




Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
Ufficio 1 - Affari generali e prodotti di interesse sanitario diversi dai dispositivi medici
Viale Giorgio Ribotta, 5 - 00144 Roma

I.5.i.d.2/785

Ministero della Salute 0010407-P-21/02/2020-DGDMF-MDS-P DGDMF 0010407-P-21/02/2020  372685830
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Spett.le
Virbac
1ère Avenue 2065 m – LID
06516 CARROS
France

**OGGETTO: Prodotto biocida Indorex.
Trasmissione decreto di autorizzazione.**

Si trasmette, in allegato, il D.D. di autorizzazione del 20 FEB. 2020 relativo al prodotto biocida indicato in oggetto n. IT/2020/00622 /MRP.

Si richiama l'attenzione in merito a quanto disposto dal Regolamento (UE) 1272/2008 del Parlamento europeo e del Consiglio relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze, delle miscele e successive modifiche e adeguamenti.

IL DIRETTORE GENERALE

D^{ra}ssa Marcella Marletta

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Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO

UFFICIO I

I.S.i.d.2/785

IT/2020/00 622 /MRP

IL DIRETTORE

VISTO l'art. 15 della Legge n. 97 del 06 agosto 2013 recante "Disposizioni per l'adempimento degli obblighi derivanti dall'appartenenza dell'Italia all'Unione europea – Legge europea 2013";
VISTO il Regolamento (UE) 528/2012 del Parlamento Europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso del biocidi, in particolare gli artt.19 e ss.;
VISTO, in particolare, gli articoli 33 e 34 del suddetto Regolamento riguardanti il riconoscimento reciproco delle autorizzazioni e delle registrazioni di prodotti biocidi in sequenza e in parallelo;
VISTA l'istanza NA-MRP con case number BC-RD023122-62 presentata sul Registro Europeo R4BP3 in data 20-04-2016;
VISTA la documentazione presentata dalla società richiedente a sostegno della suddetta istanza;
VISTO il parere dell'Istituto Superiore di Sanità, acquisito con prot. 5418 del 30/01/2020;
RITENUTA la conformità di detta documentazione alla normativa vigente in materia di immissione sul mercato di biocidi;

DECRETA:

L'autorizzazione del prodotto biocida:

DENOMINAZIONE	Indorex
PRINCIPIO ATTIVO:	Pyriproxyfen Permethrin
TITOLARE DELL'AUTORIZZAZIONE RESPONSABILE DELL'IMMISSIONE SUL MERCATO	Virbac 1ère Avenue 2065 m – LID 06516 CARROS France
NUMERO DI AUTORIZZAZIONE	IT/2020/00622 /MRP 20 FEB. 2020
SCADENZA DELL'AUTORIZZAZIONE	14/01/2030

A far data dalla notifica del presente decreto, la società VIRBAC è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato I (SPC – Sommario delle Caratteristiche del Prodotto) e nell'allegato II (Ulteriori Condizioni dell'Autorizzazione).

Avverso il presente atto è ammesso ricorso giurisdizionale presso il Tribunale Amministrativo Regionale competente entro il termine di sessanta giorni, ovvero ricorso straordinario al Capo dello Stato entro il termine di centoventi giorni.

Il presente decreto viene redatto in duplice originale, di cui un esemplare è notificato in via amministrativa alla ditta interessata e l'altro è conservato agli atti di questo Ufficio.

Roma, li

20 FEB. 2020



IL DIRETTORE GENERALE

Dr.ssa Marcella Marletta

Summary of product characteristics for a biocidal product family

Family name: Indorex

Part I.- First information level

1. Administrative information

1.1. Product type(s)

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

1.2. Authorisation holder

Authorisation number

Not defined

Date of the authorisation

Not defined

Expiry date of the authorisation

Not defined

Name and address of the authorisation holder

Name
Address

Not defined
Not defined

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	ARDEPHARM (Aerosol spray and fogger)			
Address of the manufacturer	Chemin des Iles Ferays, Les Goules	07300	TOURNON-SUR-RHONE	France
Location of manufacturing sites	Chemin des Iles Ferays, Les Goules	07300	TOURNON-SUR-RHONE	France
Name of the manufacturer	VIRBAC (pumpspray)			
Address of the manufacturer	1ère avenue 2065 m L.I.D	06516	Carros	France
Location of manufacturing sites	1ère avenue 2065 m L.I.D	06516	Carros	France

