



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO
FARMACEUTICO

Ufficio VII ex DGFDM – Prodotti di interesse sanitario diversi dai dispositivi medici
Viale Giorgio Ribotta, 5 - 00144 Roma

Ministero della Salute

DGDFSC

0001387-P-14/01/2015



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I.5.i.d.2/301

Spett.le
Cisa Adriatica S.a.s.
Viale della Libertà, 4
65010 Moscufo (PE)

OGGETTO: Prodotto biocida **BROMIOL ESCA PASTA** –
Trasmissione del decreto di modifica tecnica minore.

Si trasmette, in allegato, il decreto di modifica tecnica minore dell'autorizzazione, relativa all'immissione in commercio del biocida indicato in oggetto **reg.n.IT/2013/00128/AUT** del

13 GEN. 2015

IL DIRETTORE DELL'UFFICIO VII
Dr.ssa Paola D'Alessandro

Referente tecnico: R.Perrone 06.59942520
email: r.perrone@sanita.it

Referente amministrativo: N.D'Amico – 06.59943806
email: n.damico@sanita.it



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO VII ex DGFDM - PRODOTTI DI INTERESSE SANITARIO DIVERSI DAI DISPOSITIVI MEDICI
D.G.D.F.S.C./I.5.i.d.2/2015/301

IT/2013/00128/AUT

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IL DIRETTORE

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 dei biocidi;

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 di esecuzione del 18 aprile 2013 n.354/2013 recante il Regolamento sulle modifiche dei biocidi autorizzati a norma del Regolamento (UE) n.528/2012 del Parlamento Europeo e del Consiglio;

VISTA la direttiva 2009/92/CE della Commissione del 01 Agosto 2009 recante modifica della direttiva 98/8/CE del Parlamento europeo e del Consiglio al fine di iscrivere il **BROMADIOLONE** come principio attivo nell'allegato I della direttiva;

VISTO il D.M. del 14 Aprile 2011, recante ad oggetto "Attuazione della direttiva 2009/92/CE., recante modifica della direttiva 98/8/CE del Parlamento europeo e del Consiglio del 16 febbraio 1998, relativa all'immissione sul mercato dei biocidi al fine di procedere all'inclusione della sostanza attiva **BROMADIOLONE** nell'allegato I della direttiva";

VISTO il decreto datato 07 agosto 2013 n.IT/2013/00128/AUT con il quale questa amministrazione ha autorizzato l'immissione in commercio del prodotto biocida denominato **BROMIOL ESCA PASTA** - esca rodenticida pronta all'uso in pasta fresca, per uso professionale e non professionale con validità fino a 24 mesi - prodotto presso le officine: Ferbi S.r.l. Mosciano S. Angelo (TE), Labiofarma Società Cooperativa Aprilia (LT), I.N.D.I.A. Industrie Chimiche S.p.A. (PD), Industrialchimica S.r.l. - Arre (PD) e l'officina Vebi Istituto Biochimico S.r.l. Borgoricco (PD);

ATTESO che la titolarità del biocida predetto è attualmente attribuita alla società **CISA ADRIATICA S.a.s.** con sede legale in Viale della Libertà, 4 - 65010 Moscufo (PE) - Codice Fiscale 00455450684;

VISTA l'istanza registrata sul Registro Europeo R4BP3 - case number: BC-JS009490-29 e la nota acquisita al prot.0078815 del 11/11/2014 con cui la Società **CISA ADRIATICA S.a.s.** ha chiesto la modifica tecnica minore all'autorizzazione, relativa alla composizione del prodotto, riguardo le sostanze non attive: aggiunta di aroma alla vaniglia;

VISTA la documentazione presentata dalla società istante a sostegno della suddetta istanza di modifica dell'autorizzazione;

RITENUTA espletata l'istruttoria effettuata dall'Ufficio competente, operante presso la Direzione Generale dei Dispositivi Medici e del Servizio Farmaceutico del Ministero della Salute;

DECRETA:

La Società **CISA ADRIATICA S.a.s.** con sede legale in Viale della Libertà, 4 - 65010 Moscufo (PE) - Codice Fiscale 00455450684 in qualità di titolare della registrazione n. IT/2013/00128/AUT



relativa al prodotto biocida **BROMIOL ESCA PASTA** è autorizzata alla modifica tecnica minore relativa a sostanze non attive (**allegato 1** - Summary of Product Characteristics).

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.

