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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ADVION FLY GRANULAR

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number: 1-278

R4BP asset number: DK-0027191-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ADVION FLY GRANULAR BAIT Disparid Fly Granular Bait
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Syngenta Nordics A/S
	Address	Strandlodsvej 44 2300 København S Denmark
Authorisation number		1-278
<i>R4BP asset number</i>		DK-0027191-0000
Date of the authorisation		16/02/2022
Expiry date of the authorisation		14/09/2030

1.3. Manufacturer(s) of the product

Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Rosentalstrasse 67 CH-4058 Basel Switzerland
Location of manufacturing sites	SCHIRM, 2801 Oak Grove Road TX 75119 Ennis United States (the)

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

Active substance	Indoxacarb (enantiomeric reaction mass S:R 75:25)
Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Rosentalstrasse 67 CH-4058 Basel Switzerland
Location of manufacturing sites	FMC Corporation, Mobile Manufacturing Center, 12650 Highway 43 AL 36505 Axis United States (the)

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 (%)
Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl (S)- and methyl(R)-7- chloro- 2,3,4a,5- tetrahydro-2- [methoxycarbonyl- (4- trifluoromethoxyphenyl) carbamoyl] indeno[1,2- e][1,3,4] oxadiazine-4a- carboxylate (This entry covers the 75:25 reaction mass of the S and R enantiomers)	active substance			0,796
Potassium sorbate	Potassium (2E,4E)- hexa-2,4- dienoate	Non-active substance	24634-61-5	246-376-1	0,3
Silicon dioxide	Silicon dioxide	Non-active substance	112926-00-8	601-214-2	0,27

2.2. Type(s) of formulation

RB : ready to use grain bait

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P261: Avoid breathing dust. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P333+P313: If skin irritation or rash occurs: Get medical attention. P362+P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents to hazardous waste. P501: Dispose of container to hazardous waste. P321: Specific treatment (see ... on this label).

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Professional - Indoor in agricultural, livestock (except broilers), residential and commercial buildings

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	The granulated product is used as a bait treatment using only bait stations designed for use with granular fly control baits in agricultural, livestock (except broilers), residential and commercial buildings/structures.
Target organism(s) (including development stage)	Scientific name: <i>Musca domestica</i> Common name: house fly Development stage: adults Scientific name: Calliphoridae sp Common name: blow flies Development stage: adults
Field(s) of use	indoor use In agricultural or livestock (except broilers) sites/structures In residential and commercial sites/structures
Application method(s)	Method: bait application Detailed description: Placed into bait stations, indoors. Bait stations are placed off the ground on the walls or suspended.
Application rate(s) and frequency	Application rate: 40 g product per station, 1 bait station / 20 m ² (2 g/m ²). Dilution (%): 0.0 Number and timing of application: 40 g product per station, 1 bait station / 20 m ² (2 g/m ²). Treated areas should be re-inspected every week. If the bait has been totally consumed and there is still activity, a second application should be made.
Category(ies) of users	professional
Pack sizes and packaging material	ADVION FLY GRANULAR BAIT is supplied in loose. Loose baits are packed in: - HDPE bottle (1 L) - PP pail (5 L)

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4.1.1. Use-specific instructions

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4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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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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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- Always read the label or leaflet before use and respect all the instructions provided.
- Respect the recommended application doses.
- Avoid continuous use of products.
- In case of re-infestation, renew the application.
- Due to the mode of action of Indoxacarb, mortality of flies may be delayed within up to 72 hours.
- Do not use the product in areas where resistance to the active substance(s) contained in this product is suspected or established.
- Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- Check the efficacy of the product on site: if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.
- Inform the authorization holder if the treatment is ineffective.
- Place the bait in the bait station by using a graduated dosage device.
- Do not use the product in broilers houses.

5.2. Risk mitigation measures

- Bait stations that are specifically designed to prevent the release of granular baits, and any exposure of non-target animals, must be used.
- The product has to be placed out of reach of children.
- If there is a risk of access to bait stations from children, pets and non target animals a tamper resistant bait station must be used.
- Bait stations must be placed off the ground, attached on the wall or suspended.
- Simple or tamper resistant bait stations must be placed away from pathways and/or manure, out of reach from non-target animals and in areas protected from wet conditions.
- Do not clean the bait stations or the dosing aid with water.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) when handling and/or applying the product.
- Avoid contact with skin, eyes, contaminated tools and objects.
- Place the product away from food, drink and animal feeding stuffs as well as from utensils or surfaces that have contact with these.
- All bait stations must be removed before cleaning and/or disinfection of livestock, residential and commercial sites/structures.

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

- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- 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 warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- Inhalation of dust: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

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

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- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
 - Keep the container or label available.

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

- Dispose of unused product, its packaging and all other waste (exhausted bait stations, dead flies in and around the bait station), in accordance with local regulations.
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

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

- Store the product away from light.
- Shelf life: 2 years.

6. OTHER INFORMATION

- Implement a monitoring of scientific literature related to the resistance of the flies to the active substance Indoxacarb and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Provide an assessment of this monitoring at the renewal of the authorisation.
- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
- This product contains a bittering agent.

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.

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 mod stuefluer (*Musca domestica*) og spyfluer (*Calliphoridae sp*). Må kun anvendes indendørs. Kun til erhvervmæssig brug.”

2) I advarselsfeltet:

”ADVARSEL

Kan forårsage allergisk hudreaktion. (H317)

Skadelig for vandlevende organismer, med langvarige virkninger. (H412)

Undgå indånding af pulver.

Tilsmudset arbejdstøj bør ikke fjernes fra arbejdspladsen.

Undgå udledning til miljøet.

Bær kemisk resistente beskyttelseshandsker ved brug af produktet.” Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet.

”Undgå kontakt med hud og øjne.

Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som insektmiddel mod stuefluer (*Musca domestica*) og spyfluer (*Calliphoridae sp*). Må kun anvendes indendørs. Kun til erhvervmæssig brug.

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

På grund af risiko for forgiftning ved indtagelse, må produktet kun anvendes i områder, hvor børn, husdyr samt vilde dyr kan få adgang, hvis produktet anbringes i aflåste fluefoderstationer.

Fluefoderstationer skal hænges på vægge eller ophænges.

Fluefoderstationer skal placeres væk fra gangarealer og gødning, i områder beskyttet mod fugt.

Fluefoderstationer og målebægre må ikke rengøres med vand.

Alle fluefoderstationer skal fjernes før rengøring og/eller desinficering af husdyranlæg, landbrugs- og erhvervsbygninger samt i boliger.

Må ikke tømmes i kloakfløb.

Opbevares utilgængeligt for børn.

Må ikke opbevares i nærheden af fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Hylder, 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 GHS07

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

VED KONTAKT MED HUDEN: Vask med rigeligt sæbe og vand. Ved hudirritation eller udslæt: Søg lægehjælp.

Alt tilsmudset tøj tages af og vaskes inden genanvendelse.

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

3) I deklarationsfeltet:

- a) Teksten ”Insektmiddel BPR-reg. nr. 1-278. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (forordning (EU) nr. 528/2012)”.
- b) Oplysning om præparattype: ”granulat” for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/kg.
- d) Sætningen: ”Indeholder kaliumsorbat og siliciumdioxid.”
- 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 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: ”Rester og emballage bortskaffes som farligt affald.”

Følgende sætning skal anføres under sikkerhedssætning P501: ”Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl.”