	Panels of 15 cm * 15 cm. 3 replicates for each test condition: test product or untreated control * target organism * storage duration. Storage in a chamber at a temperature of 23 + 2°C and a relative humidity of 65 + 5%. Ambient conditions in testing and storage chamber: temperature of 20°C ± 1°C, relative humidity of 63% ± 5%, and a photoperiod of 16 hours light (800 lux) and 8 hours darkness.	Knock-down and mortality of the arthropods during the exposure period and the following 72 hours. The untreated controls demonstrated the validity of the test, with good survival of the arthropods. Until 24 months after application, the mortality of the arthropods was total after a maximum exposure time of 3 hours. After 36 months, 4 hours of exposure were necessary to kill all the flies, mosquitoes and mites. For the cockroaches, they died during the post-monitoring phase and 100% were dead 24 hours after an 8-hour exposure.	Serrano B. (2011)	2
3 A MATE (deltamethrin 0.74 % w/w)	*Musca domestica* 100 +/- 5 mixed sex adults *Stomoxy calcitrans* 50 +/- 2 mixed sex adults *Aedes aegypti* *Aedes albopictus*	Semi field test The trial was done in the laboratory in a test chamber in condition simulating the real condition of use, by setting painted panels of wood (50 % of the wall area), releasing insects and counting their mortality after 24 hours and 7 days of exposure. **The insects had the choice or not to be in contact with the**	Test chamber (6 m² floor, 3 m long x 2 m wide x 2 m high) Panels of 3 m wide x 2 m high. To simulate what happen in real conditions of use, two panels of wood painted with the product were set vertically on two adjacent walls of test chamber. A surface of 10 m² (half of the wall area) of panels was	The untreated controls demonstrated the validity of the test, with good survival of the arthropods. At the first assessments, 48 hours after the end of the treatment, after 6, 12 months of storage, the mortality of the arthropods was total at the end of the 24 hours exposure period.	Serrano B. (2017)	2

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
	Culex pipiens *Anopheles gambiae* 50 +/- 2 females adults *Dermatophagoides pteronyssinus* 100 +/- 10 mixed sex adults + larvae	**product.** The efficacy was assessed on "freshly" treated panels (48h after the second layer) and after 6 months, 12 and 24 months of storage. Product applied on plywood panels after 2 layers of an undercoat paint. Two layers of the paint, to obtain approximately **100 g of the product per m²**. Untrated control: The same procedure was used but without treated panels.	painted with the product. A few cardboards (to give harborages to insects) and water + food source were set on the floor of the test chamber. **The insects were able to reach water and food sources without being in contact with the treated surfaces.** Due to the very small size of the house dust mites, a special area of 0.1 m² (30 cm x 33.3 cm) on the floor + 0.1 m² (30 cm x 33.3 cm) on a treated wall was limited using Teflon to avoid escapes. The dust mites were released on the untreated part (floor) - some special food (dust + yeast) was also set on this untreated part. 4 replicates for each test condition: test product or untreated control * target organism * storage duration. Storage in a chamber at a temperature of 22°C + 2°C and a relative humidity of 60% + 5%. Ambient conditions in testing chamber during the period of testing, *i.e.* temperature 22°C+/-1°C, relative humidity 60%+/-5%, and 8hours of light (800 lux).	After 24 months of storage, the mortality of the arthropods was total within 24h and 7 days		