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

BAS number: 1342				
Name of the manufacturer	TAGROS Chemicals India Ltd.			
Address of the manufacturer	72, Marshalls Road, Egmore	Chennai-600 008	TAMILNADU	India
Location of manufacturing sites	Jhaver Centre, Rajah Annamalai Building IV Floor, T2, Marshalls Road, Egmore	Chennai-600 008	TAMILNADU	India
BAS number: 61				
Name of the manufacturer	SUMITOMO CHEMICAL Co. Ltd.			
Address of the manufacturer	5-33, Kitahama 4-chome, Chuo-ku,	541-8550	Osaka	Japan
Location of manufacturing sites	Misawa Works Aza-Sabishirota, Oaza-Misawa, Misawa City	033-0022	Aomori	Japan

2. Product family composition and formulation

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

BAS number	EC number	CAS number	Common name	IUPAC name	Function	Content (%)
61	429-800-1	95737-68-1	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	Active Substance	0.0063 - 0.08 %
1342	258-067-9	52645-53-1	Permethrin		Active Substance	0.017 - 0.11 %
-	200-661-7	67-63-0	Isopropyl alcohol	Propan-2-ol	Solvent	0 - 30.9543 %
-	203-523-4	107-83-5	Isohexane	2-Méthylpentane	Solvent	0 - 95.3267 %
-	200-662-2	67-64-1	Acetone	Propan-2-one	Solvent	0 - 20 %
-			Hallcomid M-8-10 (Mixture of N,N-dimethyldecanamide (38-50) and N,N-dimethyloctanamide (50-65))	N,N-dimethyldecanamide, CAS number: 14433-76-2, EC nr: 238-405-1 N,N-dimethyloctanamide, CAS number: 1118-92-9, EC nr: 214-272-5	Surfactant	0.05 - 0.0655 %
-	205-470-2	61791-12-6	Cremophor EL	Ethoxylated castor oil	Surfactant	0 - 5.2576 %
-	231-791-2	7732-18-5	Purified water	Water	Solvent/diluent	0 - 63.708 %
-	613-156-5	63148-62-9	Dimeticone	poly(dimethylsiloxane)	Anti-foam	0 - 0.1 %
-	204-696-9	124-38-9	CO2	Carbon dioxide	Propellant gas	0 - 7.2 %

2.2. Type(s) of formulation

Formulation(s) Aerosol spray, pumpspray and fogger

Part II.- Second information level - meta SPC(s)

Meta SPC identifier: meta SPC

1. Meta SPC administrative information

1.1. Product type(s)

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

BAS number	EC number	CAS number	Common name	IUPAC name	Function	Content (%)
61	429-800-1	95737-68-1	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	Active Substance	0.0063 - 0.08 %
1342	258-067-9	52645-53-1	Permethrin		Active Substance	0.017 - 0.11 %
-	200-661-7	67-63-0	Isopropyl alcohol	Propan-2-ol	Solvent	0 - 30.9543 %
-		107-83-5	Isohexane	2-Méthylpentane	Solvent	

203-523-4					0 - 95.3267 %
- 200-662-2	67-64-1	Acetone	Propan-2-one	Solvent	0 - 20 %
-		Hallcomid M-8-10 (Mixture of N,N-dimethyldecanamide (38-50) and N,N-dimethyloctanamide (50-65))	N,N-dimethyldecanamide, CAS number: 14433-76-2, EC nr: 238-405-1 N,N-dimethyloctanamide, CAS number: 1118-92-9, EC nr: 214-272-5	Surfactant	0.05 - 0.0655 %
- 205-470-2	61791-12-6	Cremophor EL	Ethoxylated castor oil	Surfactant	0 - 5.2576 %
- 231-791-2	7732-18-5	Purified water	Water	Solvent/diluent	0 - 63.708 %
- 613-156-5	63148-62-9	Dimeticone	poly(dimethylsiloxane)	Anti-foam	0 - 0.1 %
- 204-696-9	124-38-9	CO2	Carbon dioxide	Proppellant gas	0 - 7.2 %

2.2. Type(s) of formulation of the meta SPC

Aerosol spray, pumpspray and fogger

3. Hazard and precautionary statements of the meta SPC

Hazard statements Extremely flammable aerosol.
Flammable liquid and vapour.

Causes skin irritation.
May cause drowsiness or dizziness.
Causes serious eye irritation.
Very toxic to aquatic life with long lasting effects.
Toxic to aquatic life with long lasting effects.
Contains *Permethrin (iso)*. May produce an allergic reaction.

