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 SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the applicant)

BAM – Leurre Moustiques traditionnels

Product type 19

Carbon dioxide 100% w/w (Lure A)

Oct-1-en-3-ol 7.834% w/w (Lure B)

as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-HJ073860-36

Competent Authority: France

Date: 7 April 2023

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	*FR CA*	BC-HJ073860-36	07.04.2023	*[Initial assessment]*	

1 Conclusion

BAM - Leurre Moustiques traditionnels is a combination of a bottle containing carbon dioxide and a lure with oct-1-en-3-ol as active substances. The two products are used together and form a biocidal product used as a repellent (product type 19) by professionals and non-professionals for the control of mosquitoes outdoor.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the uses against mosquitoes by professional and non-professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

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

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

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substances carbon dioxide and oct-1-en-3-ol are listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that it is only for use in ready-for-use gas canisters functioning together with a trapping device*;*
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

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

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. **A shelf life of 6 months** is claimed for the product BAM - Leurre Moustiques traditionnels (which includes the olfactory lure oct-1-en-3-ol and the separated CO2 bottle). More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

The product BAM - Leurre Moustiques traditionnels is classified as **Press. Gas., H280** due to the active substance carbon dioxide, present in a separated gas bottle. It is not expected to present a significant hazard for explosive properties, flammability, self-reactivity, pyrophoric properties, self-heating properties, oxidising properties, corrosiveness to metals, self-ignition properties. No tests are required according to the composition of the product and to the safety datasheets of its ingredients.

More information is available in section 3.3 of the PAR.

Methods for detection and identification

Oct-1-en-3-ol is listed in Annex I of regulation (EU) No 528/2012 under Category 5. An analytical method for the determination of Oct-1-en-3-ol is provided and considered acceptable.

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6 and an analytical method has been provided during the assessment of the active substance.

Analytical methods for monitoring active substance residues in soil, air, water, human body fluids and tissues are no data requirement for simplified procedures according to Article 20(1) (b) of the BPR.

Efficacy against target organisms

Based on the efficacy data presented, it can be concluded that the product BAM-Leurre Moustiques traditionnel is efficient to attract and reduce the nuisance of mosquitoes (*Ochlerotatus spp*., *Aedes spp. Anopheles sp and Culex sp.*) until 60 m from the trap at the application rate of 0.2 L/min. CO2 bottle and Oct-1-en-ol lure box should be replaced every month.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

No substance of concern regarding Human health was identified.

The handling of the product and its intended use do not require personal protective equipment.

Dietary risk assessment

As carbon dioxyde and oct-1-ene-3-ol are listed in Annex I of Regulation (EU) No 528/2012 under respectively "Category 6 – Substances included in Annex I or IA to Directive 98/8/EC" and "category 5 – pheromones", a dietary risk assessment is not relevant.

Risk assessment for the environment

No substances of concern regarding environment were identified.

2 Information on the biocidal product

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

Identifier	Country (if relevant)
	BAM – LEURRE MOUSTIQUES TRADITIONNELS Leurre Moustiques traditionnels Leurre Moustique traditionnel

2.1.1.1 Manufacturer(s) of the products

Name of manufacturer	TECHNO BAM
Address of manufacturer	130 Avenue du LUBERON, 13560 SENAS France
Location of manufacturing sites	130 Avenue du LUBERON, 13560 SENAS France

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

Active substance	Carbon dioxide
Name of manufacturer	TECHNO BAM (Qista)
Address of manufacturer	130 Avenue du LUBERON., 13560 SENAS France
Location of manufacturing sites	53 Rue Jeanne d'Arc, 55190 Void Vacon France

Active substance	Oct-1-ene-3-ol
Name of manufacturer	Thermo Fisher (Kandel) GmbH
Address of manufacturer	Erlenbachweg 2, 76870 Kandel Allemagne
Location of manufacturing sites	Erlenbachweg 2, 76870 Kandel Allemagne

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

Product type(s)	PT19
Type(s) of formulation	RB (Bait (ready for use))

2.2 Uses

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

Table 2.2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/ref MS)[9]
1	Catch and reduce the nuisance caused by mosquitoes	PT19	Mosquitoes, Adults	Bait application in a trap	A trap containing an oct-1-en-ol lure box of 11g and a CO_2 bottle of 10kg (0.2 L/min flow) covers a surface up to 11300 m² (up to a radius of 60 m around the trap) for 3 weeks (use period of 15h/day)	Professional and non-professional (general public) users	**Acceptable**	

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

Codes for indicating the acceptability for each use

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

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

2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

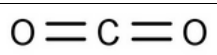
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Oct-1-en-3-ol
Chemical name	Oct-1-en-3-ol
EC number	222-226-0
CAS number	3391-86-4
Index number in Annex VI of CLP	Not listed
Minimum purity / content	98% w/w
Structural formula	

Main constituent(s)	
Common name	Carbon dioxide
Chemical name	Carbon dioxide
EC number	204-696-9
CAS number	124-38-9
Index number in Annex VI of CLP	Not listed
Minimum purity / content	100%

Structural formula	

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

The information on the source(s) of the active substance(s) is not applicable.

2.6 Candidate(s) for substitution

Not relevant, the active substance is not candidate for substitution or exclusion.

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

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in the confidential annex.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product (CO2 bottle)

	Classification	**Labelling**
Hazard Class and Category code	Press. Gas, H280	
Hazard Pictograms		
Signal word(s)	*[Warning]*	*[Warning]*
Hazard statements	H280 Contains gas under pressure; may explode if heated	
Precautionary statements*	P403 Store in a well-ventilated place	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes	*[Where necessary, add a justification for excluding certain P-statements.]*	

***P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

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

2.9 Letter of access

The product BAM – Leurre Moustiques traditionnels is eligible for simplified authorisation procedure according to Article 25 of the BPR (Regulation (EU) No 528/2012). According to Article 20(1)(b) of the BPR, a letter of access is not required for the active substances contained in biocidal products that meet the conditions laid down in Article 25, even if the active substance is listed under category 6.
Moreover, the manufacturer of the Biocidal product (TECHNO BAM under the trade name Qista) is included in the Article 95 list for the active substance CO2.

