Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ADVION GRANULES APPAT MOUCHES

Product type 18

Indoxacarb as included in the Union list of approved active substances

Case Number (NA-APP) in R4BP: BC-LP036088-23
Case Number (NA-MIC) in R4BP: BC-RY081822-96

Evaluating Competent Authority: FR

Date: June 2020
Revised: April 2024

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NOTE TO THE READER

This consolidated PAR is based on the PAR of the first authorisation and has been updated with the NA-MIC data provided by the applicant.
In this consolidated PAR, the assessments related to the new data of the product are at the end of the concerned section and are highlighted in grey.

The SPC (in the section 2.1 of the PAR) corresponds to the currently authorised uses in France.

History of the dossier

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	*FR*	*BC-LP036088-23*	15.09.2020	Initial assessment
NA-MIC	*FR*	*BC-RY081822-96*	12.04.2024	Minor change application: - replacement of a non-active substance intentionnaly incorporated - deletion of a trade name for the biocidal product

1 CONCLUSION

ADVION GRANULES APPAT MOUCHES containing indoxacarb is a granular PT18 biocidal product, for the use indoor and around farms, livestock, residential and commercial buildings, intended for professional use against flies. The granulated product is used as a bait treatment using only bait boxes designed to be used with granular fly control baits.

Conclusion on Physical, chemical and analytical method

The formulation ADVION GRANULES APPAT MOUCHES is a RB ready to use bait formulation. All studies have been performed in accordance with the current requirements. The product has an appearance of small cylindrical free flowing yellow granules with a sweetish odour, free from visible extraneous matter and hard clumps. The pH of 1% concentrated product in deionized water at 25 °C is 6.8. The bulk density of the formulated product is 0.592 g/mL. The nominal size range of granules > 500 µm to ≤ 1400 µm is 981 g/kg. The biocidal product is nearly dust free.
The product is stable after storage 14 days at 54 °C in commercial packagings (HDPE bottle and PP pail) as no significant change in the physical-chemical properties tested and no significant reduction in the content of Indoxacarb. The product is demonstrated stable for 24 months at ambient temperature (20 °C and 25 °C) in commercial packaging (HDPE bottle and PP pail), as no significant change in the physical-chemical properties tested and no significant reduction in Indoxacarb were found in the sample stored. A shelf life of 24 months can be granted based on long-term storage stability studies.
Effect of light has not been investigated. Since the packaging is not barrier to light, FR-CA recommends to store the product away from direct sunlight due to the sensitivity of the active substance to light. The mitigation measure ”store away from light” should be mentioned.
Its technical characteristics are acceptable a RB ready to use bait formulation.

The biocidal product ADVION GRANULES APPAT MOUCHES is not classified as an explosive, oxidising, flammable and self-heating substance.

The analytical method SF-895/1 for the chiral determination of active substance Indoxacarb including the active (*S*)-enantiomer and the inactive (*R*)-enantiomer (IN-KN127) in the biocidal product ADVION GRANULES APPAT MOUCHES was successfully validated. The requirements of the SANCO/3030/99 rev.4 guideline were fulfilled.

For the analytical methods for determining relevant components and/or residues in different matrices, letters of access to Annex II data have been provided for Indoxacarb. Methods are fully validated in the CAR of the active substances.

- **Minor change application (2023)**

The minor change consists of a change of co-formulant due to a lack of supply of the initial component. The product is chemically comparable, so this change has no impact on the physico-chemical properties and technical characteristics of the product.

Conclusion on efficacy

French competent authorities consider that the elements submitted in the dossier demonstrated the efficacy of the product ADVION GRANULES APPAT MOUCHES (0.5% w/w indoxacarb) at the application rate of 2 g product /m² in a bait station against house flies (*Musca domestica*, adults) and blow flies (*Calliphoridae sp*, adults) by professional users.

- **Minor change application (2023)**

Considering that the change in composition claimed in this minor change application is very slight, it is not expected to have an influence on the efficacy or palatability demonstrated in the first authorisation. Therefore, efficacy conclusions and application rates validated in the first authorisation remain unchanged.

Conclusion on human risk assessment

Considering the systemic and local effects , the risk for professional users is acceptable when the product is used in bait stations, the instructions for use and risk mitigation measures are followed and suitable PPE (gloves) are worn, and considering the product is placed out of reach of children, pets and non target animals (in order to reduce the risk of secondary exposure).

Conclusion on dietary risk assessment

Calculated WCCE is below 30 % of AEL long-term for indoxacarb. As a result, the risk for consumers via residues in food is considered acceptable.
Nevertheless, exceedance of current EU MRL in poultry fat (set under regulation (EC) No 396/2005) arising from biocidal uses intended in this dossier cannot be excluded. Consequently, intended use in broilers housing is not acceptable.

Conclusion on environmental risk assessment

Several specific risk mitigation measures and instructions for safe disposal must be applied during application and service life to ensure no emissions to environmental compartments:

- Bait stations specifically designed to prevent the release of granular baits, and any exposure of non-target animals, must be used
- Bait stations must be placed off the ground, attached on the wall or suspended.
- For outdoor uses, bait stations must be tamper resistant designed to protect the bait from rainfall and must be placed in areas protected from wet conditions and out of reach from non-target animals.
- For indoor uses, 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.

- All bait stations must be removed before cleaning and / or disinfection of livestock, residential and commercial sites/structures.
- 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.

With theses RMM, emissions are considered negligible and no unacceptable risk is identified for primary and secondary poisoning and for all environmental compartments for indoor and outdoor uses of the product ADVION GRANULES APPAT MOUCHES in commercial and residential structures or in livestock and agricultural structures.

Overall conclusion : first authorisation

According to the assessment performed for the product ADVION GRANULES APPAT MOUCHES, the following use is proposed for authorization considering the appropriate risk mitigation measures:

- Professional use against fly - Indoor and around farm, livestock (except broilers), residential and commercial buildings.

➢ **Minor change application (2023)**

The minor change has no impact on the overall conclusion on the authorised uses of the biocidal product ADVION GRANULES APPAT MOUCHES.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment (MIC 2023)

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
ADVION FLY GRANULAR BAIT	
ADVION GRANULES APPAT MOUCHES	FRANCE

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Syngenta Crop Protection AG
	Address	Rosentalstrasse 67 CH-4058 Basel Switzerland
Authorisation number	**FR-2020-0042**	
Date of the authorisation	15/09/2020	
Expiry date of the authorisation	14/09/2030	

2.1.1.3 Manufacturer 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

2.1.1.4 Manufacturer of the active substance

Active substance	Indoxacarb
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

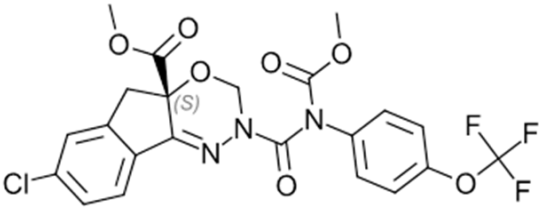
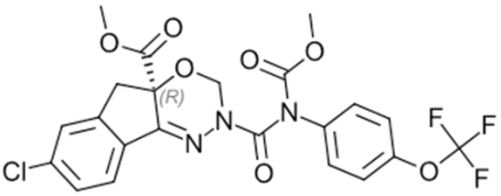
2.1.2 **Product composition and formulation**

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Indoxacarb*
IUPAC or EC name	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 ratio 75:25 of the (*S*) and (*R*) enantiomers)
EC number	N/A
CAS number	(*S*)-enantiomer: 173584-44-6 (*R*)-enantiomer: 185608-75-7
Index number in Annex VI of CLP	Not available
Minimum purity / content	0.5% w/w (1) Indoxacarb pure, in form of Indoxacarb technical corresponding to 1.07% w/w technical Indoxacarb at a minimum purity of 46.7% (2) w/w (corresponding (*S*)-Indoxacarb) (1) Insecticidally active (*S*)-Indoxacarb (2) Technical Indoxacarb as a 75:25 w/w mix of (*S*):(*R*)-Indoxacarb blended with silica.
Structural formula	 (S)-Indoxacarb  (R)-Indoxacarb

* "Indoxacarb" as defined by the International Organisation for Standardisation (ISO) refers only to the (S)-enantiomer of an isomeric mixture, which is not a racemic mixture of the S and

R enantiomers. The Annex I inclusion directive (2009/87/EC) references the active substance as Indoxacarb (enantiomeric reaction mass (S):(R): 75:25).
References in this application to Indoxacarb refer to the 75:25 (S):(R) enantiomeric reaction mass.

2.1.2.2 Candidate(s) for substitution

Indoxacarb contained in the biocidal product ADVION GRANULES APPAT MOUCHES is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal 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 ratio 75:25 of the (S) and (R) enantiomers)	Active substance	(*S*)-enantiomer: 173584-44-6 (*R*)-enantiomer: 185608-75-7	-	0.796% [0.5% (en (*S*)-Indoxacarb)]
Potassium sorbate	Potassium (2E,4E)-hexa-2,4-dienoate	Co-formulant	24634-61-5	246-376-1	0.3%
Silicon dioxide	Silicon dioxide	-	112926-00-8	601-214-2	0.27%

2.1.2.4 Information on technical equivalence

Not relevant

2.1.2.5 Information on the substance(s) of concern

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)" the potassium sorbate and the silicon dioxide are identified as substances of concern (SoCs) since they are active substances, that act as co-formulant for which a Competent Authority Report (CAR) (with agreed reference values) is available and present in the product at a concentration ≥0.1%.

Please see the confidential annex for further details.

2.1.2.6 Endocrine disruption assessment

The biocidal product contains the active substance "Indoxacarb", which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

According to our assessment, none of the co-formulants contained in the products of the ADVION GRANULES APPAT MOUCHES are regulatory identified as endocrine disruptors.

Please refer to Confidential Annex.

2.1.2.7 Type of formulation

RB : ready to use grain bait

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Chronic aquatic toxicity, Category 3 Skin Sensitisation Category 1B
Hazard statement	H317: May cause an allergic skin reaction H412: Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H317: May cause an allergic skin reaction H412: Harmful to aquatic life with long lasting effects
Precautionary statements	P261: Avoid breathing dust/fume/gas/mist/vapours/spray P272: Contaminated work clothing should not be allowed out of the workplace P273: Avoid release to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of soap and water P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P321: Specific treatment (see … on this label). P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/ container to an approved waste disposal plant
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Professional - Indoor and around farm, livestock (except broilers), residential and commercial buildings

Product Type	PT18 – insecticide, 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 (including development stage)	House fly *(Musca domestica)* Blow flies (*Calliphoridae sp*) stage adult
Field of use	In and around agricultural or livestock (except broilers) sites/structures In and around residential and commercial sites/structures
Application method(s)	Placed into bait stations, indoors and outdoors around buildings. Outdoor bait stations are designed to protect the product from rainfall and are placed off the ground on the walls or suspended.
Application rate(s) and	40 g product per station, 1 bait station / 20 m² (2 g/m²).

frequency	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 GRANULES APPAT MOUCHES is supplied in loose. Loose baits are packed in: - HDPE bottle (1 L) - PP pail (5 L)

2.1.4.2 Use-specific instructions for use

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2.1.4.3 Use-specific risk mitigation measures

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2.1.4.4 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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2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

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

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2.1.5 **General directions for use**

2.1.5.1 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 or around broilers houses.

2.1.5.2 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 acces 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.
- For outdoor uses, bait stations must be tamper resistant, designed to protect the bait from rainfall and must be placed in areas protected from wet conditions and out of reach from non-target animals.
- For indoor uses, 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.

2.1.5.3 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.
- 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.

2.1.5.4 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.

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

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

2.1.6 **Other information**

- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
- This product contains a bittering agent.

2.1.7 **Packaging of the biocidal product**

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	1 L	HDPE	HDPE Cap	Professional	Yes
Pail	5 L	PP	PP Lid	Professional	Yes

2.1.8 **Documentation**

2.1.8.1 Data submitted in relation to product application

Physico-chemical data

ADVION GRANULES APPAT MOUCHES is not the representative formulation for the inclusion of Indoxacarb. Therefore, Physico-chemical properties studies and analytical methods on the biocidal product ADVION GRANULES APPAT MOUCHES were provided by Syngenta.

Efficacy data

- Laboratory choice study according to an in-house method, with fresh formulation and 1, 2, 4 weeks aged bait of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults).
- Simulated use test according to an in-house method, with the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults).
- Field test according to an in-house method, with the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica*), Vinegar flies (*Drosophila repleta*) and Phorid flies (*Psychodidae spp*.).
- Simulated use test according to an in-house method, with fresh formulation and 10 and 12 months aged bait of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults).
- Simulated use test according to an in-house method, with fresh formulation and 1, 4, 8 weeks aged bait of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults).
- Simulated use test according to an in-house method, with fresh formulation, 4 and 8 weeks aged baits of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults).
- Simulated use test according to an in-house method, with fresh formulation and 1, 4, 8 weeks aged bait of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on house flies (*Musca domestica,* adults) susceptible and multiresistant (pyrethroid and oregano-phosphate).
- Laboratory choice study according to an in-house method, with fresh formulation and 4 weeks aged bait of the product INDOXACARB FLY BAIT (0.5% indoxacarb) on *Lucilia saricata* (green bottle flies, adults).
- Simulated use test according to an in-house method, with the product INDOXACARB FLY BAIT (0.5% indoxacarb) on *Calliphora spp.* (blow flies, adults).
- Simulated use test according to an in-house method, with the product INDOXACARB FLY BAIT (0.5% indoxacarb) on *Calliphora spp.* (blow flies, adults).

2.1.8.2 Access to documentation

Letters of access from FMC Corporation (owner of DuPont De Nemours S.A.) for data on Indoxacarb have been provided and grant access to Syngenta Crop Protection AG to these data.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Flies in agriculture

Product Type(s)	Insecticide
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 and livestock sites and structures.
Target organism (including development stage)	*Musca domestica* and other filth flies (including blow flies, *Calliphoridae*). Direct target of the bait are adults. Product works to control the population.
Field of use	In and around agricultural or livestock sites/structures
Application method(s)	Placed into bait stations, indoors and outdoors around buildings. Outdoor bait stations are designed to protect the product from rainfall and are placed off the ground on the walls or suspended. Place bait stations out of reach of farm animals.
Application rate(s) and frequency	Up to 40 g product per station, max. 1 bait station / 20 m² => max. 2 g/m². Bait stations should be inspected at regular intervals (at least every 7 days). Where bait has been consumed it should be replaced to allow supply of the product ad libitum. Apply Advion® Fly Granular Bait where fly infestation has occurred. The product should remain in place to prevent fly infestation from reoccurring. The product maybe applied throughout the year. The product is attractive and effective for up to 8 weeks under use conditions.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Please see the relevant section.

