

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Repelente

Product type(s)

PT19: Repellents and attractants

Authorisation number: PT/DGS ARM PB-17/2024

R4BP asset number: PT-0032846-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Repelente Spray repelente de mosquitos e carraças Loção repelente de mosquitos e carraças Spray repelente de mosquitos e carraças para o corpo Pele repelente de mosquitos e carraças Tecido repelente de mosquitos e carraças em spray Tecido repelente de mosquitos e carraças Vestuário Repelente de Mosquitos e Carraças Vestuário repelente de mosquitos e carraças Spray Repelente de Mosquitos e Carraças Pele e Vestuário Loção Repelente de Mosquitos e Carraças Pele e Roupas
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Terrium
	Address	246 rue du 8 mai 1945 42210 Motrond-Les-Bains France
Authorisation number	PT/DGS ARM PB-17/2024	
<i>R4BP asset number</i>	PT-0032846-0000	
Date of the authorisation	20/06/2024	
Expiry date of the authorisation	06/06/2027	

1.3. Manufacturer(s) of the product

Name of manufacturer	MERCK KGAA
Address of manufacturer	FRANKFURTER STRASSE 250 64293 DARMSTADT Germany
Location of manufacturing sites	FRANKFURTER STRASSE 250 64293 DARMSTADT Germany

Name of manufacturer	FABRICATION CHIMIQUE ARDECHOISE
Address of manufacturer	1041 CHEMIN DE LA DIGUE DU RHONE 07300 TOURNON SUR RHONE France
Location of manufacturing sites	1041 CHEMIN DE LA DIGUE DU RHONE 07300 TOURNON SUR RHONE France

Name of manufacturer	SAS SPRING
Address of manufacturer	ZI DU BOIS DE LEUZE 4 RUE BLAISE PASCAL 13310 SAINT MARTIN DE CRAU France
Location of manufacturing sites	ZI DU BOIS DE LEUZE 4 RUE BLAISE PASCAL 13310 SAINT MARTIN DE CRAU France

Name of manufacturer	PACOME
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Address of manufacturer	LOT N°17 LA ZIZA 98890 PAITA New Caledonia
Location of manufacturing sites	LOT N°17 LA ZIZA 98890 PAITA New Caledonia

Name of manufacturer	TAG LIFE CARE
Address of manufacturer	17 CHEMIN DE CHARLEMAGNE 41120 CELLETES France
Location of manufacturing sites	17 CHEMIN DE CHARLEMAGNE 41120 CELLETES France

Name of manufacturer	LABORATORIOS MONTPLET
Address of manufacturer	VIA TRAJANA, 53-59 08020 BARCELONA Spain
Location of manufacturing sites	VIA TRAJANA, 53-59 08020 BARCELONA Spain

1.4. Manufacturer(s) of the active substance(s)

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	MERCK KGAA
Address of manufacturer	FRANKFURTER STRASSE 250 64293 DARMSTADT Germany
Location of manufacturing sites	MERCK S.L.U. - POLIGONO MERCK 08100 MOLLET DEL VALLES Spain

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	MERCK S.L.U.
Address of manufacturer	CALLE MARIA DE MOLINA, 40 28006 MADRID Spain
Location of manufacturing sites	POLIGONO MERCK 08100 MOLLET DEL VALLES Spain

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate		active substance	52304-36-6	257-835-0	20

2.2. Type(s) of formulation

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264: Wash ... thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Spray to repel human head lice (general public)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Pediculidae: Pediculidae: Common name: human head louse Development stage: adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: spraying Detailed description: -
Application rate(s) and frequency	Application rate: Adults: up to 1.05 g product per application; Children from 0 to 11 years old: 0.5g per application Dilution (%): 0 Number and timing of application: Adults: up to 1.05 g product per application; Children from 0 to 11 years old: 0.5g per application - Ready-to-use (no dilution needed) - RTU leave-on product Timing: Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used to prevent reinfestation with human head lice (<i>Pediculus humanus capitis</i>) only after a pediculicidal treatment. Reapply after washing the hair and at the latest after 2 days. Dose per application: <ul style="list-style-type: none">• Adults: up to 1.05 g product per application.• Children from 0 to 11 years old: 0.5g hubs per application - Product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day: <ul style="list-style-type: none">- For pump spray (100mL) :<ul style="list-style-type: none">o Adults and children >12 years: 11 sprays, 1 to 3 times a dayo Children (1 to <12 years): 5 sprays, 1 to 3 times a day