2.10 Data submitted in relation to product authorisation

No new data on the active substances has been submitted.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Small box and lid, with inner grid (oct-1-en-3-ol lure)	11g	Box: acrylic Inner grid: polyethylene	Lid: acrylic	Professional and non-professional	Yes
Bottle (CO_2)	10 kg (height 67 cm * diameter 203 mm)	metal: stainless steel	metal: stainless steel	Professional and non-professional	Yes
Bottle (CO_2)	10 kg (height 75 cm * diameter 203 mm)	aluminium	aluminium	Professional and non-professional	Yes

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

BAM - Traditional mosquito lure consists of two lures:
- Lure in the form of pearls impregnated with oct-1-in-3-ol
- CO2 lure in the form of a stainless steel or aluminum gas bottle

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
3.1.	Appearance at 20 °C and 101.3 kPa	Visual observation	-	Carbon dioxide Gas is colourless at 20ºC, 101.3 kPa odourless at 20ºC, 101.3 kPa	CAR, IIIB 3.1	Acceptable
3.1.1.	Physical state at 20 °C and 101.3 kPa		Product BAM - Leurre Moustiques traditionnels Batch number: 56615543/1 Containing 7.834% w/w of oct-1-en-3-ol	Solid Colourless impregnated pearls with characteristic odour before and after 8 weeks at 40 ± 2°C The product BAM - Leurre Moustiques traditionnels has a characteristic odour before and after 8 weeks at 40 ± 2°C. The appearance of the test item was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C The packaging material (Transparent acrylic box with a PP Grid)was considered to be stable after an accelerated storage	[redacted], No.18-917003-004,2019	
3.1.2.	Colour at 20 °C and 101.3 kPa					
3.1.3.	Odour at 20 °C and 101.3 kPa	No guideline required				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
				procedure for 8 weeks at 40 ± 2°C; no change of weight was observed.		
3.2.	Acidity, alkalinity and pH value	-	-	The pH, acidity and alkalinity determinations of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a solid ready-to-use formulation.	-	Acceptable
3.3.	Relative density / bulk density	-	-	The bulk and tap densities of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation.	-	Acceptable
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT 46.3 method (storage stability)	-	CO2 bottle contains 100% carbon dioxide. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. There is no reactivity between active substance and containers.	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
			Product BAM - Leurre Moustiques traditionnels Batch number: 56615543/1 Containing 7.834% w/w of oct-1-en-3-ol	The test item BAM - Leurre Moustiques traditionnels and its commercial packaging (transparent acrylic box with a PP grid (containing 11 g of product)) were considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C; no change in the appearance of the test item, in the appearance and the weight of the commercial packaging was observed. The oct-1-en-3-ol content was 7.45% w/w at initial time and 7.52% w/w after the storage procedure. With a variation of + 0.9% *vs.* the value at initial time of oct-1-en-3-ol content, the test item was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C	[redacted] No.18-917003-004, 2019	Acceptable In the label, iy should be mentioned: "**store below 40°C"**
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Technical Monograph No.17, 2nd edition, CropLife	-	CO2 bottle contains 100% carbon dioxide. Carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. There is no reactivity between active substance and containers.	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
			Product BAM - Leurre Moustiques traditionnels Batch number: 56615543/1 Containing 7.834% w/w of oct-1-en-3-ol	The test item BAM - Leurre Moustiques traditionnels and its commercial packaging (transparent acrylic box with a PP grid) were considered to be stable after a long-term storage procedure for 6 months at 20 ± 2°C; no change in the appearance of the test item, in the appearance and the weight of the commercial packaging was observed. The oct-1-en-3-ol content was 7.45% w/w at initial time and respectively 7.52% w/w after 6 months (+0.9%) and 6.07% w/w after 12 months of storage at 20 ± 2°C (-18.5%) With a variation of + 0.9% vs. the value at initial time of oct-1-en-3-ol content, the test item was only considered to be stable after a long-term storage procedure for 6 months at 20 ± 2°C	[redacted] 2019 Report no.: 18-917003-005	Acceptable
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	The low temperature stability study of the test item BAM - Leurre Moustiques traditionnels is not required as the product is a solid ready-to-use formulation.	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	The light stability study of the test item BAM - Leurre Moustiques traditionnels is not required as the product is eligible for a simplified authorisation.	-	Acceptable
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Effect of Humidity and temperature has not been assessed . Carbon dioxide is compressed in a metal bottle (steel and aluminium) There is no effects on content of the active substance	-	Acceptable
				oct-1-en-3-ol lure was considered to be stable after 8 weeks at 40 ± 2°C (please refer to Storage stability test – accelerated storage). The individual commercial packagings are hermetically sealed, the packagings are leak-tight.	-	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	See the storage stability test – **long term storage at ambient temperature**	-	Acceptable
3.5.1.	Wettability	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation.	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
				Furthermore, the product is a ready-to-use formulation.		
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable
3.5.3.	Wet sieve analysis and dry sieve test	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable
3.5.5.	Disintegration time	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	The technical characteristics of the test item BAM – Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation.	-	Acceptable
3.5.7.	Persistent foaming	-	-	The technical characteristics of the test item BAM – Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable
3.5.8.	Flowability/pourability/dustability	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation.	-	Acceptable
3.5.9.	Burning rate — smoke generators	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore, the product is a ready-to-use formulation.	-	Acceptable
3.5.10.	Burning completeness — smoke generators	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore the product is a	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
				ready-to-use formulation.		
3.5.11.	Composition of smoke — smoke generators	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore the product is a ready-to-use formulation.	-	Acceptable
3.5.12.	Spraying pattern — aerosols / spray	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore the product is a ready-to-use formulation.	-	Acceptable
3.6.1.	Physical compatibility	-	-	Not applicable. The product BAM - Leurre Moustiques traditionnels is ready-to-use product and is not intended to be used in conjunction with any other product or active substances. Hence, no data on the physical compatibility of the product BAM - Leurre Moustiques traditionnels with other biocidal products, chemicals or active substances is required.	-	Acceptable
3.6.2.	Chemical compatibility	-	-	Not applicable. The product BAM - Leurre Moustiques traditionnels is ready-to-use product and is not intended	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA comment
				to be used in conjunction with any other product or active substances. Hence, no data on the chemical compatibility of the product BAM - Leurre Moustiques traditionnels with other biocidal products, chemicals or active substances is required.		
3.7.	Degree of dissolution and dilution stability	-	-	The technical characteristics of the test item BAM - Leurre Moustiques traditionnels are not required as the product is eligible for a simplified authorisation. Furthermore the product is a ready-to-use formulation.	-	Acceptable
3.8.	Surface tension	-	-	The surface tension determination of the test item BAM - Leurre Moustiques traditionnels is not required as the product is eligible for a simplified authorisation. Furthermore the product is a solid ready-to-use formulation.	-	Acceptable
3.9.	Viscosity	-	-	The viscosity determination of the test item BAM - Leurre Moustiques traditionnels is not required as the product is eligible for a simplified authorisation. Furthermore the product is a solid ready-to-use formulation.	-	Acceptable