Table 3. Intended use # 2 – Flies in residential and commercial areas

Product Type(s)	Insecticide
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 residential structures and the non-food areas of commercial, industrial, public and institutional buildings/structures, including restaurants, warehouses, food processing plants, supermarkets, hospitals, nursing homes, motels, hotels, schools, child nurseries or day-care facilities, laboratories, computer facilities, pet shops and zoos.
Target organism (including development stage)	*Musca domestica* and other filth flies (including blow flies, *Calliphoridae*). Direct target of the bait are adults. Product works to control the population.
Field of use	In and around residential and commercial areas
Application method(s)	Placed into bait stations, indoors and outdoors around buildings. Outdoor bait stations are designed to protect the product from rainfall and are placed off the ground on the walls or suspended.
Application rate(s) and frequency	Up to 40 g product per station, max. 1 bait station / 20 m² => max. 2 g/m². Bait stations should be inspected at regular intervals (at least every 7 days). Where bait has been consumed it should be replaced up to 40 g per bait station to allow supply of the product *ad libitum*. Apply Advion® Fly Granular Bait where fly infestation has

	occurred. The product should remain in place to prevent fly infestation from reoccurring. The product maybe applied throughout the year. The product is attractive and effective for up to 8 weeks under use conditions.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Bottle, 1L, HDPE Pail, 5L, PP

2.2.2 **Physical, chemical and technical properties**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
Physical state at 20 °C and 101.3 kPa	Visual	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Solid	Schilling, W (2017) Report n° USGR170020	Acceptable
Colour at 20 °C and 101.3 kPa	Visual	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Yellow	Schilling, W (2017) Report n° USGR170020	Acceptable
Odour at 20 °C and 101.3 kPa	-	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Sweetish	Schilling, W (2017) Report n° USGR170020	Acceptable
Acidity / alkalinity	Acidity: CIPAC MT 191 pH:	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w	Acidity: 0.12% (calculated as H_2SO_4) pH: 6.8 At 1% in deionized water and at 25 °C	Schilling, W (2017) Report n° USGR170020	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
	CIPAC MT 75.3	IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724			
Relative density / bulk density	CIPAC MT 186	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Pour density: 0.592 g/mL Tap density: 0.619 g/mL	Schilling, W (2017) Report n° USGR170020	Acceptable
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Analytical method SF-895/1 validated in report n° USGR160256	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Physically and chemically stable after storage for 14 days at 54 °C. Commercial packaging: HDPE bottle Please see table 2.2.2.1. below for detailed results of the report.	Schilling, W (2017) Report n° 300086404	Acceptable The product is stable in the commercial packaging (HDPE bottle) after 14 days at 54 °C.
	CIPAC MT 46.3 Analytical method SF-895/1 validated in report n° USGR160256	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Physically and chemically stable after storage for 14 days at 54 °C. Commercial packaging: PP pail Please see table 2.2.2.2. below for detailed results of the report.	Schilling, W (2017) Report n° 300086820	Acceptable The product is stable in the commercial packaging (PP pail) after 14 days at 54 °C.
Storage stability test – **long term storage at**	OECD 2.7.5 Analytical method SF-	A21741A [Indoxacarb (S)-enantiomer:	Physically and chemically stable after storage for 2 years at 20 °C. Commercial packaging: HDPE bottle	Schilling, W (2020) Report n°	Acceptable The product is stable in

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
ambient temperature	895/1 validated in report n° USGR160256	0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	Please see table 2.2.2.3. below for detailed results of the report.	300166416	the commercial packaging (HDPE bottle) after 2 years at 20 °C.
	OECD 2.7.5 Analytical method SF-895/1 validated in report n° USGR160256	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	Physically and chemically stable after storage for 2 years at 25 °C. Commercial packaging: HDPE bottle Please see table 2.2.2.4. below for detailed results of the report.	Schilling, W (2020) Report n° 300166419	Acceptable The product is stable in the commercial packaging (HDPE bottle) after 2 years at 25 °C.
	OECD 2.7.5 Analytical method SF-895/1 validated in report n° USGR160256	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	Physically and chemically stable after storage for 2 years at 20 °C. Commercial packaging: PP pail Please see table 2.2.2.5. below for detailed results of the report.	Schilling, W (2020) Report n° 300167770	Acceptable The product is stable in the commercial packaging (PP pail) after 2 years at 20 °C.
	OECD 2.7.5 Analytical method SF-895/1 validated in report n° USGR160256	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	Physically and chemically stable after storage for 2 years at 25 °C. Commercial packaging: PP pail Please see table 2.2.2.6. below for detailed results of the report.	Schilling, W (2020) Report n° 300166417	Acceptable The product is stable in the commercial packaging (PP pail) after 2 years at 25 °C.
Storage stability test – **low**	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
temperature stability test for liquids					
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	Not relevant since the test item is stored and transported in the packaging without the exposition to the light	-	Since HDPE bottle packaging is not opaque and the effect of light has not been tested, FR-CA recommends to store the product away from light due to the sensitivity of the active substance to light.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	The temperature and humidity does not affect the content of the active substance and technical properties of the biocidal product. Please refer to storage stability studies for more information.	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Both packaging types HDPE bottle and PP pail show the resistance during storage for 2 weeks at 54°C. Please refer to storage stability studies for more information.	-	Acceptable
Wettability	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
Suspensibility, spontaneity and dispersion stability	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Wet sieve analysis and dry sieve test	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
	CIPAC MT 170	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Nominal Size Range: > 500 µm sieve to ≤ 1400 µm sieve: 981 g/kg ≥ 90% was retained on the 1000 µm sieve and ≤ 10% was retained on the 1400 µm sieve	Schilling, W (2017) Report n° USGR170020	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Disintegration time	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 58.3 (Nominal size range of Granules)	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	Nominal Size Range: > 500 µm sieve to ≤ 1400 µm sieve: 972 g/kg > 150 µm sieve: 990 g/kg	Schilling, W (2017) Report n° 300086404	Acceptable
	CIPAC MT 171 (Dust content)	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer:	Dust content: 0 mg, nearly dust free	Schilling, W (2017) Report n°USGR170020	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
		0.16% w/w] Batch n° 956724			
	CIPAC MT 178 (Attrition)	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	The attrition resistance was determined to be: 99%.	Schilling, W (2017) Report n° 300086404	Acceptable
Persistent foaming	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Flowability/Pourability/Dustability	CIPAC MT 172.1 (Flowability)	A21741A [Indoxacarb (*S*)-enantiomer: 0.49% w/w IN-KN127 (*R*)-enantiomer: 0.16% w/w] Batch n° 956724	The sample of the test item dropped spontaneously through the sieve.	Schilling, W (2017) Report n°USGR170021	Acceptable
Burning rate — smoke generators	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Burning completeness — smoke generators	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Composition of smoke — smoke generators	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Spraying pattern — aerosols	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Physical	-	-	It is not foreseen that the product will be applied	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
compatibility			together with another biocidal product(s)		
Chemical compatibility	-	-	It is not foreseen that the product will be applied together with another biocidal product(s)	-	Acceptable
Degree of dissolution and dilution stability	-	-	Not relevant to be tested for biocidal product formulated as ready to use granules	-	Acceptable
Surface tension	-	-	Study technically not feasible since the product is a solid	-	Acceptable
Viscosity	-	-	Study technically not feasible since the product is a solid	-	Acceptable

- **Minor change application (2023)**

No new tests/data were presented in the dossier for physical and chemical properties.

Table 2.2.2.1. Details results of the accelerated storage stability study (14 days at 54 °C) in commercial packaging (HDPE bottle):

Test description	Method	Initial	After 14 d at 54 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.47% w/w (-4.1 %) 0.15% w/w (-6.3%) 76:24
pH (1% deionized water)	CIPAC MT 75.3	6.8	6.0
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.17%
Dust content	CIPAC MT 171.1	0 mg	0 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 976 g/kg 991 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	976 g/kg
Attrition resistance	CIPAC MT 178	99%	99%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	0.83%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.612 g/mL 0.623 g/mL

Table 2.2.2.2. Details results of the accelerated storage stability study (14 days at 54 °C) in commercial packaging (PP pail):

Test description	Method	Initial	After 14 d at 54 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.48% w/w (-2.0%) 0.15% w/w (-6.3%) 76:24
pH (1% deionized water)	CIPAC MT 75.3	6.8	6.1
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.16%
Dust content	CIPAC MT 171.1	0 mg	0.54 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 975 g/kg 990 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	977 g/kg
Attrition resistance	CIPAC MT 178	99%	99%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	0.87%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.611 g/mL 0.639 g/mL

Table 2.2.2.3. Details results of the long term storage stability study (2 years at 20 °C) in commercial packaging (HDPE bottle):

Test description	Method	Initial	After 2 y at 20 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.46% w/w (-6.1%) 0.15% w/w (-6.3%) 75:25
pH (1% deionized water)	CIPAC MT 75.3	6.8	7.0
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.15%
Dust content	CIPAC MT 171.1	0 mg	0.5 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 969 g/kg 990 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	970 g/kg
Attrition resistance	CIPAC MT 178	99%	100%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	0.51%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.635 g/mL 0.641 g/mL

Table 2.2.2.4. Details results of the long term storage stability study (2 years at 25 °C) in commercial packaging (HDPE bottle):

Test description	Method	Initial	After 2 y at 25 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.44% w/w (-10.2%) 0.15% w/w (-6.3%) 75:25
pH (1% deionized water)	CIPAC MT 75.3	6.8	6.8
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.21%
Dust content	CIPAC MT 171.1	0 mg	0.1 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 968 g/kg 987 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	978 g/kg
Attrition resistance	CIPAC MT 178	99%	100%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	0.81%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.597 g/mL 0.614 g/mL

Table 2.2.2.5. Details results of the long term storage stability study (2 years at 20 °C) in commercial packaging (PP pail):

Test description	Method	Initial	After 2 y at 20 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.46% w/w (-6.1%) 0.15% w/w (-6.3%) 75:25
pH (1% deionized water)	CIPAC MT 75.3	6.8	6.9
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.15%
Dust content	CIPAC MT 171.1	0 mg	0.9 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 962 g/kg 985 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	981 g/kg
Attrition resistance	CIPAC MT 178	99%	100%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	0.63%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.599 g/mL 0.609 g/mL

Table 2.2.2.6. Details results of the long term storage stability study (2 years at 25 °C) in commercial packaging (PP pail):

Test description	Method	Initial	After 2 y at 25 °C
Appearance	Visual	Yellow solid, with sweetish odour.	Dark yellow, with sweetish odour.
Packaging	Visual	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps	Small cylindrical free flowing granules, free from visible extraneous matter and hard clumps
Active ingredient content (*S*)-enantiomer (Indoxacarb) (*R*)-enantiomer (IN-KN127) Ratio (*S*):(*R*) (according to chromatographic peak area)	Analytical method SF-895/1 validated in report n° USGR160256	 0.49% w/w 0.16% w/w 75:25	 0.45% w/w (-8.1%) 0.15% w/w (-6.3%) 75:25
pH (1% deionized water)	CIPAC MT 75.3	6.8	6.8
Acidity (calc. as H_2SO_4)	CIPAC MT 191	0.12%	0.19%
Dust content	CIPAC MT 171.1	0 mg	0 mg
Nominal size range of Granules >500 µm to ≤1400 µm >150 µm	CIPAC MT 58.3	 972 g/kg 990 g/kg	 983 g/kg 991 g/kg
Nominal size range >500 µm to ≤1400 µm	CIPAC MT 170	981 g/kg	979 g/kg
Attrition resistance	CIPAC MT 178	99%	100%
Moisture (water content) Karl Fisher method	CIPAC MT 30.5	0.72%	1.07%
Bulk density Without taps After 50 taps	CIPAC MT 186	 0.592 g/mL 0.619 g/mL	 0.613 g/mL 0.624 g/mL

Conclusion on the physical, chemical and technical properties of the product

The formulation ADVION GRANULES APPAT MOUCHES is an RB ready to use bait formulation. All studies have been performed in accordance with the current requirements. The product has an appearance of small cylindrical free flowing yellow granules with a sweetish odour, free from visible extraneous matter and hard clumps. The pH of 1% concentrated product in deionized water at 25 °C is 6.8. The bulk density of the formulated product is 0.592 g/mL. The nominal size range of granules > 500 µm to ≤ 1400 µm is 981 g/kg. The biocidal product is nearly dust free.

The product is stable after storage 14 days at 54 °C in commercial packagings (HDPE bottle and PP pail) as no significant change in the physical-chemical properties tested and no significant reduction in the content of Indoxacarb. The product is demonstrated stable for 24 months at ambient temperature (20 °C and 25 °C) in commercial packaging (HDPE bottle and PP pail), as no significant change in the physical-chemical properties tested and no significant reduction in Indoxacarb were found in the sample stored. A shelf life of 24 months can be granted based on long-term storage stability studies.

Effect of light has not been investigated. Since the packaging is not barrier to light, FR CA recommends to store the product away from direct sunlight due to the sensitivity of the active substance to light. The mitigation measure ”store away from light” should be mentioned.

Its technical characteristics are acceptable an RB ready to use bait formulation.

- **Minor change application (2023)**

The minor change consists of a change of co-formulant due to a lack of supply of the initial component. No modification of the physico-chemical properties and the technical characteristics of the product is induced.

2.2.3 **Physical hazards and respective characteristics**

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**FR evaluation**
Explosives	ASTM E537 using Differential Scanning Calorimetry (DSC)	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	A test according to ASTM E537 using Differential Scanning Calorimetry (DSC) was performed on the product ADVION GRANULES APPAT MOUCHES. The total normalized energy output from the exothermic peaks is 632 J/g. Given that none of the components have the potential to exhibit explosive properties the DSC result is unrealistic. From the data it can be concluded that the most likely reason for this very high heat output is oxidation of the components in the crucible which has been sealed under an air atmosphere thereby allowing the effective measurement of the 'calorific' value of the materials. Although it has not been possible to determine the heat of decomposition explicitly for this material, it is believed that this will be much less than 500 J/g. ADVION GRANULES APPAT MOUCHES is not classified as an explosive substance.	Jackson, W. (2017) Report n°HT16/583	Acceptable Results of the DSC test are unrealistic and the high heat of 632 J/g is attributed to the oxidation of the components in the crucible, rather than decomposition. Although it has not been possible to determine the heat of decomposition explicitly, it is believed that this will be much less than 500 J/g". Moreover, according to the composition, the product does not contain explosive compounds. As stated in CLP regulation, it can be assumed that the product is not explosive.
Flammable gases	-	-	Not relevant to be tested since the biocidal product is not a gas.	-	Acceptable
Flammable aerosols	-	-	Not relevant to be tested since the biocidal product is not an aerosol.	-	Acceptable
Oxidising gases	-	-	Not relevant to be tested since the biocidal product	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
			is not a gas.		
Gases under pressure	-	-	Not relevant to be tested since the biocidal product is not a gas.	-	Acceptable
Flammable liquids	-	-	Not relevant to be tested since the biocidal product is not a liquid.	-	Acceptable
Flammable solids	UN Test N.1	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	A test according to UN Test N.1 as described in Section 37.4 of the UN-MTC was performed on the product ADVION GRANULES APPAT MOUCHES. The test substance did not propagate combustion. ADVION GRANULES APPAT MOUCHES is not classified as a flammable solid.	Jackson, W. (2017) Report n°HT16/583	Acceptable The biocidal product is not classified as flammable solid according to CLP regulation.
Self-reactive substances and mixtures	-	-	Not relevant to be conducted since none of the components present in the formulated biocidal product contain chemical groups there are associated with an explosive or self-reactive properties and hence the classification procedure does not need to be applied.	-	Acceptable
Pyrophoric liquids	-	-	Not relevant to be tested since the biocidal product is not a liquid.	-	Acceptable
Pyrophoric solids	-	-	Not relevant to be conducted since none of the components present in the formulated biocidal product are organo-metals or organo-metalloids and hence the classification procedure does not need to be applied. Moreover, experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures.		Acceptable
Self-heating substances and mixtures	UN Test N.4	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w	A test according to UN Test N.4 as described in Section 37.4 of the UN-MTC was performed on the product ADVION GRANULES APPAT MOUCHES.	Jackson, W. (2017) Report n°HT16/583	Acceptable The biocidal product is not classified as self-heating solid

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td></td><td>IN-KN127 (R)-enantiomer: 0.16% w/w]
Batch n° 956724</td><td>The substance showed no significant signs of exothermic activity when tested in a 100 mm wire mesh container at 140 °C.