	<ul style="list-style-type: none"> o Infants (<1 year): 5 sprays, 1 to 2 times a day - For trigger spray (250 mL) : o Adults : 2 sprays, 1 to 3 times a day o Children (1 to <12 years): 1 spray, 1 to 3 times a day o Infants (<1 year): 1 spray, 1 to 2 times a day <p>When the biocidal product is applied to children under 11 years old, the product should be applied by an adult</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

4.1.1. Use-specific instructions

- Ensure that no lice are present. First use a pediculicide.
- Evenly apply the product on clean and dry or towel dried hair close to the scalp and take care to first treat the nape of the neck and behind the ears. Then spray on the totality of hair like a lacquer. Make sure that the scalp and hair are sufficiently moistened.
- The application must be repeated after washing the hair.
- The product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day:
 - o For pump spray (100mL – 100µL per spray):
 - # Adults and children >12 years: 11 sprays, 1 to 3 times a day
 - # Children (1 to <12 years): 5 sprays, 1 to 3 times a day
 - # Infants (<1 year): 5 sprays, 1 to 2 times a day
 - o For pump spray (100mL – 300µL per spray):
 - # Adults and children >12 years: 4 sprays, 1 to 3 times a day
 - # Children (1 to <12 years): 2 sprays, 1 to 3 times a day
 - # Infants (<1 year): 2 sprays, 1 to 2 times a day
 - o For trigger spray (250mL):
 - # Adults and children >12 years: 2 sprays, 1 to 3 times a day
 - # Children (1 to <12 years) : 1 spray, 1 to 3 times a day

Infants (<1 year): 1 spray, 1 to 2 times a day

- For continued protection: Reapply at the latest after 2 days on cleaned and dry or towel dried hair. Reapply earlier, if the hair was in contact with water (like after rain or swimming) until there is no longer a risk of infestation.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

- Do not spray into the face or apply to eye area.

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

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

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

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4.2. Use description

Table 2. Spray to be applied on clothes to repel mosquitoes (temperate conditions)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism(s) (including development stage)	Scientific name: Aedes spp. Common name: mosquitoes Development stage: adults Scientific name: Culex spp. Common name: mosquitoes Development stage: adults
Field(s) of use	Autre

	Application on clothes
Application method(s)	Method: spraying Detailed description: Spray directly onto the textiles
Application rate(s) and frequency	Application rate: 0.6 mg of product per cm ² of fabric Dilution (%): 0 Number and timing of application: 0.6 mg of product per cm ² of fabric Protection time: 8 hours (in temperate conditions and tropicale conditions), even after up to 30 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100 and 250mL HDPE bottle (with sprayer)

4.2.1. Use-specific instructions

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).
- Retreat after water exposure without exceeding the maximal recommended application number.

Number of sprays:

- 100 mL bottle (300µL per spray): Apply the following number of sprays to the front of clothing:
 - For adults and children > 12 years old: 6 per part body, 3 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 2 to 3 per part body, 1 to 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
- 250 mL bottle: Apply the following number of sprays to the front of clothing:
 - For adults and children > 12 years old: 4 per part body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old: 1 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

EU only:

For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes.

In France only:

For treatment against mosquitos in temperate conditions, do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.