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
The product BAM - Leurre Moustiques traditionnels is eligible for a simplified authorisation, and therefore only stability studies must be provided for physical, chemical and technical properties. It should be noted that only studies on the olfactory lure (oct-1-en-3-ol) contained in BAM - Leurre Moustiques traditionnels are needed. The olfactory lure oct-1-en-3-ol of BAM - Leurre Moustiques traditionnels consists in colourless impregnated pearls with characteristic odour. After an accelerated storage procedure (8 weeks at 40 ± 2°C) the appearance of the olfactory lure of the product BAM - Leurre Moustiques traditionnels and of its commercial packaging (transparent acrylic box with a PP grid (containing 11 g of product)) were considered to be stable; no change in the appearance of the test item, in the appearance and the weight of the commercial packaging was observed. The oct-1-en-3-ol content was 7.45% w/w at initial time and 7.52% w/w after the storage procedure. With a variation of + 0.9% *vs.* the value at initial time of oct-1-en-3-ol content, the test item was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. The olfactory lure of the product BAM - Leurre Moustiques traditionnels and its commercial packaging (transparent acrylic box with a PP grid) were considered to be stable after a long-term storage procedure for 6 months at 20 ± 2°C; no change in the appearance of the test item, in the appearance and the weight of the commercial packaging was observed. The oct-1-en-3-ol content was 7.45% w/w at initial time and respectively 7.52% w/w after 6 months and 6.07% w/w after 12 months of storage at 20 ± 2°C. With a variation of + 0.9% vs. the value at initial time of oct-1-en-3-ol content, the test item was only considered to be stable after a long-term storage procedure for 6 months at 20 ± 2°C. The physical, chemical and technical properties of the separated CO_2 bottle of BAM - Leurre Moustiques traditionnels are fully described in the CARs of this biocidal active substance (PT15, June 2014 and PT18, May 2010). No stability study is provided to demonstrate the stability of the separated CO_2 bottle. Nevertheless, carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage. **Based on the above information, a shelf life of 6 months is claimed for the product BAM - Leurre Moustiques traditionnels (which includes the olfactory lure oct-1-en-3-ol and the separated CO_2 bottle).** The product BAM - Leurre Moustiques traditionnels should be Protect from light and store below 40°C due to the active substance oct-1-en-3-ol in a separated lure **<u>Implications for labelling:</u>** - store below 40°C

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
4.1.	Explosives	Justification for non-classification	n.a.	The two active substances contained in the product BAM - Leurre Moustiques traditionnels (carbon dioxide in a separated gas bottle, oct-1-en-3-ol in the olfactory lure) are included in Annex I of the Biocidal Products Regulation (BPR) and thus are not expected to give rise to concern regarding explosiveness. They have no explosive properties. In addition, the main component present in the olfactory lure is not expected to have explosive properties according to its safety datasheet, as it does not contain any substance with chemical group associated with explosive properties. As a result, the product BAM - Leurre Moustiques traditionnels is not expected to be explosive and test is considered as unnecessary.	Art. 28(2)(a) of the BPR and SDS of active substances	Acceptable
4.2.	Flammable gases	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not classified as a flammable gas. In addition, the olfactory lure is not	Doc A3 PT14 BPD Assessment Report 2007	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				concerned by the physical hazard "flammable gases" as it is a solid product (impregnated pearls). Therefore, the product BAM - Leurre Moustiques traditionnels is not a flammable gas and test is considered as unnecessary.	-	Acceptable
4.3.	Flammable aerosols	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "flammable aerosol" as it is not conditioned in aerosol.	-	Acceptable
4.4.	Oxidising gases	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not classified as an oxidising gas. In fact, Examination of the structural formula of carbon dioxide, along with the fact that it is widely accepted that carbon dioxide is thermodynamically stable, suggests that carbon dioxide will not exhibit oxidising properties. Moreover, the substance contains oxygen and are chemically bonded to carbon. In addition, the olfactory lure is not concerned by the physical hazard "oxidising gases" as it is a solid product (impregnated pearls). Therefore, the product BAM - Leurre Moustiques traditionnels is not an oxidising gas and test is considered as unnecessary.	Doc A3 PT14 BPD Assessment Report 2007	Acceptable
					-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
4.5.	Gases under pressure	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is classified as a gas under pressure (Press. Gas, H280) according to its safety datasheet. In addition, the olfactory lure is not concerned by the physical hazard "Gases under pressure" as it is a solid product (impregnated pearls). Therefore, the product BAM - Leurre Moustiques traditionnels is classified as Press. Gas. 1, H280 and test is considered as unnecessary.	-	Acceptable
4.6.	Flammable liquids	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "flammable liquid" as it consists in: - a separated gas bottle, containing the active substance carbon dioxide - a solid olfactory lure (impregnated pearls, the impregnated liquid having no flammable properties according to its safety datasheet). Therefore, the product is not expected to be flammable and flash point test is considered as unnecessary.	Art. 28(2)(a) of the BPR and SDS of active substances	Acceptable
4.7.	Flammable solids	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not concerned by the physical hazard "flammable solids" as it is a gas. The active substance oct-1-en-3-ol, present in the olfactory lure, is not concerned by the physical hazard "flammable solids" as the main component present in the olfactory lure	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				is not classified as a flammable solid according to its safety datasheet. Therefore, the product BAM - Leurre Moustiques traditionnels is not a flammable solid and test is considered as unnecessary.		
4.8.	Self-reactive substances and mixtures	Justification for non-classification	n.a.	The two active substances contained in the product BAM - Leurre Moustiques traditionnels (carbon dioxide in a separated gas bottle, oct-1-en-3-ol in the olfactory lure) are included in Annex I of the Biocidal Products Regulation (BPR) and thus are not expected to give rise to concern regarding self-reactivity. The main component present in the olfactory lure contains substances with no chemical group associated with self-reactive properties, and is not classified for self-reactive properties. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to present self-reactive properties and test is considered as unnecessary.	SDS of active substances and coformulants	Acceptable
4.9.	Pyrophoric liquids	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "Pyrophoric liquids" as it consists in: - a separated gas bottle, containing the active substance carbon dioxide - a solid olfactory lure (impregnated pearls, the impregnated liquid having no pyrophoric properties according to its safety datasheet). Test is not required as the product does not contain any components classified as	SDS of active substances and coformulants	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				pyrophoric according to their structures and safety/technical data sheets. The product is not expected to be a pyrophoric liquid and test is not required		
4.10.	Pyrophoric solids	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not concerned by the physical hazard "pyrophoric solids" as it is a gas. The active substance oct-1-en-3-ol, present in the olfactory lure, is not concerned by the physical hazard "pyrophoric solids" as it is a liquid, and the main component present in the olfactory lure is not classified as a pyrophoric solid according to its safety datasheet. Moreover, experience in manufacture and handling shows that the product BAM - Leurre Moustiques traditionnels does not ignite spontaneously on coming into contact with air at normal temperature. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to be a pyrophoric solid and test is not required.	-	Acceptable
4.11.	Self-heating substances and mixtures	Justification for non-classification	n.a.	The two active substances contained in the product BAM - Leurre Moustiques traditionnels (carbon dioxide in a separated gas bottle, oct-1-en-3-ol in the olfactory lure) are included in Annex I of the Biocidal Products Regulation (BPR) and thus are not expected to give rise to concern regarding self-heating properties. They have no self-heating properties according to their safety datasheets. In addition, the main component present in	SDS of active substances and coformulants	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				the olfactory lure is not expected to have self-heating properties. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to present self-heating properties and test is considered as unnecessary.		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Justification for non-classification	n.a.	Test is not required as the product BAM - Leurre Moustiques traditionnels does not contain any components classified as substances which in contact with water emit flammable gases. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to emit flammable gases in contact with water and test is not required.	-	Acceptable
4.13.	Oxidising liquids	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "oxidising liquid" as it consists in: - a separated gas bottle, containing the active substance carbon dioxide - a solid olfactory lure (impregnated pearls, the impregnated liquid having no oxidising properties according to chemical structure of the main component). None of the components in the mixture is classified for oxidising properties. Therefore, the product is not expected to have oxidizing properties and a test is considered as unnecessary.	--	
4.14.	Oxidising solids	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not concerned by the physical hazard "oxidising solids" as it is a gas. The active substance oct-1-en-3-ol, present	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				in the olfactory lure, is not concerned by the physical hazard "oxidising solids" as it is a liquid, and the main component present in the olfactory lure is not classified as an oxidising solid according to its safety datasheet. Moreover, its chemical structure contains oxygen atoms which are only chemically bonded to carbon atoms: the classification procedure doesn not apply. Therefore, the product BAM - Leurre Moustiques traditionnels is not an oxidising solid and test is considered as unnecessary.		
4.15.	Organic peroxides	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "organic peroxides" as its components are not expected to form or contain organic peroxides.	-	Acceptable
4.16.	Corrosive to metals	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not concerned by the physical hazard "Corrosive to metals" as it is a gas. The olfactory lure is a solid (impregnated pearls) containing: - the active substance oct-1-en-3-ol, which does not contain halogens, acidic or basic functional groups, and is not able to form complexes with metals; - the main component, whose melting point is 60-90°C according to its safety datasheet. According to the classification criteria, only mixtures for which the application of the UN Test C.1 (described in part III, Section 37.4.1.1 of the UN-MTC) is relevant needs to be considered. Application of classification	SDS of active substances and coformulants	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				criteria in the UN-MTC, Section 37.4 excludes solids, while "liquids and solids that may become liquids (during transport)", have to be considered for such a classification. Solids having a melting point lower than 55°C (which is the test temperature required in UN Test C.1) must then be taken into consideration. As the melting point of the main component of olfactory lure is > 55°C, the classification procedure for corrosive properties does not apply to it. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to be corrosive to metals and test is not required.		
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "auto-ignition temperature (liquids)" as it consists in: - a separated gas bottle, containing the active substance carbon dioxide - a solid olfactory lure (impregnated pearls, the impregnated liquid having no self-ignition properties according to its safety datasheet).	SDS of active substances and coformulants	Acceptable
4.17.2.	Relative self-ignition temperature for solids	Justification for non-classification	n.a.	The active substance carbon dioxide, present in a separated gas bottle, is not concerned by the physical hazard "relative self-ignition temperature for solids" as it is a gas. The active substance oct-1-en-3-ol, present in the olfactory lure, is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding auto-flammability. The auto-	-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	eCA comment
				ignition temperature of oct-1-en-3-ol is 245°C according to its safety datasheet. In addition, the main component present in the olfactory lure is not expected to have self-ignition properties according to its safety datasheet. Therefore, the product BAM - Leurre Moustiques traditionnels is not expected to present a significant hazard for self-ignition properties and test is not required.		
4.17.3.	Dust explosion hazard	Justification for non-classification	n.a.	The product BAM - Leurre Moustiques traditionnels is not concerned by the physical hazard "dust explosion" as it consists in: - a separated gas bottle, containing the active substance carbon dioxide - a solid olfactory lure (impregnated pearls which do not contain or produce dust).	-	Acceptable