ADVION GRANULES APPAT MOUCHES is not classified as a self-heating substance.</td><td></td><td>according to CLP regulation.</td></tr>
<tr><td>Substances and mixtures which in contact with water emit flammable gases</td><td>-</td><td>-</td><td>Not relevant to be conducted since none of the components present in the formulated biocidal are organo-metals or organo-metalloids and hence the classification procedure does not need to be applied. Moreover based on the experiences with handling and use, biocidal product, in contact with water, do not emit flammable gases.</td><td>-</td><td>Acceptable</td></tr>
<tr><td>Oxidising liquids</td><td>-</td><td>-</td><td>Not relevant to be tested since the biocidal product is not a liquid.</td><td>-</td><td>Acceptable</td></tr>
<tr><td>Oxidising solids</td><td>UN Test O.1</td><td>A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w
IN-KN127 (R)-enantiomer: 0.16% w/w]
Batch n° 956724</td><td>A test according to UN Test O.1 as described in Section 37.4 of the UN-MTC was performed on the product ADVION GRANULES APPAT MOUCHES.

Applied power to the ignition coil: 150 ± 7 W
The burning times for the test substance and reference substance mixtures with cellulose are tabulated below. In all cases, the test mixtures ignited and burned fully, but very slowly, with a flame.
<table>
<tr><th rowspan="2">Test No.</th><th colspan="3">Burning Times (s)</th></tr>
<tr><th colspan="2">Test Substance</th><th>Reference</th></tr>
<tr><th>4:1</th><th>1:1</th><th>3:7</th></tr>
<tr><td>1.</td><td>1005</td><td>529</td><td>109</td></tr>
<tr><td>2.</td><td>872</td><td>524</td><td>136</td></tr>
<tr><td>3.</td><td>819</td><td>492</td><td>115</td></tr>
<tr><td>4.</td><td>1128</td><td>442</td><td>146</td></tr>
<tr><td>5.</td><td>1091</td><td>488</td><td>89</td></tr>
<tr><td>Mean</td><td>983</td><td>495</td><td>119</td></tr>
</table></td><td>Jackson, W. (2017) Report n°HT16/583</td><td>Acceptable
The biocidal product is not classified as oxidising solid according to CLP regulation.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>FR evaluation</th></tr>
<tr><td></td><td></td><td></td><td>The mean burning times of the test substance/cellulose mixtures are both much greater than the mean burning time of the potassium bromate/cellulose mixtures.

ADVION GRANULES APPAT MOUCHES is not classified as an oxidising substance.</td><td></td><td></td></tr>
<tr><td>Organic peroxides</td><td>-</td><td>-</td><td>Not relevant to be conducted since none of the components present in the formulated biocidal product fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.</td><td>-</td><td>Acceptable</td></tr>
<tr><td>Corrosive to metals</td><td>ASTM NACE / ASTMG31-12a - Immersion Corrosion Testing of Metals</td><td>A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724</td><td>A test according to ASTM NACE / ASTMG31-12a was performed on the product A21741A.

The metal specimens were exposed to formulation A21741A for 7 days at 54 ± 2°C (52-56°C). The following metal specimens were analyzed: tin plate, galvanized sheet metal, sheet steel and stainless steel.

<table>
<tr><th>Test Specimens</th><th></th><th>Observation</th><th>Corrosion Rate g/m²h</th><th>Corrosion Rate mm/y</th></tr>
<tr><td>Tin Plate</td><td></td><td>No Corrosion</td><td>None Found</td><td>None Found</td></tr>
<tr><td>Galvanized Sheet Metal</td><td></td><td>No Corrosion</td><td>None Found</td><td>None Found</td></tr>
<tr><td>Sheet Steel</td><td></td><td>No Corrosion</td><td>None Found</td><td>None Found</td></tr>
<tr><td>Stainless Steel</td><td></td><td>No Corrosion</td><td>None Found</td><td>None Found</td></tr>
</table>

The product is not corrosive to tin plate, galvanized</td><td>Schilling, W (2017) Report n° USGR170020</td><td>Acceptable
The biocidal product is not corrosive to tin plate, galvanized sheet metal, sheet steel and stainless steel.
Moreover, based on the chemical evaluation none of the components present in the formulated biocidal product contain chemical groups, which could initiate an irreversible electrochemical reaction with metals leading to significant damage or destruction. It can be assumed that the</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	FR evaluation
			sheet metal, sheet steel and stainless steel.		product is not corrosive according to CLP regulation.
Auto-ignition temperatures of products (liquids and gases)	-	-	Not relevant to be tested since the biocidal product is neither a liquid nor a gas.	-	Acceptable
Relative self-ignition temperature for solids	UN Test N.4	A21741A [Indoxacarb (S)-enantiomer: 0.49% w/w IN-KN127 (R)-enantiomer: 0.16% w/w] Batch n° 956724	The substance showed no significant signs of exothermic activity when tested in a 100 mm wire mesh container at 140 °C. ADVION GRANULES APPAT MOUCHES is not classified as a self-heating substance.	Jackson, W. (2017) Report n°HT16/583	Acceptable The biocidal product is not classified as self-heating solid according to CLP regulation.
Dust explosion hazard	-	-	Not relevant to be tested since the corresponding study is only applicable to all powders and products containing or able to produce dust that can either ignite or explode when exposed to an ignition source when dispersed in air. Moreover, the biocidal is a nearly dust free granular formulation (See Part 2.2.2. Physical, chemical and technical properties).	-	Acceptable

- **Minor change application (2023)**

No new tests/data were presented in the dossier for physical hazard.

Conclusion on the physical hazards and respective characteristics of the product

The biocidal product ADVION GRANULES APPAT MOUCHES is not classified as an explosive, oxidising, flammable and self-heating substance.

- **Minor change application (2023)**

The minor change has no impact on physico-chemical classification. The physico-chemical classification (not classified) of the product remains unchanged.

2.2.4 **Methods for detection and identification**

Report: Indoxacarb A21741A - Validation of Analytical Method SF-895/1 Final Report, Shi, N. 2017
Study GLP n° USGR160256

Test facility: Syngenta Crop Protection, LLC
410 Swing Road
Greensboro, NC 27409
USA

Principle of the method:

A method to determine Indoxacarb, including the active (*S*)-enantiomer and the inactive (*R*)-enantiomer (IN-KN127) in the biocidal product A21741A (ADVION GRANULES APPAT MOUCHES) by HPLC – UV was submitted. The test item is quantified by HPLC method (Chiral column: normal phase) using UV detection (313 nm) after extraction.
The validation of this method was considered in compliance with SANCO 3030/99 rev 4.

Analytical methods for the analysis of the active substance in the product A21741A								
Analytes (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Reference**
					Acceptable range	Mean (test item fortified)	RSD (n=5) Test item not fortified	

Active substance Indoxacarb: including the active (*S*)-enantiomer and the inactive (*R*)-enantiomer (IN-KN127)	Assay validate HPLC-UV method SF-895/1	N=4 in duplicate (from 50-150% of minimal concentration in the product)	Linearity was studied by carrying out five concentrations between 50% and 150% of the concentration in the test item. The response of the detector during the analysis of (*S*)-enantiomer (Y = 0.996 X + 0.772; r = 1.000) and (*R*)-enantiomer (Y = 1.003 X + 0.196; r = 1.000) was linear.	To demonstrate the specificity of the method, four solutions are analysed and chromatograms have been provided for: solvent blank, formulation blank, reference item and test item. No interference was found: no peak appears in the formulation blank and solvent blank at the retention time of Indoxacarb ((S)-enantiomer + (R)-enantiomer). The method is specific to	**(*S*)-enantiomer:** Fortification at 0.5% w/w (approx 200 µg/mL in solution before analysis) 70%-130% according to SANCO3030/99/ rev.4 Accuracy: Accuracy was determined by comparison of the reference items and 4 reconstituted test items solutions. Two injections of each preparation are made. The accuracy results are expressed as the recovery rate. L70 = 99% (mean of 2 values) L90 = 99% (mean of 2 values) L110 = 99% (mean of 2 values) L130 = 99% (mean of 2 values) Mean recovery rate = 99% Precision: Repeatability was evaluated by analysing twice six test item solutions. RSD=0.95% for precision (6 samples of test item injected twice) Mean = 0.50% w/w	Method n° SF-895/1 Report n° USGR160256

				Indoxacarb in A21741A.	**(*R*)-enantiomer:** Fortification at 0.16% w/w (approx 70 µg/mL in solution before analysis) 70%-130% according to SANCO3030/99/ rev.4 Accuracy: Accuracy was determined by comparison of the reference items and 4 reconstituted test items solutions. Two injections of each preparation are made. The accuracy results are expressed as the recovery rate. L70 = 100% (mean of 2 values) L90 = 100% (mean of 2 values) L110 = 100% (mean of 2 values) L130 = 100% (mean of 2 values) Mean = 100% Precision: Repeatability was evaluated by analysing twice six test item solutions. RSD=0.47% for precision (6 samples of test item injected twice) Mean = 0.16% w/w	

Analytical method for the determination of Indoxacarb residues

Analytical methods for determination of active ingredients residues have already been evaluated at EU level and are presented in the CAR of the active substances. The notifier Syngenta of the product ADVION GRANULES APPAT MOUCHES is not the applicant that supported the annex II inclusion dossier of the active substances but it has a letter of access from FMC Corporation to these data.

Soil (principle of method and LOQ)	Capillary Gas Chromatography, using Mass Selective Detection, for the analysis of Indoxacarb and DPXJT333 in soil. The method was suitably validated. Limit of quantification (LOQ): 0.01 mg kg^{-1}
Air (principle of method and LOQ)	Capillary Gas Chromatography, using nitrogen and phosphorous selective detection, for the analysis of Indoxacarb in air. The method was suitably validated. Limit of quantification (LOQ): 0.10 µg m^{-3}
Water (principle of method and LOQ)	Liquid Chromatography, using Mass Spectrometry, for the analysis of Indoxacarb, IN-JT333 and IN-KT413 in ground, drinking and surface water. The method was suitably validated. Limit of quantification (LOQ): 0.05 µg $L^{-1.}$
Body fluids and tissues (principle of method and LOQ) Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Relevant when an active substance is classified as toxic or highly toxic. Indoxacarb (manufactured as DPXMP062) is classified as harmful (Xn) and so no analytical methods needed to be submitted.

Methods for body fluids and tissues and food and feeding stuffs of plant origin are not required since Indoxacarb is not classified as toxic or highly toxic and as the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

Conclusion on the methods for detection and identification of the product

The analytical method SF-895/1 for the chiral determination of active substance Indoxacarb including the active (*S*)-enantiomer and the inactive (*R*)-enantiomer (IN-KN127) in the biocidal product A21741A (ADVION GRANULES APPAT MOUCHES) was successfully validated. The requirements of the SANCO/3030/99 rev.4 guideline were fulfilled.

For the analytical methods for determining relevant components and/or residues in different matrices, letters of access to Annex II data have been provided for Indoxacarb. Methods are fully validated in the CAR of the active substances.

SoCs cannot increase during storage and thus no analytical method is required.

- **Minor change application (2023)**

The minor change has no impact on the analytical methods conclusion.

2.2.5 **Efficacy against target organisms**

2.2.5.1 Function and field of use

MG 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

The product ADVION GRANULES APPAT MOUCHES are ready to use bait product by professional users in and around buildings against adults house flies (*Musca domestica*) and blow flies (*Calliphoridae sp*).

- **Minor change application (2023)**

The replacement of a co-formulant has been requested with the same kind of co-formulant at the same content in the composition of the product (see confidential PAR).

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

According to the uses claimed by the applicant, the product ADVION GRANULES APPAT MOUCHES are used by professional users for the control of house flies (*Musca domestica*, adults) and further filth flies including blow flies (*Calliphoridae sp*, adults).

The specific target organisms to be controlled are:
- house flies (adults): *Musca domestica*
- blow flies (adults): *Calliphoridae sp*

2.2.5.3 Effects on target organisms, including unacceptable suffering

The target organisms are attracted by the bait and feed on it. The ingested bait leads to knock down and mortality of adults within a time delay of some hours. Direct target of the bait are adults. Product works to control the population.

2.2.5.4 Mode of action, including time delay

Indoxacarb is a pro-insecticide – it is not toxic to insects until it goes through an activation process. Upon ingestion by the insect, the Indoxacarb is rapidly converted to DPX-JT333 by enzymatic cleavage of the N-carbomethoxy group in the insect midgut. DPX-JT333 binds to the sodium channels within the insect, thus blocking sodium movement into the cell, resulting in mild convulsions, paralysis and ultimately death.
There is a time delay due to the time taken for the insect to ingest the Indoxacarb and then metabolise it to DPX-JT333, which is toxic and can bind to the sodium channels.
According to the efficay studies, time delay is about 24 hours for house flies and 48 to 72 hours for blow flies.