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

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

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

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4.3. Use description

Table 3. Spray to be applied on clothes to repel mosquitoes (tropical conditions)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against mosquito bites.
Target organism(s) (including development stage)	Scientific name: Aedes spp. Common name: mosquitoes Development stage: adults Scientific name: Anopheles spp. Common name: mosquitoes Development stage: adults

Field(s) of use	Autre Application on clothes
Application method(s)	Method: spraying Detailed description: Spray directly onto the textiles
Application rate(s) and frequency	Application rate: 0.6 mg of product per cm ² of fabric Dilution (%): 0 Number and timing of application: 0.6 mg of product per cm ² of fabric Protection time: 8 hours (tropical conditions), even after up to 30 days of storage of the treated cloth (before being worn). Reapply after each washing or use of the treated cloth in a closed packaging (such as a plastic bag).
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	250mL HDPE bottle (with sprayer)

4.3.1. Use-specific instructions

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).
- Retreat after water exposure without exceeding the maximal recommended application number.

Number of sprays:

- 100 mL bottle (300µL per spray): Apply the following number of sprays to the front of clothing:
 - For adults and children > 12 years old: 6 per part body, 3 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 2 to 3 per part body, 1 to 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
- 250 mL bottle: Apply the following number of sprays to the front of clothing:
 - For adults and children > 12 years old: 4 per part body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 2 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old: 1 per part body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

EU only:

For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin of children under 12 years and on their clothes.

In France only:

For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.

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

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

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

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4.4. Use description

Table 4. Spray for skin application to repel mosquitoes (temperate conditions)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Aedes spp. Common name: mosquitoes Development stage: adults Scientific name: Culex spp. Common name: mosquitoes Development stage: adults
Field(s) of use	Autre

	Skin application
Application method(s)	Method: spraying Detailed description: Spray directly on skin
Application rate(s) and frequency	Application rate: 0,6 mg of product per cm ² of skin Dilution (%): 0 Number and timing of application: Application rate in temperate conditions: 0,6 mg of product per cm ² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

4.4.1. Use-specific instructions

- Wash hands thoroughly after handling
- Do not apply the product on the hands of child under 12 years.
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:

Number of sprays (100ml – 100 µL per spray):

- Adult and children >12 years old: apply 7 sprays to the head, 1 spray on the neck, 6 sprays per arm, 2 sprays per hand, 13 sprays per leg and 3 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 3 sprays to the head, 1 spray on the neck, 3 sprays per arm, 1 spray per hand, 7 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 3 sprays per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (100ml – 300 µL per spray):

- Adult and children >12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 5 sprays per leg and 1 sprays per foot, once a day.

- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray on the neck, 1 sprays per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.

- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.

- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm and 1 spray per leg, once a day.

- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 3 sprays per leg and 1 spray per foot, once a day.

- Children from 6 to <12 years old: apply 2 sprays per arm and 2 sprays per leg, once a day.

- Children from 2 to <6 years old: apply 1 spray for both arms and 1 spray per leg, once a day.

- Children 1 to <2 years old: apply 1 spray for both arms and 1 spray for both legs once a day.

- Infants <1 year old: apply 2 sprays for the body, once a day.

In France only:

Number of sprays (100ml – 100 µL per spray):

- Adult and children >12 years old: apply 7 sprays to the head, 5 sprays per arm, 2 spray per hand and 8 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 3 sprays to the head and per arm, and 4 sprays per leg, once or twice daily.

- Children from 2 to <6 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg, once a day.

- Children 1 to <2 years old: Apply 3 sprays to the head, 1 spray per arm and per leg once a day.

- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and per leg, once a day.

Number of sprays (100ml – 300 µL per spray):

- Adult and children >12 years old: apply 2 sprays to the head, 2 sprays per arm, 1 spray per hand and 3 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 1 spray to the head and per arm, and 2 sprays per leg, once or twice daily.

- Children from 2 to <6 years old: Apply 1 spray to the head, 1 sprays per arm and per leg, once a day.

- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.

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- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 1 spray for the body, once a day.