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product BAM - Leurre Moustiques traditionnels is classified as **Press. Gas., H280** due to the active substance carbon dioxide, present in a separated gas bottle. It is not expected to present a significant hazard for explosive properties, flammability, self-reactivity, pyrophoric properties, self-heating properties, oxidising properties, corrosiveness to metals, self-ignition properties. No tests are required according to the composition of the product and to the safety datasheets of its ingredients.

3.4 Methods for detection and identification

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

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues										
Principle of the method*:* About 2.0 g of the test item BAM - Leurre Moustiques traditionnels is accurately weighed (to the nearest 0.01 mg) into a 25-mL volumetric flask and the weight was adjusted until 20 g (to the nearest 0.01 mg) with methanol. The solution was treated with ultrasounds during 1 hour then under magnetic stirring during 24 hours. Volumes of 1 mL of the previous solution and 1 mL of the Internal Standard solution were taken into a 20-mL volumetric flask and the volume was made up with methanol. Oct-1-en-3-ol is analysed by gas chromatography with flame ionisation detector (GC-FID) at retention time of about 7.1 min.										
Analyte	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurity*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Oct-1-en-3-ol	Calibration range: from 215.69 mg/kg to 637.41 mg/kg y = 9.33 $*10^{-3}$ * x + 6.22 $*10^{-2}$ (y = peak area (oct-1-en-3-ol), x = oct-1-en-3-ol amount (in mg/L), r = 0.9963	In solvent blank and blank formulation, only one peak at retention time of internal standard diethyl phthalate. In reference item and test item solutions, only one peak at retention time of oct-1-en-3-ol and one peak at	100%	2 reconstituted test item solutions for recovery determinations	98.2-99.3	98.9	-			Not required	[redacted] Défitraces, 2019 Report no.: 18-917003-006
			Formulated product	5 test item solutions analysed twice			1.77 < modified Horwitz 1.97	7.724 % w/w	5		

		retention time of oct-1-en-3-ol. Specificity is demonstrated.									

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Carbon dioxide											

Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6 and an analytical method has been provided during the assessment of the active substance.

Table 3.7 Analytical methods for soil

Analytical methods for soil									
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

Not required in the frame of a simplified national authorisation.
Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6

Table 3.8 Analytical methods for air

Analytical methods for air										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

Not required in the frame of a simplified national authorisation.
Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6

Table 3.9 Analytical methods for water

Analytical methods for water										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

Not required in the frame of a simplified national authorisation.
Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6

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

Analytical methods for animal and human body fluids and tissues										
Analyte (type of analyte e.g. active substance) **Analytical**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

method										

Not required in the frame of a simplified national authorisation.
Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6

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

Analytical methods for monitoring of active substances and residues in food and feeding stuff										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

Not required in the frame of a simplified national authorisation.
Carbon dioxide is listed in Annex I of regulation (EU) No 528/2012 under Category 6

Table 3.12 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method for the determination of oct-1-en-3-ol in the biocidal product BAM - Leurre Moustiques traditionnels is available. Specificity, linearity, accuracy, precision and reproducibility were checked and found acceptable. Methods for the detection of oct-1-en-3-ol in soil, air, water, animal and human body fluids and tissues and in food/feed of plant and animal origins are no data requirement for simplified procedures according to Article 20(1)(b) of the BPR. There are no available analytical methods for oct-1-en-3-ol residues in soil, air, water, and human body fluids and tissues. The method for detection and identification of CO_2 in the bottle is identical to the method described in the CAR of the active substance (PT15, June 2014 and PT18, May 2010): Carbon dioxide content is determined by absorption trapping in KOH while impurities are measured gravimetrically, or by spectroscopy (MS, IR, UV), atomic absorption and/or chemical analysis.

