

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Clothianidin RB 1

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number: 18-620

R4BP asset number: DK-0015766-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	MAXFORCE PLATIN
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Bayer A/S
	Address	Arne Jacobsen Alle 13 2300 Copenhagen S Denmark
Authorisation number	18-620	
<i>R4BP asset number</i>	DK-0015766-0000	
Date of the authorisation	23/07/2019	
Expiry date of the authorisation	15/10/2024	

1.3. Manufacturer(s) of the product

Name of manufacturer	Bayer S.A.S.- Division Crop Science
Address of manufacturer	16 rue Jean-Marie Leclair 69266 Lyon Cedex 09 France
Location of manufacturing sites	Bayer SAS - Division Crop Science - Site Marle, Z.I. Antoine Laurent de Lavoisier F-02250 Marle-sur-Serre France Norbert/ Jacobson Co.—3060 Southpark Blvd 30294 Ellenwood, Georgia United States (the)

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

Active substance	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3- methyl-2-n itroguanidine (Clothianidin)
Name of manufacturer	Bayer AG
Address of manufacturer	Alfred-Nobel-Str. 50 40789 Monheim am Rhein Germany
Location of manufacturing sites	Bayer AG - Chempark 41538 Dormagen Germany

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 (%)
(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin)		active substance	210880-92-5	433-460-1	1,026 % (w/w)

2.2. Type(s) of formulation

RB - Bait (ready for use) - gel

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H410: Very toxic to aquatic life with long lasting effects. EUH208: Contains 1,2-Benzisothiazolin-3-one, 5-chloro-2-methyl-isothiazol-3-one/2-methyl-isothiazol-3-one. May produce an allergic reaction.
Precautionary statements	P501: Dispose of contents to in accordance with local regulations. P273: Avoid release to the environment. P391: Collect spillage.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Ready to use insecticidal gel bait for the control of cockroach nymphs and adults and grey silverfishes.

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: <i>Periplaneta americana</i> Common name: American Cockroach Development stage: nymphs and adults Scientific name: <i>Blatta orientalis</i> Common name: Oriental Cockroach Development stage: nymphs and adults Scientific name: <i>Blattella germanica</i> Common name: German cockroach Development stage: nymphs and adults Scientific name: <i>Ctenolepisma longicaudatum</i> Common name: Grey silverfishes Development stage: mixed aged population
Field(s) of use	indoor use A ready to use insecticidal gel bait for the control of cockroach nymphs and adults. For use in : • Domestic premises • Food Handling / Storage premises • Public buildings • Small Scale Animal Housing i.e. zoos, pet shops, kennels, veterinary practices, laboratory animal houses etc. (only building, feed handling and storage premises, excluding stables, animal pens and cages where animals are located).
Application method(s)	Method: bait application Detailed description: The biocidal product is dispensed using a suitable gel applicator or a syringe.
Application rate(s) and frequency	Application rate: 0.1 - 0.3 g /m ² Dilution (%): 0 Number and timing of application: The application rate is adjusted to the density of the infestation and the type of cockroach found: 1) Against small cockroaches i.e. nymph and adult German cockroaches (<i>Blattella germanica</i>) : • at 0,1 g/m ² (moderate infestation i.e. German cockroaches rarely visible during the day). • at 0,2 g/m ² (severe infestation i.e. German cockroaches commonly visible during the day) using 2 spots of 0,1 g/m ² .

	<p>The gel baits must stay in place at least 14 days for optimal efficacy. One month after, new fresh gel baits can be reapplied if cockroaches are still visible.</p> <p>2) Against large cockroaches i.e. nymph and adult oriental cockroaches (<i>Blatta orientalis</i>) at 0,2 g/m² using 2 spots of 0,1 g/m².</p> <p>The gel baits must stay in place at least 4 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.</p> <p>3) Against nymph and adult American cockroaches (<i>Periplaneta americana</i>) at 0,2 g/m² or at 0,3 g/m² using 2 or 3 spots of 0,1 g/m² respectively.</p> <p>The gel baits must stay in place at least 12 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.</p> <p>4) Against grey silverfishes (<i>Ctenolepisma longicaudatum</i>) at 0,1422 g/m².</p> <p>The gel baits must stay in place at least 8 weeks for optimal efficacy. If grey silverfishes are still visible, new fresh gel baits can be reapplied.</p> <p>Do not apply more than once a month.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>cartridge and syringe, Plastic: PE , 10 - 30 g</p> <p>end cap provided (applicator can be re-sealed; piston is delivered with application cannulas, comprised in commercial packs (PP))</p>