Precautionary statements If medical advice is needed, have product container or label at hand.
Keep out of reach of children.

Read carefully and follow all instructions.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Use only outdoors or in a well-ventilated area.
Avoid release to the environment.
Store in accordance with *away from food, drink and animal feedingstuff*.
Store locked up.
Protect from sunlight. Do not expose at temperatures exceeding 50 °C/122 °F.
Dispose of *container to in accordance with national regulations*.
Avoid breathing *spray*.
Wash with *soap and water* thoroughly after handling.
Call a *POISON CENTER* if you feel unwell.
Store in a well-ventilated place. Keep container tightly closed.
Do not eat, drink or smoke when using this product.

4. Authorised use(s) of the meta SPC

4.1. Aerosol Spray 630.06

Product type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)		
Where relevant, an exact description of the authorised use	Indorex spray contains a combination of permethrin and pyriproxyfen. Permethrin is an insecticide and acaricide which effectively and quickly kills adult fleas and house dust mites present in the pet's environment. Pyriproxyfen is a long lasting Insect Growth Regulator that prevent re-infestations by inhibiting the development from immature stages to adults of fleas and house dust mites.		
	Control of existing infestation: Kills fleas and dust mites Knockdown effect on fleas within 30 minutes. Inhibits the development of eggs and immature stages of fleas and dust mites		
	Control of new infestations: Kills fleas for up to 21 days on carpet and 2 months on nonporous surfaces. Inhibits the development of flea eggs and larvae to adults for up to 12 months. Inhibits the development of dust mite colonies for up to 12 months		
Field(s) of use	Indoor		
	The product is for indoor use of spot treatment of infested hard and soft surfaces.		
Category(ies) of users	General public (non-professional)		
Target organisms	Scientific name	Common name	Development stage
	Ctenocephalides felis	Cat flea	Adults, larvae and eggs
	Dermatophagoides farinae	House dust mites	Adults, larvae and eggs
Application method(s)			
Method	Spraying		
Description	Spray application for spot treatment		
Rate: pyriproxyfen/ m ² .	2.5 second burst per meter strip. The discharge rate is 1.35g/ second, which is equivalent to approximately 4mg permethrin /m ² and 1.5 mg of		
Dilution:	0%		
Timing:	Ready to use product. Apply 2.5 second burst per meter strip. In case of new infestation, apply the product with a minimum of one or two months between applications and a maximum of 6 times a year, depending on the surface to be treated.		
Pack sizes and packaging material	Aerosol can, pre-pressurised tin plate can , 250 ml Aerosol can, pre-pressurised tin plate can , 500 ml		

Pre-pressurised tin plate can.

4.1.1. Use-specific instructions for use

Read all precautions before use. Do not use for any purpose other than the one for which intended.

Before spraying: Keep children away from the treated area. Ensure all windows and doors are closed before treating your home. Clean and vacuum all floors and upholstered furniture. If you need to wash the surface to be treated, it is advised to do so before applying the product as washing soon after treatment may reduce the product efficacy. Remove pets but ensure pet's bedding is treated. Remove birds and either remove or cover fish tanks, aquariums and all water storage tanks. Stop the pumps and filters of the aquarium and fish tanks. Cover or confine thoroughly food, food preparation equipment and eating utensils prior to the application.

Directions for spraying: Shake well before use. Hold vertical and use by spraying directly 40cm from surface to be treated. Pulverise by short pressure, without prolonged pulverisation. The product can be used in domestic premises on hard and soft furnishings/surfaces. Spray directly on (and if possible under) carpets and rugs, blankets, pets beddings, skirting boards.. Pay particular attention to cracks and crevices. Test on an out-of-site area before full application. Avoid wetting furniture and do not over-apply to polished wood surfaces.

Once you have sprayed: Leave the room. Wait 3.5 hours before entering the room and ventilate the room for half an hour.

4.1.2. Use-specific risk mitigation measures

Asthma sufferers are at particular risk. Asthma sufferers and sensitive people (e.g. allergy sufferers or those with multiple chemical sensitivity) should not use the preparation.

When using do not eat and drink or smoke.

All sources of naked flames (including pilot lights) should be extinguished before spraying.

Do not spray on electrical equipment or any incandescent material.

Avoid skin contact.

Wash hands after use.

Do not inhale aerosol.

Do not handle treated surfaces until dry.

If on skin, remove contaminated clothing and wash affected areas with soap and water.

Get medical advice if irritation occurs and show this container or label.