3.5 Assessment of efficacy against target organisms

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

The product BAM - Leurre Moustiques traditionnels is a ready-to-use lure against mosquitoes (*Ochlerotatus sp.*, *Culex sp*., *Aedes sp*. and *Anopheles sp*.), to be used in combination with a specific trap. The device attracts the female mosquitoes searching a host to sting for blood meal. It acts by simulating human presence with a small amount of carbon dioxide released and an olfactory lure oct-1-en-3-ol. The mosquitoes, believing that they're about to bite a human, are then aspirated into the chimney of the trap and trapped in a net inside.
The product BAM - Leurre Moustiques traditionnels attracts mosquitoes occurring in the gardens. They prevent/reduce the nuisances caused by these insects (mostly bites). They are used outdoor.

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

The product BAM - Leurre Moustiques traditionnels acts by attracting the target organisms.

For mosquitoes and other biting and nuisance insects which are attracted by 'raised levels' of carbon dioxide, the mode of action is not entirely known. However, nerve receptors in the insect are triggered by raised levels of carbon dioxide, compared to normal background levels, and fly in the direction of the raised level gradient. The reason for flying in the direction of the raised carbon dioxide gradient is that 'raised levels' of carbon dioxide are associated with the presence of animals, especially mammals, and quite commonly humans, which are the food source for the blood–sucking mosquitoes.

According to Cooperband (2006a): "Female mosquitoes detect changes in carbon dioxide concentration as minute as 50 ppm, via sensilla on their maxillary palps (Grant & O'Connell, 1996). When a host-seeking female encounters a plume of carbon dioxide, she orients upwind using optomotor anemotaxis (Kennedy, 1939; Daykin et al., 1965). The structure of the plumes of carbon dixoide and other host-odour kairomones plays an important role in the attraction of *Aedes aegypti* (L.) mosquitoes. In a Y-tube olfactometer, orientation behaviour of *Ae. aegypti* varied with plume structure and odour, with a filamentous presentation of carbon dioxide inducing improved upwind movement over a homogenous cloud of carbon dioxide (Geier et al., 1999).

According to Turner Chen et al., 2021[3], mosquitoes are attracted to host animals for blood meals using plumes of CO_2 in the exhaled breath using the receptor expressed in the A neuron of the capitate peg sensilla type on the maxillary palps. The receptor is known to also detect several other classes of odorants, including ones emitted from human skin

Octenol is also present in low concentrations in human sweat and it activates mosquito antennal receptors (Cork & Park, 1996)
The carbon dioxide and the olfactory lure oct-1-en-3-ol simulate human respiration and human presence.
There is no time delay before efficacy of the product.
No unacceptable suffering is expected

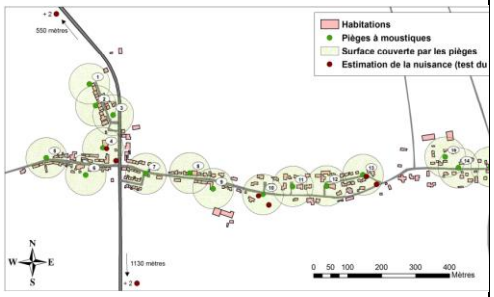
[3] doi: 10.1098/rsfs.2020.0043

3.5.3 Efficacy data

Table 3.13 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects *[address here results related to efficacy of the test product and validity of the test]*	Ref	Number in IUCLID section 6.7/Test report title
PT19 Use 1	Techno Bam traps with BAM - Leurre Moustiques traditionnels (oct-1-en-3-ol lure and carbon dioxide)	Attractant Wild insects Adults Mainly species present: *Ochlerotatus spp (Oc)* *Anopheles spp (aH)* *Others:* *Aedes spp. (Av)* *Culex spp. (Cx)* *Culiseta annulata*	Field Test Outdoor 16 traps deployed in the Sambuc hamlet (Camargue, France, 600 inhabitants) and followed between mid-April and late October 2016, compared to control sites without traps, located at 550 (grand Mas d'Avignon) and 1130 m (Marais du verdier) from the hamlet. Flow rate 0.2L/min CO_2 oct-1-en-3-ol lure replacement: every month CO_2 bottle replacement: every 3 weeks Assessment: * In the traps: - nets emptied 3-5 times a week - weight of insects trapped - determination of the number of species and individuals of biting dipterans, and number of non-target insects * By calf tests each week, *i.e.* number of mosquitoes landing on human baits, during a 10 min period, done:	From the raw data, before the activation of the traps (from April to May 2016), the level of contamination of the test site and of the control site was assessed. During this period, both sites were mainly contaminated by Ochlerotatus spp (and in a less proportion by Aedes alobopictus and Culex modestus). The level of contamination is lower in the control sites than in the future treated site, probably to the presence of the inhabitants. Considering that the efficacy assessment is the comparison of the level of contamination of the control and the treated site. This difference of contamination is considered as a worst case. *Number of mosquitoes trapped: - vary over time, with three peaks in June, July and August. - mean daily capture rate per trap from 1 (early Mai) to more than 382 mosquitoes (late August). - also vary spatially (24 to 399) - nine mosquito species captured. On the overall number of mosquitoes trapped 299408, 82.76% were *Ochlerotatus caspius*, 8.73% *Anopheleles hyrcanus*, 4.76% *Aedes vexans* and 2.13% *Culex spp.* *Nuisance = biting attempts:	[redacted] et al. 2016	S6.7_01

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>- at 3 locations in the "protected" area (i.e in the Sambuc hamlet) (at 10 and 40 m from a trap)
-2 locations outside the protected area (at 550 and 1130 m of the nearest trap)
before trap installation (60 assessments) and during the experiment.
- collection and identification of the mosquitoes landing on the human baits during the calf tests

Statistics:
- Anova on calf test results
 
</td>
<td>During the calf test, relative overall mosquito nuisance significantly lower at Sambuc (mean: 4.1 attempts / 10 min) compared to the control sites (mean: 14.1 /10 min) leading to a reduction of 70.5% of nuisance (all species combined) and 74% for Ochlerotatus sp. (main species trapped), compared to the control site
No significant difference noted between the calf tests performed at 10 and 40m from the trap