2.2.5.5 Efficacy data

The applicant submitted following studies:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied/exposure**	**Test results: effects**	**Reference**
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), aged 1 day, 1, 2 and 4 weeks	House flies (*Musca domestica*) 20 adults per replicate (mixed sex)	Laboratory test	Petri dishes, applied at concentration of 2 g /m² Assessments of knockdown and mortality at 1 hour and 1, 2, 3 and 4 days after exposure. 5 replicates per condition	Indoxacarb Fly bait (fresh formulation and 1 week aged): 100% mortality after 24 hours. Indoxacarb Fly bait (2 weeks aged): 96 % mortality after 24 hours. Indoxacarb Fly bait (4 weeks aged): 94 % mortality after 24 hours. Negative control: 5.5% mortality after 96 hours.	Linn (2017a) PPME17203 R.I.= 1
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A)	House flies (*Musca domestica*) 200 adults per replicate (mixed sex, 2-6 days old)	Simulated use test, choice trial	Pavilions made of mesh (3.0 m x 6.0 m x 2.3 m), outdoors, presence of alternative food sources, applied at the application rate of 1 or 2 g/m² Assessments of knockdown and mortality at 0, 15, 30 minutes and 1, 2, 3, 4, 24 hours after exposure. 4 replicates per condition	Indoxacarb Fly bait (1 g/m²): 89.9% mortality after 24 hours (32.5% KD in 4 hours) Indoxacarb Fly bait (2 g/m²): 91.7% mortality after 24 hours (31.3% KD in 4 hours) Negative control: 2.9% mortality after 24 hours.	Miller and Peters (2017) PPMA16273 R.I.= 1
Insecticide	In and around agricultural or livestock, residential and	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A)	House flies (*Musca domestica*) The initial number of flies caught on sticky	Field trial	Swine farm, inside barns housing pigs, 83-174 m², natural infestation, 1 bait station per 19 m² (1.95 g/m²), 33 bait stations, refilled weekly as necessary, exposure until assessment	The mortality observed was: - 17% after 24 h - 88% after 7 days - 93% after 14 days - 92% after 21 days	Buczkowski (2017a) PPME16251 R.I.= 1

	commercial sites/structures		ribbons ranged from 17-186 flies per ribbon (mean= 97 flies).		Assessments of mortality at 1 day, 1, 2, 3 weeks after exposure.		
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), fresh formulation, 10 and 12 months old product	House flies (*Musca domestica*) 50 adults per replicate (mixed sex, 2-3 days old)	Simulated use test, choice trial	Plastic storage container, (0.6 m x 0.4 m x 0.3 m = 0.072 m³), bait dispensed in shallow plastic weigh boat, 1 g bait per container (4.1 g/m²), exposure until assessment Assessments of knockdown and mortality at 1, 2, 3, 4, 6, 8, 24 and 48 hours after exposure. 5 replicates per condition	Indoxacarb Fly bait (fresh formulation, 10 and 12 months old): 100% mortality after 24 hours Negative control: 2% mortality after 24 hours. The application rate is higher than that claimed (2 g/m²).	Buczkowski (2017b) PPME17207 R.I.= 3 (supportive data)
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), fresh formulation, 1, 4 and 8 weeks aged formulation	House flies (*Musca domestica*) 30 adults per replicate (50:50 sex ratio, 3-6 days old)	Simulated use test, choice trial	Plastic storage container (0.39 m x 0.28 m x 0.28 m= 0.031 m³), 2 g bait applied in Petri dishes per container (18.3 g/m²), exposure until assessment Assessments of knockdown and mortality were made at 1, 2, 4, 24, 48 and 96 hours after exposure. 5 replicates per condition	Indoxacarb Fly bait (fresh formulation): 98.7% mortality after 24 hours (8.4% KD after 4 hours) Indoxacarb Fly bait (1 week old): 99.3% mortality after 24 hours (8.9% KD after4 hours) Indoxacarb Fly bait (4 weeks old): 98.6% mortality after 24 hours (11% KD after 4 hours) Indoxacarb Fly bait (8 weeks old): 96.5% mortality after 24 hours (11.7% KD after 4 hours)	Parker (2017) PPME17201 R.I.= 3 (supportive data)

						Negative control: 2% mortality after 24 hours. The application rate is higher than that claimed (2 g/m²).	
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), fresh formulation, aged 4 and 8 weeks (under use condtion)	House flies (*Musca domestica*) 100 adults per replicate (mixed sex)	Simulated use test, choice trial,	Test chamber, 30 m³, at the application rate of 2 g/m² in bait stations, exposure until assessment Assessments of knockdown and mortality at 1, 2, 4, 8, 24, 48, 72 and 96 hours after exposure. 4 replicates per condition	Indoxacarb Fly bait (fresh formulation): 95% mortality after 24 hours (41% KD after 8 hours) Indoxacarb Fly bait (4 weeks old): 98% mortality after 24 hours (41% KD after 8 hours) Indoxacarb Fly bait (8 weeks old): 97% mortality after 24 hours (60% KD after 8 hours) Negative control: 0% mortality after 24 hours.	Linn (2017b) PPME17205 R.I.= 1
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), fresh formulation and stored 15 months	House flies (*Musca domestica*) - Suceptible strain - Multi-resistant strain (381zb): pyrethroid and organoposphate 50 adults per replicate (50:50 sex ratio)	Simulated use test, choice trial	Transparent cage (0.6 m x 0.58 m x 0.6 m= 0.21 m³), 1 g product per cage (2.9 g/m²), exposure until assessment Assessments of knockdown and mortality at 1, 2, 24, 48 and 72 hours after exposure. 5 replicates per condition	Concerning efficacy against susceptible strain of House flies: - Indoxacarb Fly bait (fresh formulation): 96% mortality after 24 hours - Indoxacarb Fly bait (stored 15 months): 97.2% mortality after 24 hours - Negative control: less than 2% mortality after 48 hours Concerning efficacy against	Hoppé & Hofer (2017) PPMG17501 R.I.= 3

						multi-resistant strain (381zb) of House flies: - Indoxacarb Fly bait (fresh formulation): 79.2% mortality after 24 hours - Indoxacarb Fly bait (stored 15 months): 78.8% mortality after 24 hours - Negative control: less than 2% mortality after 48 hours The application rate is higher than that claimed (2 g/m²) and the resistance against pyrethroid and organoposphate of the Multi-resistant strain (381zb) has not been demonstrated.	
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A), 1 days and 4 weeks aged	*Lucilia saricata* 20 adults per replicate (mixed sex)	Laboratory test, choice trial	Petri dishes, 2 g/m², provided with a cellulose swab soaked in 10 % sugar water as alternative food Assessments of knockdown and mortality at 1 and 8 hours after exposure and assements of mortality at 1, 2, 3 and 4 days after exposure. 5 replicates per condition	Indoxacarb Fly bait (1 day old): 100% mortality after 24 hours (98% KD after 8 hours) Indoxacarb Fly bait (4 weeks old): 100% mortality after 24 hours (64% KD after 8 hours) Negative control: 1% mortality after 24 hours.	Werner (2018) PPME18 040a, BIO002b-18 R.I.= 1
Insecticide	In and around agricultural or	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A)	*Calliphora spp.* 50 adults per replicate (50:50	Simulated use test, choice trial	Transparent cage (0.6 m x 0.58 m x 0.6 m= 0.21 m³), 1g product per cage (2.9 g/m²), exposure until	100% mortality after 48 hours (26.8% after 24 hours) Negative control: 0.8%	Hoppé et al. (2018a)

	livestock, residential and commercial sites/structures		sex ratio)		assessment Assessments of knockdown and mortality at 1, 2, 24, 48 and 72 hours after exposure. 5 replicates per condition	mortality after 48 hours. The application rate is higher than that claimed (2 g/m²).	PPMG18202/B R.I.= 3 (supportive data)
Insecticide	In and around agricultural or livestock, residential and commercial sites/structures	Indoxacarb Fly Bait (0.5% w/w Indoxacarb, A21741A)	*Calliphora spp.* 50 adults per replicate (50:50 sex ratio)	Simulated use test, choice trial	Transparent cage (0.6 m x 0.58 m x 0.6 m= 0.21 m³), 0.696 g product per cage (2 g/m²), exposure until assessment Assessments of knockdown and mortality at 1, 2, 24, 48 and 72 hours after exposure. Evaluation of bait consumption after 72h 5 replicates per condition	100% mortality after 72 hours but only 74.8% mortality was reached after 48 hours and 0% after 24 hours Bait consumption: 137 mg per replicate after 72 hours Negative control: 1.2% mortality after 72 hours.	Hoppé et al. (2018b) PPMG18205 R.I.= 2

The tests have been performed with the product Indoxacarb Fly bait (0.5% w/w indoxacarb, A21741A) which corresponds to the product of the authorisation.

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the TNsG on product evaluation for PT18/19 and the results of these tests are respecting the requirements and criteria of the TNsG on product evaluation for PT18/19.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product ADVION GRANULES APPAT MOUCHES according to the uses and the application rate claimed:

- Regarding the efficacy claim against House flies (*Musca domestica*, adults):
  - The product is efficient at the application rate of 2 g product /m² in bait station with 100 % mortality 24 hours after the treatment. In the field test, a mortality of 93 % is observed after 14 days.

- Regarding the efficacy claim against blow flies (*Calliphoridae sp*, adults):
  - The product is efficient at the application rate of 2 g product /m² in bait station with 100 % mortality 72 hours after the treatment in simulated-use test.

    According to the applicant: "field trials with blow flies are not technically possible for the reasons below:
    - Blow flies develop in dead bodies and as such in an operational "field" test the normal hygiene requirements for animal housing leads normally to low levels of blowflies (normally <1%).
    - As such, blow flies will practically always occur in a "mixture" of blow flies and house flies at level of 1 blow fly for every 100 house flies on monitoring traps. The impact on the statistical relevance for such a field trial would be significant and make the simulated use test preferable."

    FR CA agrees with this justification and considers that the efficacy against blow flies has been demonstrated at the application rate of 2 g product /m² based on the simulated-use efficacy study provided.

Considering the efficacy data provided and according to the Technical Agreements for Biocides (TAB) – EFF v.2.1, 2020 (4), the claimed shelf life of 24 months is supported as the bait product contains preservative.

Conclusion on the efficacy of the product

French competent authorities consider that the elements submitted in the dossier demonstrated the efficacy of the product ADVION GRANULES APPAT MOUCHES (0.5% w/w indoxacarb) at the application rate of 2 g product /m² in a bait station against house flies (*Musca domestica*, adults) and blow flies (*Calliphoridae sp*, adults) by professional users.

- **Minor change application (2023)**

Considering that the change in composition claimed in this minor change application is very slight, it is not expected to have an influence on the efficacy or palatability demonstrated in the first authorisation. Therefore, efficacy conclusions and application rates validated in the first authorisation remain unchanged.

2.2.5.6 Occurrence of resistance and resistance management

Only very limited occurrence of resistance towards Indoxacarb has been reported so far.

The Insecticide Resistance Action committee (IRAC) continuously monitors globally for cases of resistance and according to the database (Arthropod Pesticide Resistance Database, as at September 2018) there are 7 cases of resistance recorded for *Musca domestica* against indoxacarb (https://www.pesticideresistance.org/search.php).

Laboratory bioassays suggest that Indoxacarb resistance can develop but should then be of highly recessive nature[1]. It was possible to collect wild housefly strains from farms in Punjab (Pakistan) with extensive use of insecticides showing some resistance towards Indoxacarb[2] but it has to be noted that no report of any resistance in houseflies is known from Europe or anywhere else than Punjab.

For reasons of resistance management, the bait stations should be inspected regularly and bait should always be available ad libitum. The use of ADVION GRANULES APPAT MOUCHES should be alternated with baits containing other active substances.

Feedback from users regarding any changes in perceived effectiveness of the product shall be utilized to monitor the occurrence of resistance.

In the case where a potential resistance of the product is suspected, the applicant propose a quick forced contact test done by the professional user himself. The test can be described as follows: "Catch some of the potentially resistant flies with a beaker. Introduce some granules of indoxacarb and store the closed beaker with flies and Indoxacarb for approx. 3h. All flies should be dead or moribund. If this is not the case, as a second step SYNGENTA would send a medium for oviposition in a beaker, again flies should be caught into the beaker, the beaker closed for oviposition and the medium send back to SYNGENTA laboratories for rearing and testing the flies."

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) assessed that the bait product ADVION GRANULES APPAT MOUCHES has shown a sufficient efficacy against house flies (*Musca domestica*, adults) and blow flies (*Calliphoridae sp*, adults) at the application rate of 2 g product / m² by professional users.

For information, the applicant claimed efficacy against "other filth flies (including blow flies *Calliphoridae*)". Nevertheless, since the product is a bait and only *Calliphoridae* genus have been tested in the studies, FR CA restricted the uses to only *Calliphoridae sp*. for filth flies.

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1 Shono et al. (2004): Indoxacarb resistance in the house fly, *Musca domestica*, pesticide biochemistry and physiology 80 (2004) 106-112.

2 Khan et al. (2013): Resistance to new chemical insecticides in the house fly, *Musca domestica L.*, from dairies in Punjab, Pakistan, Parasitol Res (2013) 112: 2049-2054.

Shelf-life: 2 years

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other biocidal products.

2.2.6 **Risk assessment for human health**

ADVION GRANULES APPAT MOUCHES is a ready-to-use insecticidal granular bait (RB) containing 0.796% of DPX-MP062 (indoxacarb technical) which is a sum of (S)- and (R)-enantiomers (75:25).

It is intended to be applied only by professional users, placed into bait stations, in and around residential and commercial sites/structures.

The product maybe applied throughout the year.

2.2.6.1 Assessment of effects on Human Health

Note: The product formulation code A21741A refers to the trade name ADVION GRANULES APPAT MOUCHES through this assessment report.

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method,Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
In Vitro Skin Irritation Test in the EPISKIN™ Model, OECD 439 (2015): EC No 761/2009, ANNEX III, B.46 (2009). GLP: yes Reliability: 1	Indoxacarb RB (A21741A), Batch #: 956724, 20 mg of powdered Indoxacarb RB, incubation for exposure time of 15 minutes	EPISKIN™, a three-dimensional human skin model comprising a reconstructed epidermis with a functional stratum corneum was selected for this *in vitro* test, as it is recommended by international guidelines.	Following exposure with ADVION GRANULES APPAT MOUCHES, the mean relative cell viability was 97.3% compared to the negative control value. In this *in vitro* EPISKINTM irritation assay conducted on ADVION GRANULES APPAT MOUCHES, the results indicate that the test item is non-irritant to skin.	None	XXXX (cf confidential annex)

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Skin Irritation (rabbit) OECD 404 (2015): OPPTS 870.2500 (1998); EC No 440/2008, B.4 (2008). GLP: yes Reliability: 1	New Zealand White rabbits, 3 males	Indoxacarb RB (A21741A), Batch #: 956724, 0.5 g of test item was placed on a surgical gauze pad (ca. 2.5 cm x 2.5 cm) for 4 hours. 3 scoring times: 24, 48 and 72 hours after patch removal	No local dermal signs were observed. No clinical signs of systemic toxicity were observed and no mortality occurred. The body weights of all rabbits were within the normal range of variability. All scores are equal to 0. Under the conditions of this study, Advion® Fly Granular Bait is considered to be not corrosing or irritating to the rabbit skin according to the CLP classification criteria.	None	XXXX (cf confidential annex)

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin irritating
Justification for the value/conclusion	Based on *in vitro* (*In Vitro* Skin Irritation OECD 439) and *in vivo* (Acute Skin Irritation (rabbit) OECD 404) studies.
Classification of the product according to CLP and DSD	No classification for skin corrosion or irritation of ADVION GRANULES APPAT MOUCHES is required according to EC Reg. No 1272/2008.

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Isolated Chicken Eyes OECD 438 (2013); EC No 440/2008, B.48 (2008); EPA OPPTS 870.2400 (1998), GLP: yes Reliability: 1	Indoxacarb RB (A21741A), Batch #: 956724, 30 mg were placed on the entire surface of the cornea	The enucleated eye test with isolated eyes of chicken is a validated *in vitro* test system. It represents a test system nearest to the *in vivo* test, without the need to use live animals. In the Isolated Chicken Eye (ICE) test, the tested compound is applied in one single dose onto the cornea of isolated eyes (in three replicates) and corneal effects are evaluated during 4 hours.	No significant corneal swelling (mean ≤ 5%) was observed during the four hour observation period. Slight opacity change (severity 0.5 or 1) was observed on all three eyes. Slight fluorescein retention change (severity 0.5 or 1) was noted on all three eyes. The overall ICE Class was: 1xI 2xII. Based on this *in vitro* eye irritation study in isolated chicken eyes with ADVION GRANULES APPAT MOUCHES, the test item is identified with no category and is not classified as mixture inducing serious eye damage Cat1.	None	XXXX (cf confidential annex)

[Please insert/delete rows according to the number of studies.]

