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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

BASF DocID 2021/2035507

Seclira Fly Bait

Product type 18

Dinotefuran as included in the Union list of approved active substances

Case Number in R4BP: BC-AE041512-68

Evaluating Competent Authority: eCA NL

Date: 27/09/2023

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1 CONCLUSION

The overall conclusion from the evaluation of the biocidal product, Seclira Fly Bait, containing 0.5 % w/w of the active substance dinotefuran, is that the active substance will not present an unacceptable risk to humans during and after the intended use of the product. Furthermore, the active substance will not present an unacceptable risk to animals and to the environment when following the label instructions of the biocidal product.

APCP

The biocidal product SECLIRA FLY BAIT is a flammable aerosol (AE) with an ignition distance of 90 cm. The biocidal product has supported shelf life of 3 years in PET or PE or PP coated metal can. The biocidal product should not be stored above 40°C. According to the CLP regulation, the product is classified as extremely flammable aerosol and pressurized contained, may burst if heated. Further, the biocidal product is not classified for any other physical hazards.

Conclusion on efficacy

Efficacy has been shown at the application rate of 16 g product /m² (which is equivalent to spraying for 3 seconds per linear meter) against house flies (*Musca domestica*, adults) indoor by non-professional and (trained) professional users and against (*Musca domestica*, adults) and stable flies (*Stomoxys calcitrans,* adults) in animal buildings on farms by non-professional and (trained) professional users.

Conclusion on Human Health

The risk assessment for the professional and non-professional users, including the worst case exposure by a combination of application of the product (scenario 1), washing of coveralls (scenario 2) and touching of treated areas (scenario 3) resulted in safe use for both professional and non-professional use in tier 1 assessment.

The risk assessment results in safe exposure for the general population after accidental exposure to treated surfaces for all intended uses. Combined exposure for adults applying the product and in contact with treated surfaces has been found safe.

For dietary exposure assessment, animals are exposed via inhalation, dermal and oral: through inhalation of the product itself (considered worse case as the product should not be used directly on animals), oral (through licking/chewing behaviour) and dermal, through rubbing behaviour. The product is to be applied to the 10% to the area (spot treatment). Therefore, it is not likely that animals will be constantly in contact with the product. Moreover, the product is used where flies congregate, which is likely a place not too close to the animals. Furthermore, the label instructions for use specify the following:

- Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.
- Do not store near food, drink and feed.

- Do not use near domestic animals or livestock.
- Do not apply directly on animals.

As worst case, the WCCE was calculated for exposure to spray drift.).

Considering the WCCE and the comparison to the ADI for chronic exposure or to the ARfD for acute exposure result in %ADI or %ARfD values <1% using EMA Food Basket or EFSA PRIMo v3.1, there is no concern for consumers after exposure to residues after the use of Seclira Fly Bait. In addition, the calculated residues in products from animal origin are compliant to existing MRLs (i.e. MRL values are included in Reg. (EU) No 491/2014; 0.1 mg/kg for food of animal origin, excluding poultry and eggs that is set at 0.02 mg/kg)

As the biocidal product is used as an insecticide in animal housing (PT18), secondary exposure of livestock animals towards residues of the active substance cannot be excluded. Based on the worst case assessment, based on the toxicity-exposure-ratio (TER) approach, the use of Seclira fly bait in animal housing is considered of no concern for all animals as all values are (much) higher than 5. Animal exposure is considered of no concern and no further evaluation is needed.

Conclusion Environment

The risk assessment for Seclira Fly Bait has been conducted for 3 use scenarios:

- non-professional (general public) use inside domestic buildings against flies via barrier treatments;
- professional and trained professional use inside domestic and large buildings against flies via barrier treatments;
- non-professional, professional and trained professional use inside animal buildings on farms against flies via barrier treatment.

Emission to the municipal sewer is not foreseen as the applicant added a risk mitigation measure to the SPC forcing that the product is not applied in stables with connection to the municipal sewer.