Wash contaminated clothes before reuse.

If inhaled and/or if you feel unwell, go to fresh air and call a poison centre or seek medical advice immediately and show this container or label.

The product can be safely used up to 6 times a year.

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

Do not use directly on animals or plants.

Toxic to aquatic life (fish, crustacean etc).

Do not spray in area containing non protected aquaria, fish and bowls.

Do not empty into drains.

Keep away from food, drink and feedstuffs.

Cover or confine food, food-preparing equipment and surfaces before spraying.

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

Dispose of container in accordance with local and national regulations.

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

The product can be used during 24 months under normal conditions of storage.

4.2. Pumpspray 630.07

Product type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)		
Where relevant, an exact description of the authorised use	Indorex pumpspray contains a combination of permethrin and pyriproxyfen. Permethrin is an insecticide and acaricide which effectively and quickly kills adult fleas and house dust mites present in the pet's environment. Pyriproxyfen is a long lasting Insect Growth Regulator that prevent re-infestations by inhibiting the development from immature stages to adults of fleas and house dust mites.		
	Control of existing infestation: Kills fleas and dust mites. Knockdown effect on fleas within 30 minutes. Inhibits the development of eggs and immature stages of fleas and dust mites.		
	Control of new infestations: Kills fleas for up to 2 months. Inhibits the development of flea eggs and larvae to adults for up to 12 months. Inhibits the development of dust mite colonies for up to 12 months.		
Field(s) of use	Indoor		
	The product is for indoor use of spot treatment of infested hard and soft surfaces.		
Category(ies) of users	General public (non-professional)		
Target organisms	Scientific name	Common name	Development stage
	Ctenocephalides felis	Cat flea	Adults, larvae and eggs
	Dermatophagoides farinae	House dust mites	Adults, larvae and eggs
Application method(s)			
Method	Manually triggered pumpspraying		
Description	Spray application for spot treatment		
Rate:	Apply 4 pumps to treat a surface of approximately 25cm by one meter which is equivalent to 4mg permethrin/m ² and 1.5mg of pyriproxyfen/ m ² .		
Dilution:	0%		
Timing:	Ready-to-use product.		
	Apply 4 pumps to treat a surface of approximately 25cm by one meter.		
	In case of new infestation, apply the product with a minimum of two months between applications.		
Pack sizes and packaging material	Pumpspray, PEHD bottles , 500 ml		
	PEHD bottle containing 500 ml solution		

4.2.1. Use-specific instructions for use

Read all precautions before use. Do not use for any purpose other than the one for which intended.

Before spraying: Keep children away from the treated area. Ensure all windows and doors are closed before treating your home. Clean and vacuum all floors and upholstered furniture. If you need to wash the surface to be treated, it is advised to do so before applying the product as washing soon after treatment may reduce the product efficacy. Remove pets but ensure pet's bedding is treated. Remove birds and either remove or cover fish tanks, aquariums and all water storage tanks. Stop the pumps and filters of the aquarium and fish tanks. Cover or confine thoroughly food, food preparation equipment and eating utensils prior to the application.

Directions for spraying: Shake well before use. Hold vertical and use by spraying directly 30cm from surface to be treated. The product can be used in domestic premises on hard and soft furnishings/surfaces. Spray directly on (and if possible under) carpets and rugs, blankets, pets beddings, skirting boards. Pay particular attention to cracks and crevices. Test on an out-of-site area before full application. Avoid wetting furniture and do not over-apply to polished wood surfaces.

Once you have sprayed: Leave the room. Wait two hours before entering the room and ventilate for half an hour.

4.2.2. Use-specific risk mitigation measures

Asthma sufferers are at particular risk. Asthma sufferers and sensitive people (e.g. allergy sufferers or those with multiple chemical sensitivity) should not use the preparation.

When using do not eat and drink or smoke.

Use only in well-ventilated areas.

All sources of naked flames (including pilot lights) should be extinguished before spraying.

Avoid eye contact.

Do not spray on or near naked flames.

Do not handle treated surfaces until dry.

If in eyes, flush with plenty of clear water.

Get medical advice if irritation persists and show this container or label.

If swallowed, call a poison centre or seek medical advice immediately and show this container or label.

If inhaled and/or if you feel unwell, go to fresh air and call a poison centre or seek medical advice immediately and show this container or label. T

The product can be safely used up to 6 times a year.

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

Do not use directly on animals or plants.

Toxic to aquatic organisms (fish and crustaceans).