4.1.1. Use-specific instructions

please refer to sections 5.1 and 6

4.1.2. Use-specific risk mitigation measures

please refer to 5.2

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

please refer to 5.3

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

please refer to 5.4

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

please refer to 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- The biocidal product (b.p.) is dispensed using a suitable gel applicator. When the treatment has been completed remove the empty cartridge and dispose of safely. If the cartridge is only partially used, remove it from the applicator, seal it with the end cap provided and store as directed.
- Before treatment, the professional users must survey the area to be treated in order to identify sites of cockroach and grey silverfish infestation e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc ...
- For maximum effectiveness the b.p. must be placed in and around cockroach harbourages and, if possible, between these areas and food sources.

In addition, for an optimal effectiveness, all natural source of food palatable for cockroach must be removed from the infested area to encourage the ingestion of the bait.

The biocidal product is to be placed as spot treatment in the vicinity of corners, cracks and crevices (e.g. behind or under equipment and furniture like counters, refrigerators, cookers, sinks, baths etc.), voids, service-ducts, lift shafts, pipework,

The b.p. is particularly valuable in sensitive areas where the use of conventional insecticide formulations is restricted e.g. in the vicinity of electric and electronic equipment etc. Where immigration of cockroaches has been identified, placement of additional bait in peripheral areas of the site will aid control. Apply the b.p. directly as spots or thin ribbons to surfaces in identified target areas. It should be placed out of sight and where light intensity is low. Place the bait spots in places inaccessible for children or pets. Avoid application to excessively dusty, damp or greasy locations. Do not apply in areas subject to wet cleaning. Do not apply to areas that have recently been treated with other insecticides or contaminate the bait with other insecticides.

An effect on the cockroach population can be expected very quickly with dead cockroaches evident within 24 hours of treatment. Maximum levels of control are achieved between six days and 2 months after treatment depending upon the level of infestation and as long as the gel is present. Where infestations are high, inspect the applied spots of the b.p. regularly (once a month) and make further applications as required. However do not apply more than once a month.

For use against grey silverfish: Place many small drops in areas where grey silverfish hide and live. These areas may be under/behind base/skirting boards, under wooden facing or other areas that provide cover.

Not for maintenance usage.

Do not apply in animal pens and cages.

Removal of old baits/gel spots has to be done by a professional pest control operator.

READ ALL PRECAUTIONS BEFORE USE

INFORM THE REGISTRATION HOLDER IF THE TREATMENT IS INEFFECTIVE

DO NOT APPLY ON ABSORBENT SURFACES

DO NOT EXPOSE BAIT DROPS TO SUNLIGHT OR HEAT SOURCES

PROTECT FROM RAIN

5.2. Risk mitigation measures

- Avoid application to excessively dusty, damp or greasy locations. Only apply in areas not subjected to wet-cleaning. Pay particular attention to cracks and crevices and other entry points usually used by insects, as well as areas behind or under machinery, kitchen and bathroom equipment or pipework. The product can be placed in voids, service-ducts, lift shafts, electric and electronic equipment, etc.”

Not intended for uses in stables, pens or cages for animals. Not recommended for use in insectivorous birds and reptiles' facilities.

- Keep out of the reach of children.
- Wear suitable protective gloves when the product is handled.
- Avoid contact with skin.
- Wash hands and exposed skin before meals and after use.
- Do not apply to surfaces on which food or feed is stored, prepared or eaten.

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

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- Use only in positions inaccessible to children and animals.
 - Do not attempt to open or refill cartridges.