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Eye Irritation (rabbit) OECD Test Guideline 405 (2012); EPA OPPTS 870.2400 (1998); EC No 440/2008, B.5 (2008) GLP: yes Reliability: 1	New Zealand White Rabbits, 3 young males	Indoxacarb RB (A21741A), Batch #: 956724, installation of a single dose of 0.1 g into the conjunctival sac of the left eye, 4 scoring times: 1, 24, 48 and 72 hours	Mean scores (mean of score at 24, 48 and 72h): - Conjunctival redness: 1.33/0.33/0.0 - Chemosis: 0.33/0.0/0.0 - Cornea: 0/0/0 - Iris: 0/0/0 All symptoms had fully reversed in all animals after 72 hours. No mortality occurred and the body weights of all rabbits were within the normal range of variability. Under the conditions of this study, ADVION GRANULES APPAT MOUCHES is considered to be not irritating to eyes according to the CLP classification criteria.	None	XXXX (cf confidential annex)

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating for eyes
Justification for the value/conclusion	Based on *in vitro* (Isolated Chicken Eyes OECD 438) and *in vivo* (Acute Eye Irritation (rabbit) OECD 405) studies.
Classification of the product according to CLP and DSD	No classification and labelling for serious eye damage or eye irritation of ADVION GRANULES APPAT MOUCHES is required according to EC Reg. No 1272/2008.

Respiratory tract irritation

Data waiving	
Information requirement	Not applicable
Justification	There is no study nor information on the product ADVION GRANULES APPAT MOUCHES for this endpoint. Based on available data for all ingredients of the product and physicochemical data (granule formulation and low vapour pressure) no classification for respiratory tract irritation is required for the product according to EC Reg. No 1272/2008. Morever, currently no testing methods or test guidelines are available. Hence, no further data are considered necessary.

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure** **Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**

Lymph Node Assay (LLNA) in Mice OECD Test Guideline 429 (2010); OPPTS 870.2600 (2003)GLP: yes Reliability: 1	CBA/J Mouse, 16 female mice (4 per group) + 1 female mouse for preliminary toxicity testing	Indoxacarb RB (A21741A), Batch #: 956724, Vehicle: 1% Pluronic®L92, 5%, 10%, 25% test substance in vehicle, Exposure during 3 consecutive days	Treatment with 5%, 10% and 25% of ADVION GRANULES APPAT MOUCHES resulted in stimulation index (SI) values of 1.17, 1.44 and 3.19, respectively. A SI > 3.0 was observed in the treatment group 25%. The EC3 value was calculated to be 23.4%. No dermal irritation was observed for any of the test groups at any of the test sites. Under the conditions of this study, ADVION GRANULES APPAT MOUCHES is considered to have moderate skin sensitisation (Cat 1B) potency according to the CLP classification criteria.	None	XXXX (cf confidential annex)

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin sensitizing cat. 1B
Justification for the value/conclusion	Based on *in vivo* study: Local Lymph Node Assay in mice: OECD Test Guideline 429 (2010). ADVION GRANULES APPAT MOUCHES is concluded to be a skin sensitizer based on a stimulation index (SI) greater than 3.0.
Classification of the product according to CLP and DSD	Classification for skin sensitization cat. 1B, H317 "May cause an allergic skin reaction" is required for ADVION GRANULES APPAT MOUCHES according to Reg. (EC) 1272/2008.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Not applicable
Justification	There is no study nor information on the product ADVION GRANULES APPAT MOUCHES for this endpoint. Based on available data for all ingredient of product and physicochemical data (granule formulation and low vapour pressure) no classification for respiratory sensitisation is required for the product according to EC Reg. No 1272/2008. Morever, currently no testing methods or test guidelines are available. Hence, no further data are considered necessary.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Oral Toxicity (rat): OECD Test Guideline 425 (2008), EPA OPPTS 870.1100 (2002). GLP: yes Reliability: 1	Rat, CRL:(WI) rats, 3 females	Indoxacarb RB (A21741A), Batch #: 956724, 5000 mg/kg bw, single oral gavage. The test item was administered as supplied without dilution.	No mortality occurred during the study. Treatment with ADVION GRANULES APPAT MOUCHES at the dose level of 5000 mg/kg bw did not cause any test item related effects on the animals. There were no treatment related effects on body weight or body weight gain. At necropsy, no abnormal findings were observed for any treated animal.	LD_{50} > 5000 mg/kg bw	None	XXXX (cf confidential annex)

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 5000 mg/kg bw
Justification for the selected value	Based on *in vivo* study: Acute Oral Toxicity (rat): OECD Test Guideline 425 (2008). No mortality occurred during the study.
Classification of the product according to CLP and DSD	No classification for acute oral toxicity of ADVION GRANULES APPAT MOUCHES is required according to EC Reg. No 1272/2008.

Acute toxicity by inhalation

Data waiving	
Information requirement	Acute toxicity by inhalation
Justification	No study has been performed on the product. ADVION GRANULES APPAT MOUCHES does not contain any substance to consider in the ATEmix calculation for inhalation route. According to EC Regulation No. 1272/2008 the product will not require classification for acute toxicity by inhalation.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Dermal Toxicity (rat) OECD 402 (1987); EPA OPPTS 870.1200 (1998); EC 440/2008 (2008). GLP: yes Reliability: 1	Rat, Crl:WI Wistar rats, 5 males and 5 females	Indoxacarb RB (A21741A), Batch #: 956724, 5000 mg/kg bw, semi occlusive for 24 h (on approximately 10% area of the total body surface). The test item was administered as supplied without dilution.	No mortality occurred during the study. There were no adverse clinical signs , no skin irritation was, no treatment related changes in the body weights observed in any animal throughout the study. There was no evidence of the test item-related observations at a dose level of 5000 mg/kg bw at necropsy.	LD_{50} > 5000 mg/kg bw	None	XXXX (cf confidential annex)

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 5000 mg/kg bw
Justification for the selected value	Based on *in vivo* study: Acute Dermal Toxicity (rat) OECD 402 (1987). No mortality occurred during the study.
Classification of the product according to CLP and DSD	No classification for acute dermal toxicity of ADVION GRANULES APPAT MOUCHES will be required according to EC Reg. No 1272/2008.

Information on dermal absorption

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
In vitro human skin, OECD 428, GLP, reliability 1,	Human skin from 4 donors, 8 samples, exposure time 6 h, receptor fluid samples were collected at pre-dose, 2, 4, 6, 8, 12 and 24 h post dose.	Indoxacarb RB (A21741A) concentrate: 0.67% w/w, test concentration 0.44% w/w.	Less than 75% of absorption occurs within half the study duration. The amount of applied dose penetrating within 24 hours was determined to be 0.26% (exposed skin (including tape strips 3-15), receptor fluid, receptor chamber wash), for Indoxacarb in the concentrate.	No deviations. The RB formulation concentrate was mixed with physiological saline to achieve a paste applicable to the skin samples.	XXXX (cf confidential annex)

Since less than 75% of absorption occurs within half the study duration, the tape strip 3-15 should be included in the calculation of the absorbed dose.

The absorbed dose is derived as follows:

Absorption= exposed skin (including tape strips 3-15) + receptor fluid + receptor chamber wash.

The recovery are not normalised since the the calculated not-normalised dermal absorption is <5% (according to the EFSA Guidance on dermal absorption 2017[3], section 5.2, point 2). To address variability between replicates (eight), the dermal absorption is calculated as follows:
Dermal absorption = absorption (mean) + k*SD.
Dermal absorption = 0.18 + 0.84*0.089 = 0.26%.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Indoxacarb RB (A21741A) concentrate: 0.67% w/w, test concentration 0.44% w/w.
Value(s)	0.26%
Justification for the selected value(s)	Experimental data according to EFSA guidance 2017

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", an ingredient of the product has been identified as substance of concern.

An active substance (PT8) that act as co-formulant for which a Competent Authority Report (CAR) (with agreed reference values) is available and present at a concentration ≥0.1% have been identified in the product :

Co formulant (Trade name)	**Substance of concern**	**CAS number**	**Reference Values (AR[4])**
POTASSIUM SORBATE GRANULATED FCC	Potassium sorbate	24634-61-5	$AEL_{AT, MT, LT}$ = 13.4 mg/kg bw/d (potassium sorbate) Dermal absorption: 25% (EFSA Guidance on dermal absorption (2017), concentrate ready-to-use bait (RB) formulation) Oral absorption: 100%

A fully quantitative risk assessment is performed for each relevant exposure scenario. For calculation details, see output tables Annex 3.2.

[3] Guidance on dermal absorption, EFSA Journal 2017;15(6):4873, adopted in 24 May 2017.
[4] Assessment Report Potassium Sorbate, PT8 (wood protective), february 2015.

Endocrine disruption assessment

According to our assessment, none of the co-formulants contained in the products of the ADVION GRANULES APPAT MOUCHES are regulatory identified as endocrine disruptors.

Please refer to Confidential Annex.

Available toxicological data relating to a mixture

The initial premix of active substance (DPX-MP062-MUP) is a sum of (S)- and (R)-enantiomers (75:25) blended with impurities and 25.6% silica dioxide (CAS n°112926-00-8).
The silica dioxide is an active substance (PT18) present at a concentration ≥0.1% for which a Competent Authority Report (CAR) (with agreed reference values) is available, and should be identified as Substance of Concern according to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)".

Mixture	**Substance of concern**	**CAS number**	**Reference Values (AR[5])**
Premix DPX-MP062-MUP	Silicon dioxide	112926-00-8	$AEC_{AT,\ MT}$ = 0.2 mg/m^3 AEC_{LT}= 0.1 mg/m^3

A fully quantitative risk assessment is performed for each relevant exposure scenario.
For calculation details, see output tables Annex 3.2.

Other

Not revelant

2.2.6.2 Exposure assessment

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	n.a.	n.a.	No	No	n.a.
Dermal	n.a.	Yes	n.a.	n.a.	No	No	n.a.
Oral	n.a.	No	n.a.	n.a.	No	Yes	Yes

[5] Assessment Report Synthetic amorphous silicon dioxide (Rentokil initial, PT18, march 2014.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Filling and placing of bait stations	**Primary exposure** Filling and placing of bait stations	Professionals
2.	Cleaning of bait stations	**Primary exposure** Cleaning of bait stations i.e. by pouring	Professionals
3.	Ingestion of product by a toddler	**Secondary exposure** Oral exposure of toddler by ingestion of grain bait	Toddler

Industrial exposure

Not relevant.

Professional exposure

Scenario [1]

Description of Scenario [1]

Primary exposure: Filling and placing of bait stations

ADVION GRANULES APPAT MOUCHES is a granulated product intended to professional users only using bait stations.

The exposure assessment is performed considering a worst-case application rate of 40g of product per station, a maximum of 1 bait station / 20 m² (→ 2 g/m²) and a maximum area treated by day of 1200 m² (applicant information).

In these conditions, an operator will fill a maximum of 60 bait stations per day giving a total of 2.4 kg product handled per working day.

The TNsG exposure model "Mixing and loading model 5"[6]considers a professional pouring granule formulation from a container into a portable receiving vessel. The models are derived from data relating to mixing and loading of agricultural pesticides and cover relatively large volumes.

The process of placing bait stations after filling is considered to not trigger exposure upper than the mixing and loading scenario (as bait stations are used).

A tier I assessment of exposure is performed assuming no PPE is worn.

The exposure assessment is performed with the active substance indoxacarb and the two substances of concern potassium sorbate and silicon dioxide.

	Parameters[1]	Value	Source
Tier 1	Concentration of Indoxacarb	0.796% w/w	-
	Concentration of Potassium sorbate	0.3% w/w	-
	Concentration of SiO_2	0.27% w/w	-
	Adult body weight	60 kg	Ad hoc Recommandation 14[7]
	Application rate	2 g/m²	Applicant data
	Area treated	max 1200 m^2 per day	Applicant data
	Application frequency	max 60 bait stations per day	-

[6] Mixing and Loading model 5 TNsG (2002) part 2, as cited in ECHA (2015): Biocides Human Health Exposure Methodology, complement to ECHA Guidance on Exposure Assessment (Chapter 3, Part B).

[7] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (agreed in WG III on 12 june 2017)

	Dermal absorption Indoxacarb	0.26%	Study: XXXX (cf confidential PAR)
	Dermal absorption Potassium sorbate	25%	AR Potassium sorbate
	Inhalation absorption (default)	100%	
	indicative hand exposure	171 mg/kg a.s	Mixing and Loading model 5 (BHHEM)
	Indicative inhalation exposure	0.036 mg/kg a.s.	

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] Indoxacarb	Tier I/ No PPE	1.15 $x10^{-5}$	1.42 $x10^{-4}$	n.a.	1.53 $x10^{-4}$
Scenario [1] Potassium sorbate	Tier I/ No PPE	4.32 $x10^{-6}$	5.13 $x10^{-3}$	n.a.	5.13 $x10^{-3}$
Scenario [1] Silicon Dioxide	Tier I/ No PPE	3.89 $x10^{-5}$	n.a.	n.a.	3.89 $x10^{-5}$

Scenario [2]

Description of Scenario [2]
Primary exposure, Cleaning of bait stations i.e. by pouring Cleaning of bait stations will only be performed by professional operators by pouring. It is reasonable to assume that exposure during cleaning bait stations (emptying station into a bucket and removing residues from the station) will not be higher than during loading the stations. The exposure is therefore covered by the exposure assessment during mixing and loading.

Non-professional exposure

Not relevant.

Exposure of the general public

Scenario [3]

Description of Scenario [3]
Secondary exposure, Oral exposure of toddler by ingestion of grain bait However, for a worst-case assessment, acute secondary exposure to the product may be anticipated for toddlers (1-2 years of age) who may have oral contact with the bait. For the scenario "oral exposure by ingesting bait", a reverse scenario was calculated. Secondary exposure by inhalation is not expected and is considered negligible compared to the exposure by oral ingestion. The exposure to silicon dioxide is not relevant since it has only local effect (inhalation).

	Parameters[1]	Value	Reference
Tier 1	Concentration of Indoxacarb	0.796% w/w	-
	Concentration of Potassium sorbate	0.3% w/w	-
	Oral absorption of Indoxacarb	30%	AR Indoxacarb
	Oral absorption of Potassium sorbate	100%	AR Potassium sorbate
	Toddler body weight	10 kg	Ad hoc Recommandation 14[8]

Based on the AEL_{acute} of 0.125 mg a.s/kg bw/day for indoxacarbe, a body weight of 10 kg and an oral absorption of 30% [as stated in the Assessment report of indoxacarb], ingestion of more than 523 mg of product per day by an toddler is needed to exceed the AEL of indoxacarbe.

Considering the reference values (Acute AEL) and the concentrations of the two substances relevant for this scenario (indoxacarb and potassium sorbate), the assessment of exposure to the active substance Indoxacarb is a worst-case.

Monitoring data

Not relevant

Dietary exposure

The product ADVION GRANULES APPAT MOUCHES is intended to be used in bait stations for fly control in agricultural and livestock sites and structures (use 1) as well as in residential and non food areas of commercial structures (use 2). Bait stations are to be placed off the ground, attached to walls or suspended, out of reach of livestocks. Intended uses are therefore not expected to induce food or feed contamination. Nevertheless, exposure of poultry through consumption of dead flies contaminated with the product has to be considered. Indeed, poultry seek out dead insects intentionnaly.