Do not spray in area containing non protected aquaria, fish and bowls.

Do not empty into drains.

Avoid release to the environment.

Keep away from food, drink and feedstuffs.

Cover or confine food, food-preparing equipment and surfaces before spraying.

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

Dispose of container in accordance with local and national regulations

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

Store below 30°C. The product can be used during 24 months under normal conditions of storage.

4.3. Fogger 630.08

Product type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indorex fogger contains a combination of permethrin and pyriproxyfen. Indorex fogger is particularly adapted to control extended infestations. Permethrin is an insecticide and acaricide which effectively and quickly kills adult fleas and house dust mites present in the pet's environment. Pyriproxyfen is a long lasting Insect Growth Regulator that prevent re-infestation by inhibiting the development from immature stages to adults of

fleas and house dust mites.
 Control of existing infestation: Kills fleas and dust mites Knockdown effect on fleas within 2 hours. Inhibits the development of eggs and immature stages of fleas and dust mites.
 Control of new infestations: Kills fleas for 5 days on carpet and up to 1,5 months on nonporous surfaces. Inhibits the development of flea eggs and larvae to adults for up to 12 months.
 Inhibits the development of dust mites colonies for up to 12 months.

Field(s) of use	Indoor		
	The product is for indoor use for treatment of general surfaces/whole rooms.		
Category(ies) of users	General public (non-professional)		
Target organisms	Scientific name	Common name	Development stage
	Ctenocephalides felis	Cat flea	Adults, larvae and eggs
	Dermatophagoides farinae	House dust mites	Adults, larvae and eggs
Application method(s)			
Method	Fogging		
Description	Fogger generation for surface treatment		
Rate:	75ml and 150ml foggers treat respectively 30m ² and 60m ² floor surfaces, which is equivalent to 2mg permethrin /m ² and 1.5 mg of pyriproxyfen/ m ² .		
Dilution:	0%		
Timing:	Maximum two times a year.		
Pack sizes and packaging material	Aerosol can, pressurised tin plate can , 75 ml Aerosol can, pressurised tin plate can , 150 ml		

Pressurised tin plate cans containing 75ml or 150 ml solution

4.3.1. Use-specific instructions for use

Read all precautions before use. Do not use for any purpose other than the one for which intended.

Before spraying: Ensure all windows and external doors are closed before treating your home, but open the internal doors. Clean and vacuum all floors and upholstery or remove furniture from the room to ensure a better spread and coverage of the actives ingredients. If you need to wash the surface to be treated, it is advised to do so before applying the product as washing soon after treatment may reduce the product efficacy. Get the children and pets out but ensure pet's bedding is treated. Remove birds and either remove or cover thoroughly fish tanks, aquariums and all water storage tanks. Stop the pumps and filters of the aquarium and fish tanks. Cover or confine thoroughly food, food preparation equipment and eating utensils prior to the application. Do not use in kitchen.

Directions for spraying: Shake well before use. Elevate the fogger at a height comprised between 40 to 80 cm from the floor and place it in the center of the room to be treated. To start the product diffusion, press the valve and release: the product comes out of the can automatically.

Once you have released the fogger: Leave the room IMMEDIATELY and wait three hours before ventilating the treated area for half an hour.

4.3.2. Use-specific risk mitigation measures

Asthma sufferers are at particular risk. Asthma sufferers and sensitive people (e.g. allergy sufferers or those with multiple chemical sensitivity) should not use the preparation.

When using do not eat and drink or smoke.

All sources of naked flames (including pilot lights) should be extinguished before fogger activation.

Avoid skin and eye contact.

Do not inhale aerosol.

Do not handle treated surfaces until dry.

Wash hands and exposed skin after use.

If in eyes, flush with plenty of clear water.

If on skin, remove contaminated clothing and wash affected areas with soap and water.

Wash contaminated clothes before reuse.

Get medical advice if irritation occurs and persists and show this container or label.

If swallowed, seek medical advice immediately and show this container or label.

If inhaled and/or if you feel unwell, go to fresh air and call a poison centre or seek medical advice immediately and show this container or label.

The product can be safely used up to 2 times a year

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

Do not use directly on animals or plants.

Toxic to fish and crustaceans.

Do not spray in area containing non protected aquaria, fish and bowls.

Do not empty into drains.

Avoid release to the environment.

Keep away from food, drink and feedstuffs.

Cover or confine food, food-preparing equipment and surfaces before spraying.

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

Dispose of container in accordance with local and national regulations.