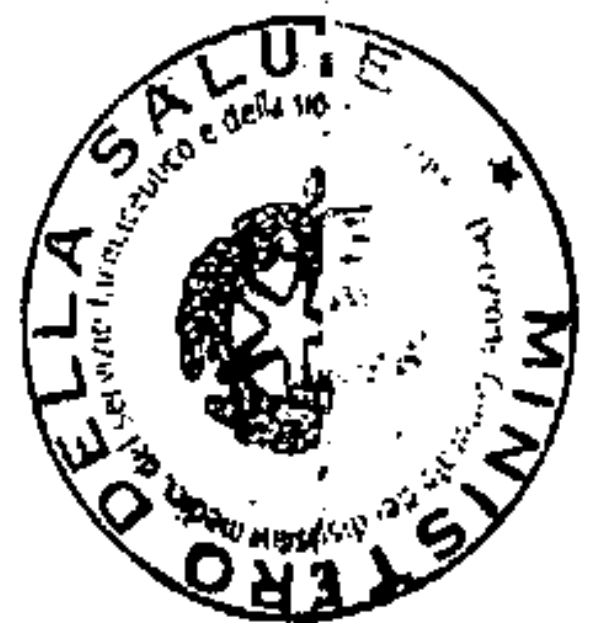
Roma, li **13 GEN. 2015**



IL DIRETTORE UFFICIO VII
Dr.ssa Paola D' Alessandro



RP/ND



Italy Bromiol esca pasta
 Ferbi S.r.l. Viale 1° Maggio - Contrada Ripoli 64023 Mosciano Sant'Angelo Italy Viale 1° Maggio - Contrada Ripoli 64023 Mosciano Sant'Angelo Italy
 LABIOFARMA SOCIETA' COOPERATIVA Via Nettunense Km 23,40004011 Aprilia Italy Via Nettunense Km 23,40004011 Aprilia Italy
 I.N.D.I.A. INDUSTRIE CHIMICHE S.p.a. Nona Strada 53/5735100 Padova Italy Nona Strada 53/5735100 Padova Italy
 INDUSTRIALCHIMICA S.r.l. Via Sorgaglia 2535020 Arre Italy Via Sorgaglia 2535020 Arre Italy
 VEBI ISTITUTO BIOCHIMICO S.r.l. Via Desman 4335010S. Eufemia di Borgoricco Italy Via Desman 4335010S. Eufemia di Borgoricco Italy
 Dr Tezza S.r.l. Via tre ponti, 2287050 Santa Maria de Zevio (VR) Italy Via tre ponti, 2287050 Santa Maria de Zevio (VR) Italy
 12249-205-928772-56-7 Bromadiolone 3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one Active Substance 0.005203-049-8102-71-6 Triethanol amine Triethanol amine (2,2,2-nitrioltriethanol) Emulsifier 0.3500-038-225322-68-3 Polyethylene glycol 200 Poly(oxy-1,2-ethanediy) Solvent 0.15200-338-057-55-6 Propylene glycol 1,2-Propanediol Emulsifier 1.85
 PA - Paste
 No classification
 Keep out of reach of children.
 Read label before use.
 Keep only in original container.
 Do not breathe *dust*.
 Do not get in eyes, on skin, or on clothing.
 Do not eat, drink or smoke when using this product.
 Avoid release to the environment.
 Get medical *advice* if you feel unwell.
 Dispose of *container* to in accordance with local/regional/national/international regulation.
 IF SWALLOWED:
 Immediately call a *POISON CENTER*.

Use in and around buildings

PT14 - Rodenticides (Pest control) Use in and around buildings Indoor/Indoor/Industrial Trained professional/Professional/General public (non-professional) Mus musculus House mouse Adults Rattus rattus Roof rat Adults Rattus norvegicus Brown rat Adults

In bait boxes Baits shall be placed in bait boxes Rats: 60-100g of pasta bait per 100m² of infested area; Mice: 40 g of pasta bait per 100m² of infested area 100 Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.

Sachet Paper, cardboard 20g
 For non-professional use packs with 40-100-160-200-260-300-400-500g For professional use packs with 1-2-3-5-10-20-25Kg

BROMIOL ESCA PASTA is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. The number of bait points employed is dependent on: the treatment site; the size and severity of the infestation; the user; and the user requirements and needs. Inspect and resupply the bait stations once a week as long as the bait is consumed. Remove all bait points after the end of treatment. The amount of bait per bait point and distances between bait points must be respected. Products have always to be used in accordance with the label.

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

The active ingredient in the form of bait may be palatable to humans and non-target species in sufficient quantity to produce toxic effects. Effects result from the inhibition of blood coagulation as Bromadiolone interacts with vitamine K1 inducing hemorrhages over the course of several days. If large quantity are ingested, induce vomiting, perform gastric lavage and monitor prothrombine activity. Note to doctor: the product BROMIOL ESCA PASTA contains an anticoagulant-rodenticide, treatment with vitamin K1 could be needed for a long time. Emergency measures to protect the environment: In case of accidental contamination, avoid spreading in house drains, rainy waters and environment. In case of a release had already occurred, the competent authority has to be warned.

Always read the label before use and follow the instruction provided. Keep out of reach of children. Keep away from food, drink and animal feeding stuff. Avoid contact with skin. If swallowed, seek medical advice immediately (show the label when possible). Do not smoke, eat or drink while handling this product. Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals. Bait boxes must be placed in areas inaccessible to children, companion animals and non-target animals. Bait boxes must always be clearly labelled "Do Not Touch" and warn of the contents. In public areas (such as business premises, schools, hospitals etc) it must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product and dead rodents.
 Store away from light. Keep container tightly closed in fresh and dry places. Keep out of the reach of

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children. Keep away from food, drink and animal foodstuffs. Store in the original container. The product could be conserved 24 months since the manufacturing date. To be indicated on bait stations: Keep out of the reach of children. Keep away from food, drink and animal foodstuffs.

use in open areas

PT14 - Rodenticides (Pest control) use in open areas Outdoor outdoor Industrial Trained professional Professional General public (non-professional) Mus musculus House mouse Adults Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Adults

In bait boxes Baits shall be placed in bait boxes Rats: 60-100g of pasta bait per 100m² of infested area; Mice: 40 g of pasta bait per 100m² of infested area 100 Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.

Sachet Paper, cardboard 20g

For non-professional use packs with 40-100-160-200-260-300-400-500g For professional use packs with 1-2-3-5-10-20-25Kg

BROMIOL ESCA PASTA is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. The number of bait points employed is dependent on: the treatment site; the size and severity of the infestation; the user; and the user requirements and needs. Inspect and resupply the bait stations once a week as long as the bait is consumed. Remove all bait points after the end of treatment. The amount of bait per bait point and distances between bait points must be respected. Products have always to be used in accordance with the label.

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