4.4.2. Use-specific risk mitigation measures

4.4.3. Use-specific risk mitigation measures

- When the biocidal product is applied to children under 12 years, the product should be applied by an adult
- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area

EU only:

- Temperate condition:
- Apply only one time per day.
- Do not apply the product simultaneously on the skin of children under 12 years and on their clothes.
- For adult and children more than 12 years, do not apply the product on skin under clothes.

In France only:

- Apply only on head, arms, hands and legs.
- For adult and children of 6 years and more, apply up to two times per day.
- For children younger than 6 years, apply one time per day.
- For children of 2 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day. Do not apply the product on skin under clothes.
- Do not apply the product simultaneously on the skin of children younger than 2 years and on their clothes.

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

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

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

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4.5. Use description

Table 5. Spray for skin application to repel mosquitoes (tropical conditions)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Aedes spp. Common name: mosquitoes Development stage: adults Scientific name: Anopheles spp. Common name: mosquitoes Development stage: adults
Field(s) of use	Autre Skin application
Application method(s)	Method: spraying Detailed description: Spray directly on skin
Application rate(s) and frequency	Application rate: 0,8 mg of product per cm ² of skin Dilution (%): 0 Number and timing of application: Application rate in tropical conditions: 0,8 mg of product per cm ² of skin Protection time: 3 hours in tropical conditions
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

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4.5.1. Use-specific instructions

- Wash hands thoroughly after handling
- Do not apply the product on the hands of child under 12 years.
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:

Number of sprays (100ml – 100µL per spray):

- Adult and children >12 years old: apply 9 sprays to the head, 1 spray to the neck, 8 sprays per arm, 3 sprays per hand, 18 sprays per leg and 4 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 4 sprays to the head, 2 sprays on the neck, 4 sprays per arm, 1 spray per hand, 9 sprays per leg and 2 sprays per foot, once a day.
- Children from 2 to <6 years old: apply 4 sprays to the head, 2 sprays on the neck, 3 sprays per arm, 1 spray per hand, 6 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 4 sprays per leg and 1 spray per foot, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 3 sprays per leg and 1 spray per foot, once a day.

Number of sprays (100ml – 300 µL per spray):

- Adult and children >12 years old: apply 3 sprays to the head, 1 spray to the neck, 3 sprays per arm, 1 spray per hand, 6 sprays per leg and 2 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 3 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per leg and 1 spray per foot, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm, 1 spray per leg and 1 spray per foot, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 2 sprays to the head, 1 spray to the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.

- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand, and 2 sprays per leg, once a day.

- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray per arm and 2 sprays per leg, once a day.

- Children 1 to <2 years old: apply 1 spray to the head, 1 spray for both arms and 1 spray per leg, once a day.

- Infants <1 year old: apply 4 sprays for the body, once a day.

In France only:

Number of sprays (100ml- 100µL per spray):

- Adult and children >12 years old: Apply 9 sprays to the head, 7 sprays per arm, 3 sprays per hand and 11 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 4 sprays to the head and per arm, and 5 sprays per leg, once daily.

- Children from 2 to <6 years old: Apply 4 sprays to the head, 3 sprays per arm and per leg, once a day.

- Children 1 to <2 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg once a day.

- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and 2 sprays per leg, once a day.

Number of sprays (100ml – 300µL per spray):

- Adult and children >12 years old: Apply 3 sprays to the head, 2 sprays per arm, 1 spray per hand and 4 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 2 sprays to the head, 1 spray per arm, and 2 sprays per leg, once daily.

- Children from 2 to <6 years old: Apply 2 sprays to the head, 1 spray per arm and per leg, once a day.

- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.

- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 2 sprays to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.

- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once daily.

- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.

- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray for both arms and 1 spray for both legs once a day.

- Infants <1 year old: apply 1 spray for the body, once a day.

4.5.2. Use-specific risk mitigation measures

4.5.3. Use-specific risk mitigation measures

- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area.
- When the biocidal product is applied to children, the product should be applied by an adult.

EU only:

- Apply only one time per day.
- Do not apply on children younger than 6 years.
- Do not apply the product simultaneously on the skin of children under 12 years and on their clothes.
- For adult and children more than 12 years, do not apply the product on skin under clothes.

