

Summary of product characteristics for a biocidal product

Product name: AGITA® 10WG

Product type(s): PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

Authorisation number: 891-3

R4BP 3 asset reference number: DK-0012116-0000

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	3
5. General directions for use	5
5.1. Instructions for use	6
5.2. Risk mitigation measures	6
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	6
5.4. Instructions for safe disposal of the product and its packaging	6
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	6
6. Other information	6

Administrative information

1.1. Trade names of the product

AGITA® 10WG
MS Thia-Fly

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Elanco Animal Health Inc.
	Address	Mattenstrasse 24A 4058 Basel Switzerland
Authorisation number		891-3
R4BP 3 asset reference number		DK-0012116-0000
Date of the authorisation		12/06/2018
Expiry date of the authorisation		11/06/2028

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Kwizda Agro GmbH
Address of the manufacturer	Werk Leobendorf B6 Laaer Straße, Kwizda-Allee 1 2100 Leobendorf Austria
Location of manufacturing sites	Werk Leobendorf B6 Laaer Straße, Kwizda-Allee 1 2100 Leobendorf Austria

Name of the manufacturer	Schirm GmbH
Address of the manufacturer	Dieselstraße 8 85107 Baar-Ebenhausen Germany
Location of manufacturing sites	Dieselstraße 8 85107 Baar-Ebenhausen Germany

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

Active substance	54 - thiamethoxam
Name of the manufacturer	Syngenta Crop Protection AG
Address of the manufacturer	Syngenta Crop Protection AG CH-4002 Basel Switzerland
Location of manufacturing sites	Deccan Fine Chemicals (India) Private Limited Santa Monica Plant Corlim, Illhas, 403110 Goa India
	ESIM Chemicals GmbH St-Peter-Strasse 25 4020 Linz Austria
Active substance	65 - cis-tricos-9-ene (Muscalure)
Name of the manufacturer	Denka International B.V.
Address of the manufacturer	Hanzeweg 1 3771 Barnveld Netherlands
Location of manufacturing sites	Hanzeweg 1 3771 Barnveld Netherlands

2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
thiamethoxam	thiamethoxam	Active Substance	153719-23-4	428-650-4	10
cis-tricos-9-ene (Muscalure)	cis-Tricos-9-ene; (Z)-Tricos-9-ene	Active Substance	27519-02-4	248-505-7	0,05

2.2. Type of formulation

WG - Water dispersible granules

3. Hazard and precautionary statements

Hazard statements

Very toxic to aquatic life with long lasting effects.

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.

Avoid release to the environment.

Collect spillage.

Dispose of contents to an approved incinerator.

4. Authorised use(s)

4.1 Use description

Use 1 - Professional

Product type

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

Where relevant, an exact description of the authorised use

For the control of adult house flies (*Musca domestica*) in animal housings.

Target organism(s) (including development stage)

Scientific name: *Musca domestica*
Common name: House fly
Development stage: Adults

Field(s) of use

Indoor

AGITA 10WG is a formulation suitable for the control of adult house flies in animal housing including poultry, pig and dairy operations, stables, animal handling or holding facilities and other associated areas where housefly control is necessary. The product should be applied where flies are typically seen feeding or resting such as but not

	<p>limited to window sills, tops of walls, pen partitions, and pathways. Product to be applied by hang-board only.</p>
<p>Application method(s)</p>	<p>Hang-board -</p> <p>100 g of product to be dispersed in 80 ml of water. Apply dispersed product (via brush/roller) to ten 20 cm x 30 cm, hang-boards. 10 hang-boards to be hung per 80-120 m² of wall surface.</p> <p>Applications may be repeated every 6 weeks.</p> <p>Product may take up to 4 weeks to be effective. Only retreat the area after a minimum of 6 weeks.</p> <p>Reapply if dust has covered the treated area or if insects have consumed the bait.</p>
<p>Application rate(s) and frequencies</p>	<p>100 g of product to be dispersed in 80 ml of water. Apply dispersed product to ten 20 cm x 30 cm, hang-boards. 10 hang-boards to be hung per 80-120 m² of wall surface. - Disperse 100g in 80ml of water -</p> <p>If necessary, applications may be repeated every 6 weeks.</p> <p>Product may take up to 4 weeks to be effective. Only retreat the area after a minimum of 6 weeks.</p> <p>Reapply if dust has covered the treated area or if insects have consumed the bait.</p>
<p>Category(ies) of users</p>	<p>Professional</p>
<p>Pack sizes and packaging material</p>	<p>HDPE bottle 100 g – 5 kg</p> <p>PET/Alu/PET/PE printed laminate sachet - 25 x 20 g sachets stored in rigid cardboard box dispenser.</p>