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

General advice:

If significant amounts are spilled, the following advice is applicable. Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.

If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!

Skin contact: Wash off thoroughly with plenty of soap and water, subsequently rinse with water. If skin irritation /sensitization occurs, persists or intensifies seek medical advice.

Eye contact: Immediately flush eyes with plenty of lukewarm water. Check for and remove any contact lenses. Continue to rinse for at least 5 minutes. If symptoms persists, seek medical attention

Ingestion: Call a poison center or physician. Rinse mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink.”

Advice for medical and healthcare personnel:

Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER.

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

- Dispose of contents/container in accordance with local regulation.
- Unwanted gel can be removed when freshly applied by sponging with a 5% sodium chloride solution. Sponges/tissues used should be disposed of as solid waste.
- Aged gel can be removed with spatulas and disposed of as solid waste

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

Conditions of storage: Do not allow to freeze. Keep in a safe place.

Shelf life at ambient temperature: 2 years

6. OTHER INFORMATION

correct formulation of P501: Dispose contents/container in accordance with all local, national and international regulations.

Information: Some sensitive materials e.g. textiles may be stained by the product. If in doubt, apply to a small, inconspicuous area first.

The potential resistance of target insects to clothianidin could be of concern and, as such, resistance management measures should be included in the authorisation of products. These could include (but should not be restricted to) the following factors:

- Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.
- Products should always be used in accordance with label recommendations, in terms of dose to be applied and treatment intervals. The effective dose must be applied and no higher or lower doses.
- Treatments should be alternated with products with different modes of action, i.e. avoid rotating different neonicotinoids. It is advisable to avoid using Maxforce Platin exclusively and continuously as the sole agent for cockroach control. Maxforce Platin should be used as one component of an integrated pest management program which features gel formulations with different food bases, and products from alternative chemical classes with different application methods.
- Levels of effectiveness should be monitored (periodic checks), and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product with the same mode of action especially neonicotinoids should be avoided.
- If signs of resistance begin to appear (as indicated either by control failures or through the test procedure) then every effort should be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical measures.

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen[1].

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

- 1) I hovedfeltet:
”Insektmiddel

Må kun anvendes som insektmiddel til erhvervmæssig bekæmpelse af tysk, orientalsk og amerikansk kakerlak (*B. Germanica*, *B. Orientalis*, *P. Americana*) og skægget sølvkræ (*Ctenolepisma longicaudatum*). Må kun anvendes indendørs.

- 2) I advarselsfeltet:
” ADVARSEL

Meget giftig med langvarige virkninger for vandlevende organismer (H410)

Undgå udledning til miljøet.

Udslip opsamles.

Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som insektmiddel til erhvervsmæssig bekæmpelse af tysk, orientalsk og amerikansk kakerlak (*B. Germanica* , *B. Orientalis* , *P. Americana*) og skægget sølvkræ (*Ctenolepisma longicaudatum*). Må kun anvendes indendørs.

Må ikke anvendes i stalde, fjerkræhuse, væksthuse og lignende.

Må ikke anvendes på arealer der rengøres med vand.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Må ikke tømmes i kloakfløb.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Hyder, borde og andre flader, hvor levnedsmidler skal ligge eller opbevares, må ikke behandles og skal efter arbejdet omhyggeligt renses for eventuelle stænk og spild.”

Farepiktogrammet GHS09

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

- a) Teksten ”Insektmiddel BPR-reg. nr. 18-620. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.
- b) Oplysning om præparattype: ”gel” for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C
- d) Sætningen: ”Indeholder 1,2-benzisothiazolin-3-on (BIT) og 5-chloro-2-methyl-isothiazol-3-on/2-methyl-isothiazol-3-on (CMIT/MIT) kan udløse allergisk reaktion”.
- e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
- f) Batchnummer eller – betegnelse skal anføres.
- g) Pakningsstørrelse i L eller kg.
- h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: ”Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”

Derudover skal mærkningen ske efter retningslinjerne:

”Rester skal afleveres til den kommunale affaldsordning for farligt affald. Tomme beholdere kan bortskaffes med dagrenovationen.”