[8] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (agreed in WG III on 12 june 2017)

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
1.	Animal husbandry	Dietary exposure to poultry contaminated through ingestion of dead flies contaminated with the product	Poultry and consumer

[1] e.g. animal husbandry, food industry, professional use, residential use.
[2] e.g. chicken, milk, beer

Information of non-biocidal use of the active substance

Residue definitions
Indoxacarb (sum of indoxacarb and its R enantiomer)

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products	Insecticide on various crops	MRLs according to Reg. 396/2005 : from 0.01*-30 mg/kg[1]

[1] Current MRL regulation : Reg. (EU) 2015/845.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of Scenario [1]		
Consumption of dead flies contaminated with the product is the only way livestock can be exposed to indoxacarb since the product is intended to be used out of reach of animals and has a very low vapour pressure (approx 1 x 10^{-10} Pa, 20°C, see AR (2008)). This oral exposure is only relevant for poultry according to ECHA guidance on the BPR (volume III Human Health) as it is the only livestock specie that seeks out dead insects intentionally.		
	Parameters[1]	Value
Tier 1	Concentration of indoxacarb in BP	0.796 % w/w
	Biocidal product consumption by flies (default value : guidance on BPR, vol. III, parts B+C, section 6)	3.5 mg/fly/day
	Max amount of indoxacarb per fly	0.028 mg/fly/d

	Fly consumption per animal (default value : guidance on BPR, vol. III, parts B+C, section 6)		10 flies/day
	Oral absorption		100%
	Body weights (default values : guidance on BPR, vol. III, parts B+C, section 6)	Broilers	1.7 kg
		Laying hen	1.9 kg
		Turkey	7 kg

Calculations for estimating livestock exposure for Scenario [1]

Internal dose received by the animal and WCCE*				
Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products. BfR calculator The internal dose received by poultry is equal to the estimated oral exposure since a value of 100 % is considered for oral absorption. For the WCCE calculation, the worst case for meat (broiler) and the worst case for eggs (laying hen) are used.				
	Animal	Oral exposure (Total exposure) in mg a.s./kg bw/d	Trigger value of 0.004 mg/kg bw/d exceeded?	WCCE* (mg a.s/kg bw/d)
Scenario [1]	Broiler	0.1647	Yes	0.0016
	Laying hen	0.1474	Yes	
	Turkey	0.04	Yes	

**Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey).* A default body weight of 60 kg for an adult is used.

It should be noted that the estimated concentrations of indoxacarb in poultry tissues and eggs exceed the MRLs of 0.01* mg/kg in poultry tissues and 0.02 mg/kg in eggs currently set under regulation (EC) No 396/2005. According to the EU Commission note regarding biocidal MRL[9], biocidal uses should respect MRLs already established under PPP regulation. As a result, the applicant proposed to use the metabolism study in poultry assessed in the Assessment Report for indoxacarb initial approval under PPP regulation[10] to refine indoxacarb levels in poultry tissues and products arising from biocidal uses intended in this present dossier. The refinement proposed by the applicant is presented below :

[9] CA-March17-Doc.7.6.c-final. Note for agreement with Competent Authorities for Biocidal Products. An interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials.

[10] *Li, Y.(1997): Metabolism of 14C-DPX-JW062 (Racemic mixture of DPX-KN128 and IN-KN127) in laying hens. Report no. AMR 3187-94.*

"*This metabolism study in poultry is summarised in the DAR (The Netherlands (2000), DAR Indoxacarb, Vol. 3, B7, point B.7.2.3; also summarised in the RAR : France (2017), RAR Indoxacarb, Vol 3CA, B7, Indoxacarb_RAR_09_Volume_3CA_B-7_2017-08_public.pdf, page 37). It was performed with 10 mg/kg feed. In this study, total radioactive residues in eggs ranged between 0.01 and 0.33 mg a.s. equivalents/kg. No single metabolite was found at concentrations higher than 0.05 mg/kg. Residues of the parent indoxacarb were max. 0.01 mg/kg. In muscle, total radioactive residues ranged between 0.02 and 0.04 mg/kg. No single substance found occurred at > 0.01 mg/kg. Residues of indoxacarb in liver were also only 0.01 mg/kg and residues of indoxacarb in fat were 0.02 mg/kg.*

With a feed intake of 0.12 kg/d for broiler, 0.13 kg/d for layers and 0.5 kg/d for turkey (see EFSA livestock intake model), the calculated maximum intake with treated flies (0.28 mg/day) according to your first tier exposure calculation would correspond to max. 2.33 mg/kg feed. Thus, the dose rate tested in the metabolism study is more than 4 times higher than the maximum expected intake by poultry. Therefore, residues of indoxacarb in poultry eggs and tissues are expected to be well below 0.01 mg/kg and therefore below the current MRL set under Regulation (EC) No. 396/2005".

eCA considered as more accurate to use the poultry feeding study (assessed in the Assessment Report for indoxacarb renewal of approval under PPP regulation[11]) to estimate indoxacarb levels in poultry tissues and eggs.
In this feeding study on poultry, four groups of laying hens, each consisting of ten animals were dosed for 28 consecutive days with indoxacarb (as R and S isomers) at levels of 1.75, 7, 21 and 70 mg/kg in the diet (equivalent to 0.11, 0.44, 1.33 and 4.42 mg/kg b.w).
Indoxacarb concentration in tissues of broiler and eggs of laying hen corresponding to their total exposure (calculated in scenario [1]) is estimated based on the results obtained from the feeding study and using the OECD animal model calculator 2017 (file available on European Commission website:
https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en).
Output values from the calculator are displayed in the table below:

Animal commodity	**Residues at the closest feeding level** (mg/kg)	**Estimated residues at the total estimated exposure of poultry (mg/kg)**	**MRL proposal** (mg/kg)	**Current EU MRL**
Poultry (all diets) Closest feeding level[(a)]: 0,111 mg/kg bw (0,7 N) Broiler (highest diet)				
Muscle	0.0030	0.0045	0.005	0.01*
Fat	0.0080	0.0140	**0.015**	0.01*
Liver	0.0030	0.0045	0.005	0.01*
Poultry (layer only) Closest feeding level[(a)]: 0,111 mg/kg bw (0,8 N) Broiler (highest diet)				
Eggs	0.02	0.02	0.02	0.02

[11] *Magnitude of residues of indoxacarb (as DPXMP062) in laying hen tissue and eggs: a feeding study conducted to EPA guidelines Inveresk Research, PTRL Europe, Dr. Specht & Partner Chemische Laboratorien GmbH DuPont-8305 GLP: Yes Published: No.*

(a): Closest feeding level and N dose rate related to the total exposure

Current EU MRL in poultry fat (of 0.01* mg/kg) is exceeded. As a result, based on the assessment conducted, MRL exceedance in poultry fat arising from biocidal uses intended in this dossier cannot be excluded. Consequently, intended use in broilers housing is not acceptable.

It should be noted that poultry exposure calculation via consumption of contaminated dead flies, based on the EU agreed scenario (ECHA 2017), is a worst case. As no further information has been provided by the applicant, it is not possible to refine the poultry exposure in this dossier.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

Exposure associated with production, formulation and disposal of the biocidal product

Not relevant

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Indoxacarb

Reference	Study	AF	Value
AELshort-term	Rat acute neurotoxicity study	100	0.125 mg/kg/day
AELmedium-term	90 day rat study	100	0.021 mg/kg/day
AELlong-term	2-year rat study	100	0.006 mg/kg/day

Potassium sorbate

Reference	Study	AF	Value
AELshort-term/ medium-term/ long-term	90-d dog/ multi-gen. rat, supported by rat and mouse long-term studies	100	13.4 mg/kg bw/d

Silicon Dioxide

Reference ($AEC_{inhalation}$)	Value
AEC short-term/ medium-term	0.2 mg/m^3
AEC long-term	0.1 mg/m^3

Maximum residue limits or equivalent

Residue definitions
Indoxacarb (sum of indoxacarb and its R enantiomer)

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	EU Reg. 396/2005	All products of plant and animal origin listed in part A of annex I to Reg. 396/2005.	See Reg. (EU) 2015/845

Specific reference value for groundwater

Risk for industrial users

Not relevant.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1] Indoxacarb	Tier I/ No PPE	0.006	1.53 $x10^{-4}$	2.6	Yes
Scenario [1] Potassium sorbate	Tier I/ No PPE	13.4	5.13 $x10^{-3}$	0.038	Yes

For the active substance silicon dioxide, no systemic effect have been observed and no systemic reference toxicological value has been derived in the CAR. Only a local effect risk assessment has been performed.

Local effects

Quantitative risk assessment

For the active substance silicon dioxide, no systemic effect have been observed and no systemic reference toxicological value has been derived in the CAR. A local effect risk assessment should be performed.

Task/ Scenario	Tier	$AEC_{inhalation}$ mg/m^3	Estimated inhalation exposure mg/m^3	Estimated uptake/ AEC (%)	Acceptable (yes/no)
Scenario [1] Silicon Dioxide	Tier I/ No PPE	0.1	3.89 $x10^{-5}$	0.04%	Yes

Qualitative risk assessment

Considering the skin sensitization (cat1B) of the product and according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C) Version 4 - December 2017, a qualitative risk characterization for local effects is required.

Characteristics of the product					Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)		Relevant RMM & PPE Conclusion on risk
Hazard Category	**Effects in terms of C&L**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	
H317							
Medium hazard[12]	Skin sens. 1B, H317	Professional	Mixing and Loading	Dermal	Few minutes per day or less	High level of containment, practically no exposure;	**Considering the following recommendations (RMM and PPE) the risk is acceptable:** **Technics** - Containment as appropriate; - Segregation of the emitting process; - Good standard of general ventilation; - Minimisation of manual phases; - Regular cleaning of equipment and work area; - Avoidance of contact with contaminated tools and objects; **Organisation** - Minimise number of staff exposed; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice;

[12] Guidance on information requirements and chemical safety assessment – Part E: Risk characterisation – version 3 – May 2016 E.3.4.2 p24-28

							- Good standard of personal hygiene **PPE** - Substance/task appropriate gloves; - Skin coverage with appropriate barrier material based on potential for contact with the chemicals;

Conclusion

Considering the systemic and local effects, the risk for professional users is acceptable when suitable PPE (gloves) are worn and the product is used in bait stations following the RMMs below:

- *Place the bait in the bait station by using a graduated dosage device;*
- *Avoid contact with skin, eyes, contaminated tools and objects.*

Risk for non-professional users

Not relevant

Risk for the general public

Systemic effects
Secondary exposure by inhalation is not expected and is considered negligible compare to the exposure by oral ingestion. The exposure to silicon dioxide is not relevant since it has only local effect (inhalation).

Considering the reference values (Acute AEL) and the concentrations of the two substances relevant for this scenario (indoxacarb and potassium sorbate), the assessment of exposure to the active substance Indoxacarb is a worst-case.

The scenario "oral exposure by ingesting bait" as a reverse scenario results to an ingestion of more than 523 mg of product per day by a toddler is needed to exceed the AEL (acute).

The weight of one individual granule from ADVION GRANULES APPAT MOUCHES is < 2 – 2.5 mg and up to 40g of product is applied by bait station. This means the ingestion of more than 209 granules, corresponding to 1.3% of a bait station content by a toddler will conduce to exceed the AEL (acute).

This indicates that toddlers are exposed to a risk of poisoning.

Therefore, even ADVION GRANULES APPAT MOUCHES contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children.
Good practice advise users to prevent access to bait by children and infants.

Local effects

Not relevant.

Conclusion

For the secondary exposure scenario "oral exposure by ingesting bait" as a reverse scenario) indicates that toddlers are at significant risk of poisoning.

In addition to the content of a bittering agent, risk mitigation and protection measures such as to place the product out of reach of children are essential to reduce the risk of secondary exposure.

Considering the systemic effects and the risk mitigation measure " The product has to be placed out of reach of children" and "If there is a risk of acces to bait stations from children, […] a tamper resistant bait station must be used", the risk for general public is acceptable.

Risk for consumers via residues in food

The long-term AEL of 0.006 mg/kg bw/day is used to assess risk linked to dietary exposure to indoxacarb.

WCCE (mg a.s/kg bw/d)	AEL long-term (mg/kg bw/d)	% AEL long-term
0.0016	0.006	**26.97**

Calculated WCCE is below 30 % of AEL long-term for indoxacarb. As a result, the risk for consumers via residues in food is considered acceptable.
As a result, no risk for consumers via residues in food is expected from intended uses of ADVION GRANULES APPAT MOUCHE.

Silicon dioxide and potassium sorbate are identified as substances of concern for human health in this dossier. Both substances are approved food additives under regulation (EC) No 1333/2008. Silicon dioxide is authorised at "quantum satis" and potassium sorbate at a maximum level of 20 mg/kg in final food. Negligible levels of these substances are expected from biocidal uses of ADVION GRANULES APPATS MOUCHES compared to those arising from food additive uses. As a result, a risk assessment linked to dietary exposure to silicon dioxide and potassium sorbate is considered as not necessary.

For intended uses other than in livestock buildings assessed above, no exposure to residues in food is expected. Then, no assessment has been performed. Nevertheless, the following instruction for use is proposed to prevent any food and feed contamination :

- Place the product away from food, drink and animal feeding stuffs as well as from utensils or surfaces that have contact with these.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

2.2.7 Risk assessment for animal health

- Risk for livestock

Consumption of dead flies contaminated with the product is the only way that livestock can be exposed to indoxacarb since the product is intended to be used out of reach of animals and has a very low vapour pressure (approx 1 x 10-10 Pa, 20°C, see AR (2008)). This oral exposure is only relevant for poultry according to ECHA guidance on the BPR (volume III Human Health) as it is the only livestock specie that seeks out dead insects intentionally.

The internal dose received by poultry was calculated in the above section "Estimating Livestock Exposure to Active Substances used in Biocidal Products".

In order to conclude on the risk for poultry, the internal dose is compared to the relevant reference value of the active substance.

Internal dose received by the animal	
Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products. BfR calculator The internal dose received by poultry is equal to the estimated oral exposure since a value of 100 % is considered for oral absorption. For the WCCE calculation, the worst case for meat (broiler) and the worst case for eggs (laying hen) are used.	
Animal	Oral exposure (Total exposure) in mg a.s./kg bw/d
Broiler	0.16
Laying hen	0.15
Turkey	0.04

The worst-case internal dose for poultry was calculated for broiler.

For indoxacarb, the $NOEL_{birds}$ of 14,8 mg a.s./kg bw/d (Derivated from the $NOEC_{birds}$ =144 mg a.s./kg diet considering the average initial body weight (205g) and the average feeding per bird per day (21g), study for "Effects on reproduction of birds", doc III.A CAR of indoxacarb, 2008) was taken as relevant reference value.

Calculation of a safety factor for broiler: 14,8/0.16= 92.

There is a safety factor of 92 between the internal dose for broiler (worst-case for poultry) and the relevant reference value for birds. In this way, no risk is expected for poultry from biocidal uses of ADVION GRANULES APPATS MOUCHES.

- Risk for companion animals (pets)

According to the Technical Agreements for Biocides (November 2018), point Tox48 "Risks to companion animals (pets) should be considered at the member *state level, at the* product authorisation stage. The predominant approach should be to use appropriate risk management measures, e.g. labelling instructions. *The underlying assumption is that the hazard assessment, which is performed for humans, will cover the companion animals as well, while the exposure patterns will differ. It would not be sensible to try to perform an exposure assessment and risk characterisation for all companion animal species, especially given that suitable methodology is lacking. Risks to companion animals will therefore be left for the member state authorities to consider at product authorisation."*

As described in the AR of the a.s. indoxacarb, in practice, an infant or pet is considered unlikely to become exposed to the product as the product is to be placed by professionals, in a bait station, who will be advised on the label to place in areas which are inaccessible to children and pets, and any exposure is likely to be a very rare event. The risk of inappropriate baiting is minimal as professional users can be expected to give proper care and attention to, and comply with, the instructions on the product-label.