4.1.1 Use-specific instructions for use

<p>Read the label and product information before use</p> <p>Product contains Thiamethoxam which is toxic to bees</p> <p>For professional use only</p> <p>For indoor use only</p> <p>Keep away from food, drink and animal feeding stuff.</p> <p>Remove uncovered foodstuffs and feedstuffs before application.</p> <p>Apply out of reach of children and animals.</p> <p>Mix and stir the indicated quantity of AGITA 10WG in the corresponding volume of lukewarm water in a separate container. Use a container with a volume 1/3rd larger than the amount of water to be added and wait until foaming subsides before application (via brush/roller).</p> <p>Product must only be applied to hang-boards</p> <p>Apply only to non-absorbent hang-boards which are then to be fixed to walls or ceilings where flies prefer to rest.</p> <p>Do not apply the product directly onto surfaces (e.g. walls) in the building</p> <p>For the mixing / loading and the application step, the applicator must wear disposable clothes (e.g. paper smocks, aprons, overall) to</p>
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avoid emissions to the sewer system due to washing of contaminated clothes

Wash hands and exposed skin immediately after handling the product.

The area, where mixing/loading and the application to cardboard take place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.

Do not clean the treated area

Remove all hang-boards which are treated with the biocidal product before (pre)-cleaning and/or disinfectant events

Equipment used in connection with the paint-on application (e.g. brushes, rollers, hang boards) must not be cleaned after use. All contaminated equipment may be reused without cleaning (if possible) and always be disposed of safely according to local regulation (with no discharge to waste water)

The product should be used in combination with a larvicide and alternated with an adulticide of different mode of action. If this is ineffective it should be reported to the authorisation holder.

Product may take up to 4 weeks to be effective. Only retreat the area after a minimum of 6 weeks.

4.1.2 Use-specific risk mitigation measures

See use specific instructions for use

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

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Remove the affected person from the danger zone to a well-ventilated room or to fresh air, and prevent hypothermia.

Inhalation : Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact : Wash off with soap and water. Get medical attention if irritation develops and persists. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Eye contact : Rinse with water. Get medical attention if irritation develops and persists. Rinse eyes with clean water for several minutes.

Ingestion : Rinse mouth. Get medical attention if symptoms occur. If swallowed, seek medical advice immediately and show this container or label. No specific antidote is known! Apply symptomatic therapy

In case of accidental release stop the flow of material, if this is without risk. Dike far ahead of spill for later disposal. Following product recovery, flush area with water

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

Dispose of contents to an approved incinerator in accordance with local legislation

Remains of the applied product, washing water from treatment equipment and other waste (e.g. empty pack-ages, exhausted card boards) must be disposed of according to local waste regulations

Do not discharge any waste product or washing water from treatment equipment to drains.

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

A shelf life of 2 years is supported.

Store in original container.

Keep container closed.

Protect from light and humidity.

Storage temperature: store below 25 °C

5. General directions for use

5.1. Instructions for use

See 4.1.1

5.2. Risk mitigation measures

See 4.1.2

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

See 4.1.3

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

See 4.1.4

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

See 4.1.5

6. Other information

Monitoring of the potential for the occurrence of resistance should be conducted on a continuous basis, and the relevant strategies for resistance management should be included on the label as follows:

'This product should not be used continuously against houseflies in intensive or controlled environment animal houses as this could cause failure due to insecticide resistance.

Thiamethoxam is the active component of AGITA 10WG which belongs to the class of neonicotinoid insecticides have a different mode of action to other classes of insecticides such as pyrethroids and organophosphates.

The use pattern as hang-boards ensures that most of the animal house is not treated thereby reducing the likelihood of contacting a sub-lethal deposit. Nevertheless, to minimise the chances of resistance developing in the future, it is advisable to avoid using AGITA 10WG exclusively and continuously as the sole agent for fly control.

AGITA 10WG should be used as one component of an integrated pest management program which features products from alternative chemical classes and non-chemical means (e.g. fly screens, sanitary practices).

Toxic to bees

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 fluer (*Musca domestica*) i stalde. Må kun anvendes indendørs."

2) I advarselsfeltet:
"ADVARSEL

Meget giftig med langvarige virkninger for vandlevende organismer.

Undgå udledning til miljøet.

Udslip opsamles.

Vask huden efter arbejde.”

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

”Må kun anvendes som insektmiddel til erhvervsmæssig bekæmpelse af fluer (*Musca domestica*) i stalde. Må kun anvendes indendørs.

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

Må ikke tømmes i kloak afløb.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Under blanding og påføring af produktet skal der anvendes engangsdragt og -handsker.

Ved blanding og påføring af produktet skal underlaget afdækkes, således at eventuelt spild opsamles.

Alle rester af det påførte produkt, vaskevand fra rensning af behandlingsudstyr, engangsdragter og -handsker og afdækning skal bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”

Farepiktogrammet GHS09.

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

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

a) Teksten ”Insektmiddel BPR-reg. nr. 786-1. Aktivstoffer og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.

b) Oplysning om præparattype: ”granulat” for dette præparat.

c) Indholdet af aktivstoffer i vægtprocent (% w/w) og g/kg.

d) 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.

e) Batchnummer eller – betegnelse skal anføres.

f) Pakningsstørrelse i kg.

g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning: ”Indholdet/beholderen 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.”