In France only:

- Apply only on head, arms, hands and legs.
- For adult and children more than 12 years, apply up to two times per day.
- For children under 12 years, apply one time per day.
- For treatment against mosquitos in tropical conditions, do not apply the product simultaneously on the skin and on clothes for children younger than 6 years.
- For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product more than one time per day and do not apply on skin under clothes.

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

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

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

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4.6. Use description

Table 6. Spray to be applied on clothes to repel ticks

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Ready to use repellent product to treat clothes (cotton and polyester) in order to protect the user against ticks.
Target organism(s) (including development stage)	Scientific name: <i>Ixodes ricinus</i> Common name: hard ticks Development stage: adults Scientific name: <i>Ixodes ricinus</i> Common name: hard ticks Development stage: nymphs
Field(s) of use	Autre Application on clothes
Application method(s)	Method: spraying Detailed description: Spray directly onto the textiles
Application rate(s) and frequency	Application rate: 0.85 mg of product per cm ² of fabric Dilution (%): 0 Number and timing of application: 0.85 mg of product per cm ² of fabric Protection time (in temperate conditions) during 6 hours even after 7 days of storage of the treated cloth (before being worn) in a closed packaging (such as a plastic bag). Reapply after each washing or use of the treated cloth.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100 and 250mL HDPE bottle (with sprayer)

4.6.1. Use-specific instructions

- In case of storage before wearing, the treated clothes must be stored in a closed packaging (such as a plastic bag).
- Retreat after water exposure without exceeding the maximal recommended application number.

Number of sprays:

- 100 mL bottle (300 µL per spray): Apply the following number of sprays to the front of clothing:

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- For adults and children > 12 years old: 9 per shirt body, 4 per leg, 2 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 3-5 per shirt body, 2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old : 2 per shirt body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - 250 mL bottle: Apply the following number of sprays to the front of clothing:
 - For adults and children > 12 years old: 6 per shirt body, 3 per leg, 2 per sleeve. Repeat on the back of the clothes.
 - For children from 2 to 12 years old: 2-3 per shirt body, 1-2 per leg, 1 per sleeve. Repeat on the back of the clothes.
 - For children under 1 to 2 years old : 1-2 per shirt body, 1 per leg, 1 per sleeve. Repeat on the back of the clothes.

4.6.2. Use-specific risk mitigation measures

4.6.3. Use-specific risk mitigation measures

EU only:

- Do not apply on clothes of children younger than 1 year.
- For treatment against ticks, do not apply the product simultaneously on the skin of children under 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

In France only:

- Do not apply on clothes of children younger than 1 year.
- Do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

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

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

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

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4.7. Use description

Table 7. Spray for skin application to repel ticks

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Ixodes ricinus Common name: hard ticks Development stage: adults Scientific name: Ixodes ricinus Common name: hard ticks Development stage: nymphs
Field(s) of use	Autre Skin application
Application method(s)	Method: spraying Detailed description: Spray for skin application to repel ticks
Application rate(s) and frequency	Application rate: 0,6 mg of product per cm ² of skin Dilution (%): 0 Number and timing of application: 0,6 mg of product per cm ² of skin Protection time: 4 hours in temperate conditions
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	100-250mL HDPE bottle (with sprayer)

4.7.1. Use-specific instructions

- Wash hands thoroughly after handling

- Do not apply the product on the hands of child

- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.

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- Retreat after water exposure without exceeding the maximal recommended application number.