In addition to the content of a bittering agent, the following risk mitigation measures will ensure to expect no risk for pets and non-target animals:

- Bait stations [...], must be placed, [...] out of reach from non-target animals.

  If there is a risk of acces to bait stations from children, pets and non target animals a tamper resistant bait station must be used.

2.2.8 **Risk assessment for the environment**

The product ADVION GRANULES APPAT MOUCHES is formulated as a ready to use fly bait, based on the active substance Indoxacarb (0.5% S-enantiomer and 0.17% R-enantiomer) and is to be used in bait stations. It is intended to be used for control of flies in and around buildings – residential and commercial sites/structures and agricultural or livestock sites/structures.
According to the applicant, the bait points are to be placed indoor or outdoor on walls or ceiling, away from external drains and in areas inaccessible to wash-out by rain with 1 bait station per 20 m^2 and containing maximum 40 g of product per station. The risk mitigation measures proposed for the authorisation of this product, especially the fact that ' *bait stations must be tamper resistant designed to protect the bait from rainfall and must be placed in areas protected from wet conditions',* cover the intended use of the product. These initial applicant specifications will be not further indicated in the SPC.

2.2.8.1 Effects assessment on the environment

All agreed endpoints have been taken from the final PT 18 Assessment Report Indoxacarb (2008[13]). The predicted no effect concentration values (PNEC) are summarised in the table below:

	Indoxacarb	**IN-KT413**	**IN-JT-333**
STP ($mg.L^{-1}$)	1.00E+01	-	-
Surface water ($mg.L^{-1}$)	9.00E-03	3.90E-02	2.90E-05
Freshwater sediment ($mg.kg_{wwt}^{-1}$)	1.01E+00	3.22E-01	2.20E-04
Soil ($mg.kg_{wwt}^{-1}$)	4.96E-03	-	-
PNEC oral bird ($mg.kg_{food}$)	4.80E+00	-	-

Bees

The fly bait formulation ADVION GRANULES APPAT MOUCHES is formulated as a ready-to-use granular bait (diameter>500µm) to be used in bait station only. As the formulation contains saccharose at 50%, it could be attractive to bees. However, since the product is

[13] Indoxacarb Assessment Report, Product-type 18 (Insecticide), 20 May 2008

intended for use in bait stations placed in restricted areas protected from rain, floods and cleaning water by professional only, risk to bees is considered limited.

Primary poisoning

Due to included food attractants and the fact that the bait is formulated as a granule the risk via primary poisoning has to be addressed for ADVION GRANULES APPAT MOUCHES according to the recommendations given in the ESD for PT 18.

Secondary poisoning
Due to a log K_{OW} > 3 and a BCF > 100 L/kg wwt, it is indicated that Indoxacarb has a bioaccumulation potential. Exposure via secondary poisoning is foreseen through consumption of flies having consumed the bait or earthworms exposed via soil or fish exposed via water or sediment. A $PNEC_{oral}$ of 4.8 mg/kg food is given in the Assessment Report Indoxacarb (2008). This value has been derived from a birds' reproduction study.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

All relevant data can be extrapolated from the active substance Indoxacarb. Testing of the product is not required.

Further Ecotoxicological studies

Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies								
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure		Results		Remarks	Refe-rence
					LD_{50} (µg a.i./bee)	LD_{100} (µg a.i./bee)		
OECD No. 213 and No. 214 (1998) GLP RI 1	Honey bee *Apis mellifera*	$LD50_{oral}$ $LD50_{contact}$	0.03, 0.05, 0.1, 0.21 and 0.42 µg a.i./bee 0.013, 0.025, 0.05, 0.1 and 0.2 µg a.i./bee	24h 48h 72 h	Oral: 24 h = 0.15 48 h = 0.13 72 h = 0.13 Contact: 24 h = 0.09 48 h = 0.04 72 h = 0.04	Oral: 24 h = 0.42 48 h = 0.42 72 h = 0.42 Contact: 24 h = 0.2 48 h = 0.2 72 h = 0.2	Test item: Indoxacarb RB (A217441A) CAS 173584-44-6 indoxacarb 0.65% (0.16% (R)+ 0.49%(S))	Kling, A (2017)

A new study has been provided on the acute oral and contact toxicity of the product A217441A with 0.49% indoxacarb w/w to *Apis mellifera* L. in laboratory conditions. In the oral toxicity test, the test item was added to acetone and the test solutions were prepared with 50% (w/v) aqueous sucrose solution containing 10% acetone. Assessments of mortality and behavioural abnormalities in the oral toxicity test were carried out at 4, 24, 48 and 72 hours after start of feeding bees with the test solutions. In the contact toxicity

test, bees were treated with A217441A dissolved in acetone by topical application of a 2-µL droplet to the dorsal thorax of each bee.

In both control groups of the oral and contact toxicity tests, the mean mortality is <10%. The 24-hour oral and contact LD_{50} values for the reference item were 0.10 and 0.19 µg dimethoate/bee, respectively. Consequently, validity criterion for both control and reference item mortality were met and the test was deemed valid.
In the oral toxicity test, at the doses of 0.03, 0.05, 0.10, 0.21 and 0.42 µg a.i./bee, respectively 5.0, 5.0, 25.0, 95.0 and 100% mortality was observed after 72 hours.
In the contact toxicity test, no mortality was observed in the two lowest concentrations of 0.013 and 0.025 µg a.i./bee. At the target doses of 0.05, 0.1 and 0.2 µg a.i./bee 77.5, 92.5 and 100% mortality was observed, respectively after 72 hours.

Data from this study, specifically the $LD_{100\ oral}$ (24 h) of 0.42 µg a.s./bee, has been used only for the secondary poisoning risk assessment (see 2.2.8.2 Secondary poisoning).

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	$LD_{50\ oral}$ (72 h) = 0.13 µg a.s./bee $LD_{50\ contact}$ (72 h) = 0.04 µg a.s./bee
Justification for the value/conclusion	LD_{50} contact and oral values have been derived from the exposure of honeybees to the product A217441A containing 0.49% indoxacarb w/w.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data available.

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk - Waiver
Justification	Effects on any other specific, non-target organisms believed to be at risk are not expected. Additional studies are not required and all relevant data can be derived from active substance data.

Supervised trials to assess risks to non-target organisms under field conditions

No data available.

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions - waiver

Justification	The bait is supplied in bait stations which will be fixed on top of walls and ceilings. This in first instance clearly reduces the access to the bait station for mostly all mammalian species that may be attracted by the bait. Secondly, the bait stations itself are constructed in a way that the bait is not accessible for birds and mammals.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	The bait is supplied in bait stations which will be fixed on top of walls and ceilings. This in first instance clearly reduces the access to the bait station for mostly all mammalian species that may be attracted by the bait. Secondly, the bait stations itself are constructed in a way that the bait is not accessible for birds and mammals.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Secondary ecological effects are not expected.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Please refer to section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

All agreed endpoints on fate and behaviour in the environment have been taken from the final PT 18 Assessment Report Indoxacarb (2008[14]). No further studies with the product are submitted and available.

Leaching behaviour (ADS)

A leaching test is not relevant for assessed biocidal product ADVION GRANULES APPAT MOUCHES as a ready to use granular fly bait.

Testing for distribution and dissipation in soil (ADS)

No new data presented. Please refer to the CAR of Indoxacarb (2008).

[14] Indoxacarb Assessment Report, Product-type 18 (Insecticide), 20 May 2008

Testing for distribution and dissipation in water and sediment (ADS)

No new data presented. Please refer to the CAR of Indoxacarb (2008).

Testing for distribution and dissipation in air (ADS)

Based on the Assessment Report Indoxacarb (2008), no assessment of the air compartment was necessary as the active substance was not considered volatile due to low vapour pressure reported for both of the enantiomers (DPX-KN128 = 9.8×10^{-9} Pa at 20°C, DPX-JW062 = 1.3×10^{-10} Pa at 20°C).

Measured aquatic bioconcentration
No data available.

Estimated aquatic bioconcentration
No data available.

Data waiving	
Information requirement	Not required.
Justification	All relevant data can be extrapolated from the active substance Indoxacarb.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Use inside buildings (commercial, residential, agricultural and livestock sites/structures) in bait stations Scenario 2: Use around buildings (commercial, residential, agricultural and livestock sites/structures) in a bait stations
ESD(s) used	Emission Scenario Document for Product Type 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, June 2008 (ENV/JM/MONO(2008)14).
Approach	Scenario 1 and 2: Average consumption
Distribution in the environment	Scenario 1: No direct or indirect exposure of the product to the environment is considered for the use of the product indoor due to the application form (in bait stations). Scenario 2: For outdoor use emissions are considered negligible since this product is applied in bait stations placed above the ground and protected from rain events.
Groundwater simulation	Not relevant since negligible levels of indoxacarb are predicted to reach directly and indirectly the terrestrial compartment.
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: Yes
Remarks	Production of the active substance and formulation of the product takes place outside the EU. Therefore, the emissions from these two life-cycle steps are not assessed.

Emission estimation

The following bait stations can be used for indoor application only (A) and for indoor and outdoor applications (B), keeping granules in a contained space away from surfaces:

(A) Simple bait station

(B) Tamper resistant bait station

Scenario 1: **Use inside buildings (commercial, residential, agricultural and livestock sites/structures) as a bait station**

Emissions of the active substance to the environment following indoor treatment are considered negligible since the product is used in a bait station preventing any environmental exposure. In the ESD for PT 18 (OECD, 2008) it is stated that "*emissions to the environment during the treatment are negligible. The only possible emission is when the box is eliminated to waste during indoor uses*". Furthermore, waste disposal of the empty bait stations is considered to follow the national legislation and would not pose risk to the environment.
Considering this, the environmental risk assessment is not relevant for indoor use of the product ADVION GRANULES APPAT MOUCHES in commercial and residential structures or in livestock and agricultural structures.

Scenario 2 Use around buildings commercial, residential, agricultural and livestock sites/structures) as a bait station

The relevant scenario to estimate direct and indirect emissions of the active substance to the environment following outdoor treatment with ADVION GRANULES APPAT MOUCHES is described in the ESD for PT 18 (OECD, 2008) as the sub scenario "ant bait station". In this scenario, exposure to the environment is assumed as a result of 20% product remaining in the bait station which is then emitted via a) flooding/rain events and b) transport via the insects. Nevertheless, in case of the product ADVION GRANULES APPAT MOUCHES this sub scenario "ant bait station" is considered not representative, because:

- The product has to be placed above the ground in a way that it is protected from rain (e.g. under roof overhangs) and this instruction will be part of the product label. Therefore flooding or wash-off is no relevant emission pathway of the product into the environment.
- Environmental exposure as a result of the dispersal of contaminated flies remains a potential environmental release pathway. However, the relevance of this environmental fate pathway for fly baits is limited by the high dispersal rate of flies. The default 'receiving compartment' i.e. the total area of soil into which the active substance is assumed to disperse for bait traps for crawling insects is 0.5 m × 0.5 m × 0.5 m = 0.125 m^3 or 4.25 m^3 for the terrace scenario. Contaminated flies will

spread out over a much larger area than crawling insects, and a soil contamination *via* the dead flies is not foreseen.

Moreover, the TAB (2018), ENV 158 indicate:

"The product is intended either for use in bait stations (general public and professionals) or for any professional use, but only used on paved surfaces, and not on bare soil and the product is to be applied in roof-covered areas, which cannot be affected by flooding, and which are protected from rain fall or cleaning wash, thus emissions are unlikely to occur. Therefore no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment."

In conclusion, the emission to the environment following the outdoor use of the product ADVION GRANULES APPAT MOUCHES is assumed to be negligible.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway						
	STP	**Freshwater**	**Freshwater sediment**	**Air**	**Soil**	**Groundwater**
Scenario1 – Indoor	-	-	-	-	-	-
Scenario 2 – Outdoor	-	-	-	-	-	-

++ Direct emissions expected
+ Indirect emissions expected
- No emission expected

Summary of the physico-chemical, environmental fate and behaviour parameters for the active substance and its relevant metabolites according to the list of endpoints validated at EU level (AR, 2008)

Parameter / Variable	**Unit**	**Indoxacarb**	**IN-KT413***	**IN-JT333****
Molecular mass	[$g.mol^{-1}$]	527.8	512.8	469.8
Vapour pressure (20°C)	[Pa]	9.80E-09	-	-
Water solubility (20°C)	[$mg.L^{-1}$]	2.25E-01	-	-
Koc	[$L.kg^{-1}$]	5.13E+03	***	1.73E+04
Log Kow	[$L.kg^{-1}$, pH7]	4.60E+00	-	-
DT_{50} soil	[d at 12°C]	1.14E+01	-	-
BCF fish	[$L.kg_{wwt}^{-1}$]	9.51E+02	-	-
BCF earthworm	[$L.kg_{wwt}^{-1}$]	5.37E+02	-	-

STP fraction				
$F_{STP, water}$	[%]	5.50E+01	-	-
$F_{STP, sludge}$	[%]	4.50E+01	-	-

* – Relevant metabolite of indoxacarb in water and sediment with a maximum of 13.8% and 11% of applied radioactivity, respectively.
** – Relevant metabolite of indoxacarb in sediment with a maximum of 20.9% of applied radioactivity, respectively.
*** – Only a kfoc of 344 L/Kg availble

Calculated PEC values

PEC in STP

As stated above, negligible levels of indoxacarb are predicted to reach the STP compartment. PEC in STP is therefore not relevant.

PEC in surface water via STP

As stated above, negligible levels of indoxacarb are predicted to reach aquatic compartment. PEC in surface water is therefore not relevant.

PEC in sediment via STP

As stated above, negligible levels of indoxacarb are predicted to reach aquatic compartment. PEC in sediment is therefore not relevant.

PEC in soil (direct and indirect release via sludge application)

As stated above, negligible levels of indoxacarb are predicted to reach directly and indirectly the terrestrial compartment. PEC in soil is therefore not relevant.

PEC in groundwater

As stated above, negligible levels of indoxacarb are predicted to reach directly and indirectly the terrestrial compartment. PEC in groundwater is therefore not relevant.

Primary and secondary poisoning

Primary poisoning

According to the Emission Scenario Document for PT 18 (ESD PT 18)[15], the direct consumption of insecticidal products by birds and mammals mainly occurs when insecticides are applied together with food attractants or are applied as granular formulation. Both applies for ADVION GRANULES APPAT MOUCHES. Therefore primary poisoning has to be addressed for ADVION GRANULES APPAT MOUCHES.
However, ADVION GRANULES APPAT MOUCHES is supplied in bait stations which must be fixed in the upper part of walls and closed to the ceilings. The bait stations should be designed so that the baits are not accessible for birds and mammals. In case of spillage all excess granular product must be collected and disposed as stated on the product label.
Consequently, the risk for primary poisoning is considered as negligible for indoor and outdoor application since it is very unlikely that wild birds or mammals will gain access to the bait.

Secondary poisoning

Secondary poisoning may occur through consumption of flies having consumed the bait or earthworms exposed via soil or fish exposed via water or sediment.