At the genus level:
<table>
<tr><th></th><th colspan="2">Traps</th><th colspan="4">Human Bait (Calf Tests)</th></tr>
<tr><th></th><th>%</th><th>% Biting</th><th colspan="2">Mean (SE) Biting Rate/10 min</th><th>Reduction</th><th colspan="2">ANOVA Statistics</th></tr>
<tr><th>Mosquito Species</th><th>Captures</th><th>Attempts</th><th>Control</th><th>Treated</th><th>Rate (%)</th><th>$F_{(1,294)}$</th><th>p value</th></tr>
<tr><td>Ochlerotatus caspius</td><td>82.76</td><td>51.39</td><td>7.68 (0.92)</td><td>1.97 (0.54)</td><td>74</td><td>28.7</td><td><0.00001</td></tr>
<tr><td>Anopheles hyrcanus</td><td>8.73</td><td>35.27</td><td>3.44 (1.54)</td><td>1.87 (0.89)</td><td>46</td><td>0.4</td><td>0.37</td></tr>
<tr><td>Aedes vexans</td><td>4.76</td><td>2.05</td><td>0.57 (0.07)</td><td>0.03 (0.04)</td><td>94</td><td>38.7</td><td><0.00001</td></tr>
<tr><td>Culex pipiens</td><td>1.99</td><td>0.23</td><td>0.03 (0.01)</td><td>0.01 (0.01)</td><td>67</td><td>1.57</td><td>0.21</td></tr>
<tr><td>Oc. detritus/coluzzii</td><td>1.40</td><td>6.77</td><td>1.86 (0.19)</td><td>0.03 (0.11)</td><td>98</td><td>70.8</td><td><0.00001</td></tr>
<tr><td>Culex modestus</td><td>0.14</td><td>4.16</td><td>0.44 (0.41)</td><td>0.22 (0.24)</td><td>50</td><td>0.22</td><td>0.64</td></tr>
<tr><td>Culiseta annulata</td><td>0.06</td><td>0.03</td><td>0.017 (0.01)</td><td>0</td><td>100</td><td>6.05</td><td>0.014</td></tr>
<tr><td>Aedes albopictus</td><td>0.01</td><td>0.07</td><td>0</td><td>0.007 (0.01)</td><td></td><td>0.5</td><td>0.48</td></tr>
<tr><td>Anopheles maculipennis</td><td>0.14</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Coquillettidia richiardii</td><td></td><td>0.03</td><td>0.017 (0.01)</td><td>0</td><td>100</td><td>6.06</td><td>0.014</td></tr>
<tr><td>Total</td><td>299,408</td><td>3051</td><td>14.06 (1.16)</td><td>4.15 (1.99)</td><td>70.5%</td><td>18.46</td><td>0.00002</td></tr>
</table>
It is observed that 93.5% of the biting attempts were caused by Ochlerotatus sp. and Anopheles sp.

Due to the low contamination of the test site by Aedes sp. and Culex sp., efficacy observed for these species should considered as an indication only.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT19
Use 1</td>
<td>Techno Bam traps with BAM - Leurre Moustiques traditionnels (oct-1-en-3-ol lure and carbon dioxide)</td>
<td>Attractant
Wild insects
Adults
Ochlerotatus sp.
Anopheles sp.
Aedes sp.
Culex sp.</td>
<td>Field Test
Outdoor

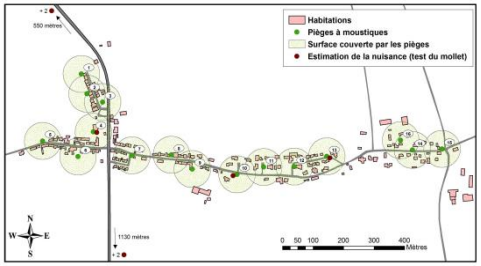
16 traps deployed in the Sambuc hamlet (Camargue, France, 600 inhabitants) and between mid-April and late November 2017.
Compared to 2 control sites without traps, located at 550 and 1130 m from the hamlet.

Assessment:</td>
<td>Number of mosquitoes trapped:
- vary over time, with two peaks in July and August.
- mean daily capture rate per trap from 1 to 417 mosquitoes.
- also vary spatially (82 to 316)
- four mosquito species captured.
Over the test period, the number of mosquitoes caught was 466 134.

Nuisance = biting attempts:
- prior to trap installation in 2015, relative</td>
<td>[redacted]</td>
<td>S6.7_01</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>* In the traps:
- nets emptied 3 times a week
- weight of insects trapped
- determination of the number of species and individuals of biting dipterans, and number of non-target insects

* By calf tests each week, i.e. number of mosquitoes landing on human baits, during a 10 min period, done:
- at 3 locations in the "protected" area (i.e in the Sambuc hamlet) (at 10m from a trap)
-2 locations outside the protected area (at 550 and 1130 m of the nearest trap)
- collection and identification of the mosquitoes landing on the human baits during the calf tests

Statistics:
- Anova on calf test results
 
</td>
<td>mosquito nuisance was higher at Sambuc than at the control sites
- during experiment, relative mosquito nuisance significantly lower at Sambuc compared to the control sites.
- overall, mosquito nuisance reduced by 94%. This results should be taken with care considering the low level of capture in the calf test in the control area with a mean of 3.09 biting attempts per 10 min all species included despite a high number of mosquitoes trapped.

<table>
<tr><th></th><th>pièges</th><th colspan="7">Captures test du mollet</th></tr>
<tr><th></th><th></th><th colspan="2">Témoin</th><th colspan="2">Qista</th><th colspan="2">Bti</th><th></th></tr>
<tr><th>Espèce de moustique</th><th>% captures</th><th>% de gêne</th><th>Captures /10 min</th><th>Captures /10 min</th><th>% réduction nuisance</th><th>Captures /10 min</th><th>% Réduction nuisance</th><th>$F_{(2,154)}$</th><th>P</th></tr>
<tr><td>Ochlerotatus caspius</td><td>78.7</td><td>56.0</td><td>2.14</td><td>0.07</td><td>97</td><td>0.02</td><td>99</td><td>25.0</td><td><0.00001</td></tr>
<tr><td>Anopheles hyrcanus</td><td>14.0</td><td>28.2</td><td>0.55</td><td>0.11</td><td>80</td><td>0.55</td><td>62</td><td>0.89</td><td>0.41</td></tr>
<tr><td>Culex pipiens</td><td>4.6</td><td>12.1</td><td>0.46</td><td>0.05</td><td>88</td><td>0</td><td>100</td><td>5.23</td><td>0.006</td></tr>
<tr><td>Aedes vexans</td><td>0.8</td><td>3.7</td><td>0.20</td><td>0</td><td>100</td><td>0</td><td>100</td><td>2.20</td><td>0.11</td></tr>
<tr><td>Toutes les espèces</td><td>466 134</td><td></td><td>3.09</td><td>0.39</td><td>94</td><td>0.49</td><td>91</td><td>18.6</td><td><0.00001</td></tr>
</table></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT19

Use 1</td>
<td>Techno Bam traps with BAM - Leurre Moustiques traditionnels (oct-1-en-3-ol lure and</td>
<td>Attractant

Culex pipiens

Adults females</td>
<td>Simulated use test (no choice)

Cage 30m^3, temperature 26 ±2°C, RH 50 - 70%

Photoperiod 10h light / 14h dark

CO_2 flow rate of the trap : 0.2L CO_2/min</td>
<td>In all the conditions tested, the mortality of the mosquitoes was lower than 10% (maximum 1%).