EU only:

Number of sprays (100ml– 100 µL per spray):

- Adult and children >12 years old: apply 7 sprays to the head, 1 spray on the neck, 6 sprays per arm, 2 sprays per hand, 13 sprays per leg and 3 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 3 sprays to the head, 1 spray on the neck, 3 sprays per arm, 1 spray per hand, 7 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 3 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 4 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 3 sprays per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (100ml – 300 µL per spray):

- Adult and children >12 years old: apply 2 sprays to the head, 1 spray on the neck, 2 sprays per arm, 1 spray per hand, 5 sprays per leg and 1 sprays per foot, once a day.
- Children from 6 to <12 years old: apply 1 spray to the head, 1 spray on the neck, 1 sprays per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children from 2 to <6 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm, 1 spray per hand, 2 sprays per leg and 1 spray per foot, once a day.
- Children 1 to <2 years old: apply 1 spray to the head, 1 spray on the neck, 1 spray per arm and 1 spray per leg, once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray on the neck, 1 spray per arm and 2 spray per leg, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 3 sprays per leg and 1 spray per foot, once a day.
- Children from 6 to <12 years old: apply 2 sprays per arm and 2 sprays per leg, once a day.
- Children from 2 to <6 years old: apply 1 spray for both arms and 1 spray per leg, once a day.
- Children 1 to <2 years old: apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 2 sprays for the body, once a day.

In France only:

Number of sprays (100ml– 100 µL per spray):

- Adult and children >12 years old: apply 7 sprays to the head, 5 sprays per arm, 2 spray per hand and 8 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 3 sprays to the head and per arm, and 4 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 3 sprays to the head, 2 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 3 sprays to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 2 sprays to the head, 1 spray per arm and per leg, once a day.

Number of sprays (100ml – 300 µL per spray):

- Adult and children >12 years old: apply 2 sprays to the head, 2 sprays per arm, 1 spray per hand and 3 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head and per arm, and 2 sprays per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 sprays per arm and per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray to the head, 1 spray per arm and per leg once a day.
- Infants <1 year old: apply 1 spray to the head, 1 spray per arm and per leg, once a day.

Number of sprays (250ml):

- Adult and children >12 years old: apply 1 spray to the head, 1 spray per arm, 1 spray per hand and 2 sprays per leg, once or twice daily.
- Children from 6 to <12 years old: Apply 1 spray to the head, 1 spray per arm, and 1 spray per leg, once or twice daily.
- Children from 2 to <6 years old: Apply 1 spray to the head, 1 spray per arm and 1 spray per leg, once a day.
- Children 1 to <2 years old: Apply 1 spray for both arms and 1 spray for both legs once a day.
- Infants <1 year old: apply 1 spray for the body, once a day.

4.7.2. Use-specific risk mitigation measures

4.7.3. Use-specific risk mitigation measures

- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Do not apply on the eye area.
- When the biocidal product is applied to children under 12 years, the product should be applied by an adult.

EU only:

- Apply only one time per day. Do not apply the product simultaneously on the skin of children under 6 years and on their clothes.
- For adult and children more than 6 years, do not apply the product on skin under clothes.

In France only:

- Apply only on head, arms, hands and legs.
- For adult and children of 6 years and more, apply up to two times per day.
- For children younger than 6 years, apply one time per day.
- For adult and children of 6 years and more, if the product is used in combination with clothes treatment, do not apply the product on skin more than one time per day and do not apply the product on skin under clothes.
- Do not apply the product simultaneously on the skin of children younger than 6 years and on their clothes.

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- Always read the label or leaflet before use and follow all the instructions provided.
- Respect the recommended application doses.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can lower it.
- The spraying device should be oriented at 10-20 cm toward the surface to be treated.
- The user should inform the registration holder if the treatment is ineffective.
- The use of the product with other repellent products is not recommended.

5.2. Risk mitigation measures

- Do not spray close to the eyes.
- Use in well-ventilated areas.

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

- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.
- Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- If medical advice is needed, have product container or label at hand.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Keep out of reach of children
- Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.
- Advice on safe handling: Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.
- Environmental exposure controls: Do not let product enter drains.
- Shelf life : 30 months
- The product should not be stored at temperatures $>40^{\circ}\text{C}$

6. OTHER INFORMATION

Considering the importance of this active substance in vector control, the authorisation holder has to implement a monitoring of scientific literature toward the active substance IR3535. Results of this assessment must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.

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