Since the specific intended use of ADVION GRANULES APPAT MOUCHES in bait stations, exposure to the environment is assumed to be negligible and then, the risk of secondary poisoning for fish- and earthworms- eating birds and mammals is considered not relevant.

Regarding the risk of secondary poisoning for vertebrates consuming flies, a PT-specific exposure assessment is given in the ESD PT 18. This scenario is primarily developed for spray applications around buildings. Instead of the usual term PEC_{oral}, the estimated theoretical exposure (ETE) is used which considers interspecific variations of the exposed vertebrates.
Relevant indicator species for the assessment are presented. The sparrow (*Passer domesticus*) is the appropriate indicator species to be considered since its natural habitats are urban and rural areas and its main food type consists of small insects. No mammalian species are considered as relevant indicator species for the risk assessment of ADVION GRANULES APPAT MOUCHES since, for none of the presented mammalian species, the fly is considered as the main food type.
To estimate the theoretical exposure to a single sparrow, the following formula has to be applied according to the ESD PT 18:

$$ETE = (FIR/BW) \times C \times AV \times PT \times PD \text{ (mg/kg bw/d)}$$

FIR/BW = Food intake rate of indicator species (fresh weight) / body weight [g/d]
C = Concentration of active compound in fresh diet (bait) [mg/kg]
AV = Avoidance factor
PT = Fraction of diet obtained in treated area
PD = Fraction of food type in diet

In this case, the concentration of active compound in the fresh diet corresponds to the amount of a.s. in contaminated fly. To get an estimation of the concentration of active compound in the fresh diet, bee toxicity data derived from an acute oral toxicity study have been extrapolated to flies considering that the maximal load on the target will be the dose leading to mortality (Kling, 2017; see 2.2.8.1 New ecotoxicological study). The following parameters and endpoint were used in the calculations:

[15] Emission Scenario Document for Product Type 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, June 2008 (ENV/JM/MONO(2008)14)

Mass fly = 12 mg[16]
Mass bee = 100 mg
LD_{100} (oral) = 0.42 µg a.s./bee (S-enantiomer, corresponding to 0.557 µg S+R enantiomer/bee) (see Kling, A. (2017))

Assuming that the body-weight related dose that causes 100% mortality is similar for bees and flies, the resulting estimated LD_{100} of a single fly is 0.067 µg/fly (S+R enantiomer), corresponding to 5.58 mg a.s./kg food (flies).

When extrapolating the FIR of 18 g food/d (ESD PT 18) from the relevant indicator species sparrow to the $PNEC_{oral}$ (4.8 mg a.s./kg food, Assessment Report Indoxacarb) this corresponds to 0.0864 mg a.s./18 g food. To calculate the corresponding number of dead flies, this value was divided by the LD_{100} of a single fly (0.067 µg/fly). Therefore, a single sparrow has to ingest 1289 contaminated flies within one day to achieve the $PNEC_{oral}$. This value is in the same range as the total daily amount of 1500 flies a sparrow has to ingest to achieve its FIR. According to these calculations, birds would have to consume 86% of their daily diet in form of contaminated flies to ingest a dose that corresponds to the PNEC. Considering the dispersion of flies and the diversity of the food consumption, this scenario is considered over conservative.

Additionally, flies are very mobile and will leave the bait station and fly around for a short time after ingesting the bait. Thus, dead flies will be distributed over a wider area and might become accessible for birds, but will not accumulate on one place. In a study by Stafford et al (2002)[17], the question whether birds consume invertebrates that are killed by a chemical application was investigated by offering live, fresh-dead and desiccated insects to birds. The study was divided into a laboratory test and a field test. In the laboratory trials, these 3 food sources were individually offered to wild-caught birds. In the field study the same food choices were offered to birds in plots placed in two agricultural crops, a cornfield and an orchard. It can be concluded that dead insects are not an attractive food source and that birds show a clear preference for alive over dead insect prey as food. Movement of the insects was described as the primary stimulus or major factor for birds to locate their prey. Birds are hunting specifically for visual cues e.g. live and moving prey and completely over-looking all relatively rare food items like dead or desiccated insects.

In conclusion, a risk via the consumption of contaminated flies can be considered as acceptable.

[16] Draft Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment & Evaluation (Parts B+C), version 4.0, p. 63

[17] Stafford, J.M., Brewer, L.W., Gessaman, J.A. (2002): Avian food selection with application to pesticide risk assessment: Are dead and desiccated insects a desirable food source? Environmental Toxicology and Chemistry, Vol. 22, No. 6, pp. 1335 - 1339

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:
The vapour pressure of the two isomers DPX-KN128 and DPX-JW062 is very low (9.8 × 10-9 Pa and 1.3 × 10-10 Pa, respectively) indicating that DPX-MP062 is not volatile. This is further supported by the fact that the product is formulated as a solid bait. Thus, it can be concluded that the use of ADVION GRANULES APPAT MOUCHES does not pose an unacceptable risk to the air compartment.

Sewage treatment plant (STP)

Conclusion:

As negligible levels of indoxacarb are predicted to reach the STP, the level of risk is considered to be acceptable.

Aquatic compartment

Conclusion:

As negligible levels of indoxacarb are predicted to reach the aquatic compartment, the level of risk is considered to be acceptable.

Terrestrial compartment

Conclusion:

As negligible levels of indoxacarb are predicted to reach the terrestrial compartment, the level of risk is considered to be acceptable.

Groundwater

Conclusion:

As negligible levels of indoxacarb are predicted to reach the groundwater, the level of risk is considered to be acceptable.

Primary and secondary poisoning

Primary poisoning

ADVION GRANULES APPAT MOUCHES is supplied in bait stations which must be fixed in the upper part of walls and closed to the ceilings. The bait stations should be designed so that the baits are not accessible for birds and mammals. In case of spillage all excess granular product must be collected and disposed as stated on the product label.
Consequently, the risk for primary poisoning is considered as negligible for indoor and outdoor application since it is very unlikely that wild birds or mammals will gain access to the bait.

Secondary poisoning

Since the specific intended use of ADVION GRANULES APPAT MOUCHES in bait stations, environmental exposure is assumed to be negligible and then, the risk of secondary poisoning for fish- and earthworms- eating birds and mammals is not relevant.
Based on a quantitative assessment, the risk for birds and mammals consuming the target pest is considered as acceptable.

Mixture toxicity

As negligible levels of indoxacarb are predicted to reach the environment, no assessment of mixture toxicity has been carried out.

Aggregated exposure (combined for relevant emmission sources)

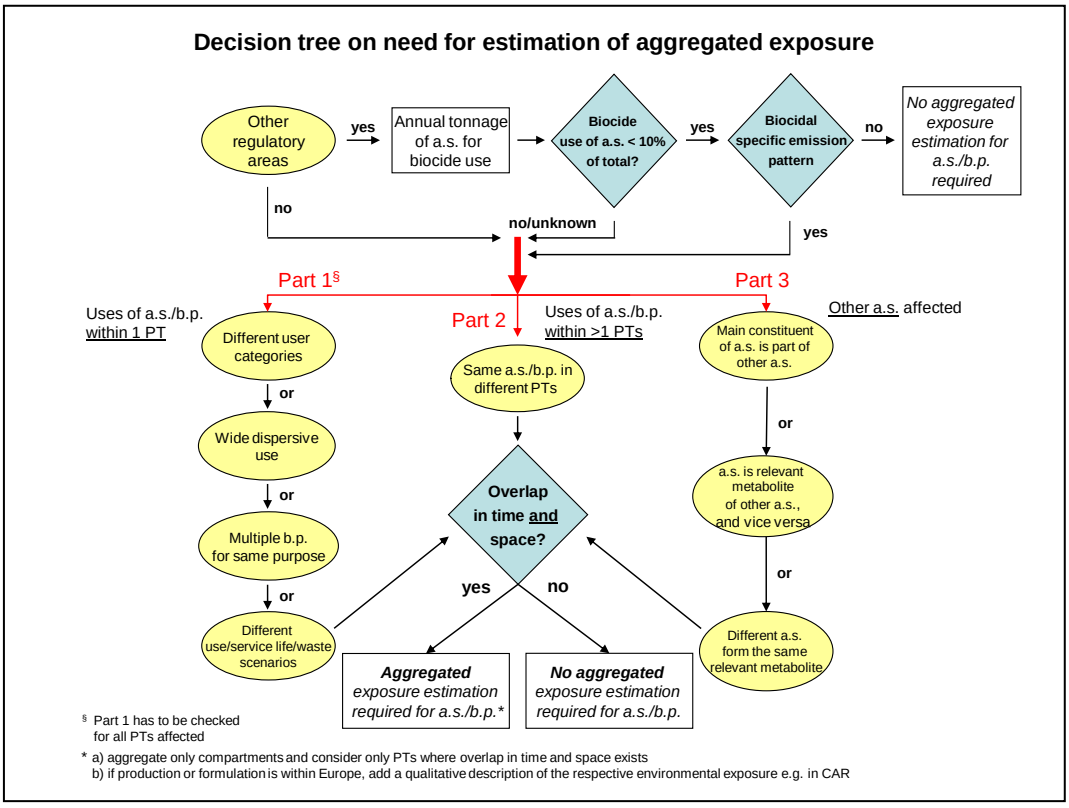

Figure 1: Decision tree on the need for estimation of aggregated exposure

Not relevant

Overall conclusion on the risk assessment for the environment of the product
The overall conclusion of the environmental risk assessment for the product ADVION GRANULES APPAT MOUCHES is that acceptable risk is identified for primary and secondary poisoning and for all environmental compartments. This is based on the assumption that this product is only to be used in bait stations placed off the ground on the wall or suspended and designed for use with granular fly control baits and to protect the product from rainfall. Various specific risk mitigation measures and instructions for safe disposal must be applied during application and service life to ensure that emissions cannot reach environmental compartments: - Bait stations that are specifically designed to prevent the release of granular baits, and any exposure of non target animals, must be used - Bait stations must be placed off the ground, attached on the wall or suspended - For outdoor uses, bait stations must be tamper resistant designed to protect the bait from rainfall and must be placed in areas protected from wet conditions and out of

reach from non-target animals.

- For indoor uses, 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.
- All bait stations must be removed before cleaning and / or disinfection of livestock, residential and commercial sites/structures.
- 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

2.2.9 **Measures to protect man, animals and the environment**

Please refer to the summary of product characteristics (SPC).

2.2.10 **Assessment of a combination of biocidal products**

Not relevant

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
Schilling, W	2017	A21741A - PHYSICAL PROPERTIES OF BATCH 956724 Syngenta Crop Protection, Inc., NC, USA Syngenta Report n°USGR170020 GLP study Unpublished	Yes	Syngenta	2017
Schilling, W	2017	A21741A - STORAGE STABILITY AND SHELF LIFE STATEMENT (2 WEEKS AT 54°C) OF BATCH 956724 IN PACKAGING MADE OF HDPE ACCORDING TO CIPAC MT 46.3 Syngenta Crop Protection, Inc., NC, USA Syngenta Report n°300086404 GLP study Unpublished	Yes	Syngenta	2017
Schilling, W	2017	A21741A - STORAGE STABILITY AND SHELF LIFE STATEMENT (2 WEEKS AT 54°C) OF BATCH 956724 IN PACKAGING MADE OF PP ACCORDING TO CIPAC MT 46.3 Syngenta Crop Protection, Inc., NC, USA Syngenta Report n°300086820 GLP study Unpublished	Yes	Syngenta	2017
Jackson, W.	2017	INDOXACARB A21741A - SAFETY STUDY FINAL REPORT Process Hazards Section Syngenta Technology & Engineering, Huddersfield, UK Syngenta Report n°HT16/583 GLP study Unpublished	Yes	Syngenta	2017

Shi, N.	2017	INDOXACARB A21741A – VALIDATION OF ANALYTICAL METHOD SF-895/1 FINAL REPORT Syngenta Crop Protection, LLC 410 Swing Road Greensboro, NC 27409 USA Syngenta Report n°USGR160256 GLP study Unpublished	Yes	Syngenta	2017
Sihvonen, S.	2017	BITREX A21741A - VALIDATION OF ANALYTICAL METHOD SFA-895/1 FINAL REPORT Syngenta Crop Protection, LLC 410 Swing Road Greensboro, NC 27409 USA Syngenta Report n°USGR170162 GLP study Unpublished	Yes	Syngenta	2017
Linn, C.	2017a	Laboratory test to determine the efficacy of granule products against house flies. BioGenius GmbH Syngenta Report-no. BIO100a-17 (PPME17 203) GLP/GEP: no Published: no	yes	SYN	
Miller, P.F., Peters, B.A.	2017	Semi-field evaluation of syngenta and competitor granular and paint-on fly baits against houseflies. Insect Research Laboratory Faculty of Science University of Technoly, Sydney, Australia Syngenta Report-no. R16-2083, PPMA 16273 GLP/GEP: no Published: no	yes	SYN	
Buczkowski, G.	2017a	Field evaluation of indoxacarb fly bait against the house fly, *Musca domestica* in a commercial swine facility. Center for Urban and Industrial Pest Management Department of Entomology Purdue University West Lafayette, IN Syngenta	yes	SYN	

		Report-no. 6/15/17, PPME16251 GLP/GEP: no Published: no			
Buczkowski, G.	2017b	Laboratory evaluation of fresh and aged indoxacarb fly bait against the house fly, *Musca domestica.* Center for Urban and Industrial Pest Management Department of Entomology Purdue University West Lafayette, IN Syngenta Report-no. PPME17207 GLP/GEP: no Published: no	yes	SYN	
Parker, R.	2017	Laboratory bioassay to determine the efficacy of fly bait formulations against housefly, *Musca domestica*. i2L Research Ltd., Cardiff UK Syngenta Report-no. 17/140, PPME17201 GLP/GEP: no Published: no	yes	SYN	
Linn, C.	2017b	Simulated-use test to determine the efficacy of granule products against house flies. BioGenius GmbH Syngenta Report-no. BIO102a-17 (PPME17205) GLP/GEP: no Published: no	yes	SYN	
Hoppé, M., Hofer, D.	2017	Protocol: does the insecticidal activity of indoxacarb fly bait decline with time? Syngenta Crop Protection AG Syngenta Report-no. PPME17501 GLP/GEP: no PUBLISHED: NO	yes	SYN	

Werner, L.	2018	Biological test report, laboratory test to determine the efficacy of granule products against house flies. Syngenta Crop Protection AG Syngenta Report-no. PPME18 040a – BIO002b-18 GLP/GEP: no Published: NO	yes	SYN	
Hoppé, M. et al.	2018a	Evaluation of indoxacarb fly bait for efficacy against filth flies/blow fly. Syngenta Crop Protection AG Syngenta Report-no. PPMG18202/B – PH WST 18 002 GLP/GEP: no PUBLISHED: NO	yes	SYN	
Hoppé, M. et al.	2018b	Evaluation of indoxacarb fly bait for efficacy against filth flies/blow fly. Syngenta Crop Protection AG Syngenta Report-no. PPMG18205 – PH WST 18014 GLP/GEP: no PUBLISHED: NO	yes	SYN	
Kling A.	2017	Indoxacarb RB (A21741A) – Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. under laboratory conditions. Syngenta Ltd, UK. Report Number: S17-04771.	yes	SYN	

3.2 Output tables from exposure assessment tools

Human heath risk assessment:

expo ADVION FLY GRANULAR BAIT .xls:

3.3 Confidential annex

See confidential annex.