The percentage of attractivity (mean of 5 replicates were:
- Techno BAM trap + oct-1-en-3-ol lure + carbon dioxide: 98.8%
- Techno BAM trap +carbon dioxide: 86%</td>
<td>[redacted]
2022</td>
<td>S6.7_02</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>carbon dioxide)</td>
<td></td>
<td>4 modalities tested:
- Techno BAM trap + oct-1-en-3-ol lure + carbon dioxide
- Techno BAM trap +carbon dioxide
- Techno BAM trap + oct-1-en-3-ol lure
- Techno BAM trap without lure and carbon dioxide

Replicates: 5 per modalities

Negative control: yes (Techno BAM trap without lure and carbon dioxide).

Insects: Culex pipiens adults female, 100 per replicates.

The traps were activated one hour before the introduction of the mosquitoes

Assessment: % attractivity 24 hours post exposure (i.e number of insects trapped / number of insects released.

Statistics: ANOVA on % attractivity</td>
<td>- Techno BAM trap + oct-1-en-3-ol lure: 75.8%
- Techno BAM trap without lure and carbon dioxide: 5.2%
All modalities are statistically different to each other

Each condition has been tested separately including for the control, but as the conditions of the test are identical, it can be concluded that the Techno Bam traps showed a ratio higher than 4:1 of the insects trapped against Culex spp.</td>
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<tr>
<td>PT19

Use 1</td>
<td>Techno Bam traps with BAM - Leurre Moustiques traditionnels (oct-1-en-3-ol lure)</td>
<td>Attractant

Culex pipiens

Adults females</td>
<td>Simulated use test

Cage 30m^3, temperature 26°C, RH 70%

One modality tested: Techno BAM trap + oct-1-en-3-ol lure (without Co2)

4 replicates

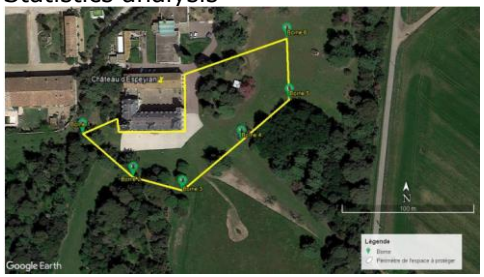
Control : no

Insects: Culex pipiens adults female, 100 per replicates.

Assessment: % attractiveness measured at 1, 15, 23, 31, 37 and 42 days after the beginning of the trial</td>
<td>This trial has been performed in the same test site and in the same conditions than the study 6.7-02.
Even if no control has been performed. The following data are acceptable to assess the residual efficacy of the lure (oct-1-3-ol).
The highest mortality recorded in all the repetitions and conditions tested was 6%.

The mean percentage of attractiveness (mean of 4 replicates) is presented in the table below.
% attractiveness (means 4 replicates)
<table>
<tr><td></td><td>Attractiveness (%)</td><td>Stat group</td></tr>
<tr><td>D1</td><td>75.1</td><td>a</td></tr>
<tr><td>D15</td><td>76.09</td><td>a</td></tr>
<tr><td>D23</td><td>74.1</td><td>a</td></tr>
</table>
</td>
<td></td>
<td>S6.7_03</td>
</tr>
</table>

			Statistics: ANOVA on % attractiveness	<table><tr><td>D 31</td><td>65.47</td><td>b</td></tr><tr><td>D 37</td><td>56.64</td><td>c</td></tr><tr><td>D 42</td><td>50.5%</td><td>c</td></tr></table> Up to 23 days % attractiveness is similar to results obtained with lure alone in the previous SU test (6.7_02), i.e 75%. From 23 days, a significant reduction of the attractiveness is observed. This study demonstrated that the lure keeps the same level of attractiveness during 3 weeks and should be replaced after.		
PT19 Use 1	Techno Bam traps with BAM - Leurre Moustiques traditionnels (oct-1-en-3-ol lure and carbon dioxide)	Attractant Wild insects Adults *Aedes sp.* *Culex sp.*	Field Test Outdoor 6 traps deployed 40 to 60 m apart in the park of the Espeyran castle (Camargue, France) between mid-Mai and Mid-November 2021. The traps are activated 19 hours a day between 4:00 and 23:00 CO2 bottle replacement every 3 weeks Lure replacement every month. Assessment: * In the traps: - nets 2 times a week - determination of the number of mosquitoes caught per species. * By calf tests each week, *i.e.* number of mosquitoes landing on human baits, during a 15 min period between 9 am and 12 am, done: - at 3 locations in the "protected" area (i.e between 10 and 20m from the nearest trap) -at 3 locations outside the protected area (more than 30 m from the trap) - collection and identification of the	Number of mosquitoes trapped: - vary over time, with two peaks in August and September. - mean daily capture rate per trap of 122 mosquitoes. - also vary spatially between traps - eleven mosquito species captured (*Anopheles sp. culex sp; Aedes sp. culiseta sp*). Over the test period, the number of mosquitoes caught was 85 390. The main species caught was *Aedes caspius* 62.9% followed by *Aedes vexans* (24%) and *Aedes detritus* (8.1%). Then *Aedes sp.* represented 95% of the mosquitoes trapped. Nuisance = biting attempts: - prior to trap installation, the level of contamination of all the locations (control and treated) was assessed based on the calf tests. The level of contamination was similar (also confirmed by the statistical analysis) 4.17 ± 3.37 catches in control area and 4.33 ± 2.88 catches in the protected area in 15 minutes. All the mosquitoes caught were *Aedes caspius*.	[redacted] 2022	S6.7_04

			mosquitoes landing on the human baits during the calf tests Statistics analysis 	- during experiment, relative mosquito nuisance is significantly lower in the treated site 1.46 ±2.79 catches compared to the control sites 5.51±9.51 catches in 15 min. Conclusions: From this trial, where the site was contaminated mainly by *Aedes sp*., it can be concluded that the system Techno Bam traps with BAM - Leurre Moustiques traditionnels (CO2 + lure) is able to reduce the level of nuisance by 74.9 % when the traps are spaced from 40 to 60 meters.		