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

The product can be used during 24 months under normal conditions of storage.

5. General directions for use of the meta SPC

5.1. Instructions for use

Indorex

Read all precautions before use. Do not use for any purpose other than the one for which intended.

5.2. Risk mitigation measures

Indorex

See section 4.1.2, 4.2.2 and 4.3.2

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

Indorex

Do not use directly on animals or plants.

Toxic to fish and crustaceans.

Do not spray in area containing non protected aquaria, fish and bowls.

Do not empty into drains.

Avoid release to the environment.

Keep away from food, drink and feedstuffs.

Cover or confine food, food-preparing equipment and surfaces before spraying.

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

Indorex

Dispose of container in accordance with local and national regulations

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

Indorex

The product can be used during 24 months under normal conditions of storage.

The pumpspray must be stored below 30°C.

6. Other information

INDOREX, GB
 INDOREX, FR
 INDOREX, IE
 INDOREX, DE
 INDOREX, AT
 INDOREX, ES
 INDOREX, IT
 INDOREX, PT
 INDOREX, GR
 INDOREX, PL
 INDOREX, HU
 INDOREX, CZ
 INDOREX, SK
 INDOREX, RO
 INDOREX, EE
 INDOREX, LT
 INDOREX, LV
 INDOREX, CH

7. Third information level: individual products in the meta SPC**7.1. Product****7.1.1. Trade names of the product****7.1.3. Qualitative and quantitative information on the composition of the product**

BAS number	EC number	CAS number	Common name	IUPAC name	Function	Content (%)
61	429-800-1	95737-68-1	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2- pyridyloxy)propyl ether	Active Substance	
1342	258-067-9	52645-53-1	Permethrin		Active Substance	
-	200-661-7	67-63-0	Isopropyl alcohol	Propan-2-ol	Solvent	
-	203-523-4	107-83-5	Isohexane	2-Méthylpentane	Solvent	
-	200-662-2	67-64-1	Acetone	Propan-2-one	Solvent	
-			Hallcomid M-8-10 (Mixture of N,N-dimethyldecanamide (38-50) and N,N-dimethyloctanamide (50-65))	N,N-dimethyldecanamide, CAS number: 14433-76-2, EC nr: 238-405-1 N,N-dimethyloctanamide, CAS number: 1118-92-9, EC nr: 214-272-5	Surfactant	
-	205-470-2	61791-12-6	Cremophor EL	Ethoxylated castor oil	Surfactant	
-	231-791-2	7732-18-5	Purified water	Water	Solvent/diluent	
-	613-156-5	63148-62-9	Dimeticone	poly(dimethylsiloxane)	Anti-foam	
-	204-696-9	124-38-9	CO2	Carbon dioxide	Proppellant gas	

Allegato I SPC

Allegato II - Ulteriori Condizioni dell'Autorizzazione

ETICHETTATURA

- L'etichetta del prodotto biocida oggetto della presente autorizzazione dovrà essere redatta nel rispetto delle disposizioni di cui all'articolo 69 del Regolamento (UE) n.528/2012 riportando le informazioni di cui al sommario delle caratteristiche del prodotto riportato in Allegato I.
- Tutte le etichette del prodotto biocida devono riportare il numero di autorizzazione attribuito dal presente decreto, con la seguente dicitura:

“PRODOTTO BIOCIDA (PT 18)

AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2020/00 622 /MRP”

- Per ogni categoria di utilizzatore autorizzata (Professionisti/ Professionisti formati/ Utilizzatori non professionisti) deve essere predisposta una etichetta distinta.
- L'etichetta dovrà contenere l'indicazione dell'officina di produzione e sito produttivo del formulato autorizzato.
- Nell'etichetta l'esatta denominazione del biocida dovrà comunque essere individuabile attraverso una colorazione e un carattere unici in contrasto con le altre eventuali colorazioni e caratteri usati nel testo degli stampati autorizzati.
- L'etichetta del prodotto non contiene le formule «biocida a basso rischio», «non tossico», «innocuo», «naturale», «rispettoso dell'ambiente», «rispettoso degli animali» o indicazioni analoghe comportanti una sottovalutazione degli effetti potenziali del prodotto da parte dell'utilizzatore e non devono riportare indicazioni riferite al prodotto che possano generare confusione per quanto concerne i rischi che il prodotto comporta per l'uomo o l'ambiente.

E' consentita l'immissione sul mercato dei biocidi a condizione che le indicazioni dell'etichetta siano redatte in lingua italiana.