3.5.4 Efficacy assessment

The applicant has performed a simulated-use test in order to demonstrate the capacity of the traps to attract and catch mosquitoes (*C. pipiens* which is the most common genus in Europe). The trap including both CO2 and oct-1-en-3-ol lure showed the better attractiveness (near from 100%) while the trap alone is few attractive (only 5%). Based on these results, the product BAM - Leurre Moustiques traditionnels fulfils the efficacy criteria of the ECHA efficacy guidance (2021) vol II parts B/C i.e a ratio of 4:1 of the insects trapped in the trap with attractant compared to the control trap within the test period.
Another simulated-use test has been provided to demonstrate the persistence of action of the oct-1-en-3-ol lure. The attractiveness of the trap with only oct-1-en-3-ol lure has been measured within 42 days. Results showed that after 23 days, the attractiveness of the trap to Culex declines significantly.
Nevertheless, based on the results of the first simulated-use test, the Techno BAM trap with carbon dioxide only has shown an efficacy higher than 80%. After 4 weeks, the Techno BAM trap with lure only, has shown on non-negligible attractiveness percentage of 65.47%, it can be assumed that in combination (CO_2 and lure) remain effective until 1 month.

Three field tests have been performed in the south of France (2016/2017/2021) (two in Sambuc hamlet: 600 inhabitants and 1 in Espeyran park castle). Mosquitoes trapped are counted and identified in each site. Calf tests are also implemented in order to assess the reduction of nuisance (biting attempts) due to the presence of the product in comparison with untreated area.
Mosquito species caught and identified in the different sites are representative of mosquitoes commonly found in Europe (*Ochlerotatus sp*., *Culex sp., Aedes sp, Anopheles sp*. ...).
Calf tests were carried out at specific time of the day for 10 to 15 min near the traps and outside of the treated areas (therefore species involved in calf tests (nocturnal/diurnal behaviour) are linked to the day moment of the test. Nuisance, i.e biting attempts are observed in both situations (treated and non-treated) and a reduction of nuisance is calculated. On average over the 3 sites, a significant reduction is demonstrated on species *Ochlerotatus sp.* (74% on site 1 in 2016), Anopheles sp. (80% on site 2 in 2017), and *Aedes sp*. (approximately 75% on site 3 in 2021). It has to be noted that even if *Culex* species are less present in these studies, 70 to 90% of reduction of biting attempts are observed.

Based on the CO2 flow rate (0.2L/min) of the trap that is used 15h/day, for a CO2 bottle of 10 Kg (with a CO2 density of 1.527 g/L, the CO2 bottle should be replaced every month

3.5.5 Conclusion on efficacy

Based on the efficacy data presented, it can be concluded that the product BAM-Leurre Moustiques traditionnel is efficient to attract and reduce the nuisance of mosquitoes (*Ochlerotatus spp*., *Aedes spp. Anopheles spp. and Culex spp.*) until 60m from the trap at the application rate of 0.2 L/min. CO2 bottle and Oct-1-en-ol lure box should be replaced every month.

3.5.6 Occurrence of resistance and resistance management

Up to now, no resistance has been identified in the literature review in any flying insect species, which is attracted by carbon dioxide and Oct-1-en-3-ol.

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

3.5.7 Known limitations

No known limitation

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

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

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoint(s) for the active substances and available information for the non-active substances.

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

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

3.6.3 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of non-active substances, refer to the respective section of the confidential annex.

3.6.4 Exposure assessment and risk characterisation for human health

The product BAM – Leurre Moustiques Traditionnels is a ready-to-use bait to be used with a Qista trap system by professionals and non-professionals and placed outdoors. It attracts the female mosquitoes by stimulating human presence with the diffusion of CO2 and an olfactory cocktail containing oct-1-en-3-ol. Mosquitoes are then aspired into the chimney of the trap and blocked in the net inside.
The carbon dioxide bottle is clipped directly on the device. The oct-1-en-3-ol olfactory lure is impregnated onto pearls that are contained within a sealed box with holes to allow the product to evaporate. The lid of the box is removed prior to the product being placed within the device. A plastic grid incorporated into the jar prevents direct contact with the impregnated pearls, even when the lid is removed. Considering this, no dermal, oral and inhalation exposure to the product is expected during the loading phase by the user.
The system is activated remotely through a mobile application.

Secondary exposure via inhalation to the general public presents outside in the vicinity of the device could occur. Taking into account that there is also a natural ventilation outside around the trap, the exposure of the general public is considered very low. Therefore, the risk characterisation is not considered relevant and no personal protective equipment is required during the use of the product.
It should be noted that the active substance carbon dioxide presents a Community OEL of 9000 mg/m3. However, it is not relevant for the general public.

Conclusion

The product BAM – Leurre Moustiques Traditionnels meets conditions of art. 25 for Human Health.

3.7 Risk assessment for the environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.7.1 Classification

Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified. One of active substances is listed in Annex I of Regulation (EU) No 528/2012, the other one is not classify for the environment and both without any restriction for the environment. There is no need for risk mitigation measure to protect the environment.

3.7.2 Substance(s) of concern

The product BAM – LEURRE MOUSTIQUES TRADITIONNELS does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.7.3 Screening for endocrine disruption relating to non-target oganisms

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.8 Assessment of a combination of biocidal products

Not relevant.

3.9 Comparative assessment

Not relevant, none of the active substance are candidate for substitution or exclusion.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Not relevant

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Not relevant

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

Not relevant.

4.3 List of studies for the biocidal product

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

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2017	Rapport intermédiaire sur le suivi scientifique annuel mené en 2017 en parallèle aux opérations de démoustication au Bti sur le périmètre du Parc naturel régional de Camargue Publication *Report and Study No. not provided* [redacted]	6.7 Efficacy data to support these claims (efficacy data)	6.7_01 field		*Study sponsor not provided*	No	no

		[redacted]						
[redacted]	2017	Rapport sur le suivi scientifique annuel mené en 2016 en parallèle aux opérations de démoustication au Bti sur le périmètre du Parc naturel régional de Camargue Publication *Report and Study No. not provided* [redacted]	6.7 Efficacy data to support these claims (efficacy data)	6.7_01 field	YYY	*Study sponsor not provided*	No	no
[redacted]	2017	Mosquito Traps: An Innovative, Environmentally Friendly Technique to Control Mosquitoes Publication *Report and Study No. not provided* Int J Environ Res Public Health. 2017 Mar; 14(3): 313.	6.7 Efficacy data to support these claims (efficacy data)	6.7_01 field		*Study sponsor not provided*	No	no
[redacted]	2022	Rapport 2: Evaluation de l'attraction du leurre 'moustiques traditionnels (octénol)' et son association avec le CO2 dans les bornes anti-moustiques	6.7 Efficacy data to support these claims (efficacy data)	6.7_02 Simulated use		Qista / Technobam	No	yes

		Qista Study report Report No.: Rapport 2 ; Study No.: Rapport 2						

4.4 References

4.4.1 References other than list of studies for the biocidal product

- Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year

- Last name(s), Initial(s) of the first name(s), Last name(s), Initial(s) of the first name(s). [Title of the publication], *name of the journal*, **number**, year

4.4.2 Guidance documents

- [Title of the guidance document], year

- [Title of the guidance document], year

4.4.3 Legal texts

- Regulation (EU) No XXX/year of the European Parliament and of the Council of day Month year concerning (topic)

4.5 Confidential information

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