The PEC/PNEC ratios in all environmental compartments of relevance for dinotefuran, MNG and DN are <1. Dinotefuran groundwater concentrations were < 0.1 µg/l for all soil types in Pearl. On basis of the original CAR parameters for MNG all groundwater concentrations are below 0.1 µg/L, except for emission of treated manure to grassland on Jokioinen soil. Member states where this use and Jokioinen soil type is relevant a refinement can be considered taking into consideration updated endpoints for the Koc and freundlich adsorption coefficient (1/n) from studies evaluated by the eCA, but due to the late submission not discussed for EU harmonisation. Pearl calculations using these parameters show MNG groundwater concentrations <0.1 ug/L also in this soil type.
Therefore acceptable risk has been demonstrated following the intended uses of SECLIRA FLY BAIT in accordance with the SPC.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
SECLIRA FLY BAIT	The Netherlands (Reference Member State)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BASF Nederland B.V.
	Address	Groningensingel 1, 6835 EA Arnhem, Netherlands
Authorisation number	Not yet available	
Date of the authorisation	Not yet available	
Expiry date of the authorisation	Not yet available	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	BASF Corporation
Address of manufacturer	100 Park Avenue –Florham Park – NJ 07932 United States of America
Location of manufacturing sites	PLZ Aeroscience 1101 Integram Drive Pacific, MO 63069 USA Czech Aerosol, a.s. Velvěty 33 415 01 Rtyně nad Bílinou Czech Republic AEROSOL SERVICE GmbH Helmstedter Str. 58 c 38126 Braunschweig Germany JagoPRO Sp.z o.o. Szczakowska Street 35 43-600 Jaworzno Poland

[1] Seclira Fly Bait

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Dinotefuran
Name of manufacturer	LKC Chem-Regs Ltd (Acting for Mitsui Chemicals Crop & Life Solutions, Inc., Japan) Ireland
Address of manufacturer	Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027 Japan
Location of manufacturing sites	Mitsui Chemicals Inc./Omuta Works, 30 Asamuta-Machi, Ohmuta Shi, Fukuoka, 836-8610 Japan

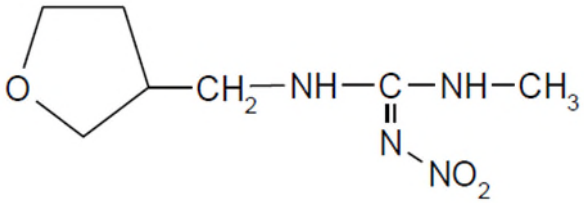
2.1.2 Product composition and formulation

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	Dinotefuran
IUPAC or EC name	(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine
EC number	None assigned
CAS number	165252-70-0
Index number in Annex VI of CLP	Not listed
Minimum purity / content	99.1 % w/w (991 g/kg)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Dinotefuran is identified as a candidate for substitution in accordance with BPR Article 10(1)(d), meeting two of the PBT criteria for very persistent/persistent (vP/P) in water and toxic (T) to insects, but not meeting the criteria for bioaccumulation and does not meet the exclusion criteria of BPR Article 5(1) as detailed in the Dinotefuran PT18 Assessment Report (November 2015). During the public consultation on potential candidates for substitution between 29/11/2013 and 28/01/2014, no additional information was provided to ECHA.

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 (% w/w)
Dinotefuran	(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine	Active substance	165252-70-0	None assigned	0.501 (Pure) 0.505 (Technical)
Acetone	Acetone	Non-active substance	67-64-1	200-662-2	25.3

2.1.2.4 Information on technical equivalence

The notified source of dinotefuran (Mitsui Chemicals Crop & Life Solutions, Inc.) is the same as that identified in the Dinotefuran PT18 Assessment Report (November 2015) for active substance approval.

A letter of access has been provided to the applicant for authorisation (BASF Nederland B.V) by the active substance source Mitsui Chemicals Crop & Life Solutions, Inc. permitting eCA NL access to the active substance dossier on behalf of BASF Nederland B.V.

2.1.2.5 Information on the substance(s) of concern

Acetone

Toxicology: Acetone is contained in the product at a concentration > 20% and is classified for STOT SE 3; H336. It will therefore contribute to the classification of SECLIRA FLY BAIT and be considered as a SoC Band A when applying the banding scheme (ECHA Guidance on BPR: Volume III Parts B+C, Version 4.0, Dec. 2017). No quantitative risk assessment is required for SoCs in Band A. Appropriate risk mitigation measures, in the form of precautionary statements normally associated with the concerned hazard statements triggered by STOT SE 3; H336 are applied to the formulation: P261, P271, P304+P340, P312, P403+P233, P405, P501.

IOELV values have been set for acetone (limit values (8hrs) 1210 mg/m³; 500 ppm) established by the Scientific Committee on Occupational Exposure Limits (SCOEL) pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC therefore it also qualifies as a potential SoC Band C, triggering the need for a quantitative exposure assessment of acetone through the use of the Seclira Fly Bait.

Information on endocrine disruption properties

An assessment of the endocrine disruption is presented in section "Assessment of effects" for human health aspect and in section "Effects assessment on the environment" for the environmental aspect, and the confidential annex.

For the active substance Dinotefuran no ED assessment is required because for active substance which have been approved, the EU assessment should be followed. The Assessment Reports for Dinotefuran (2014) state that this active substance would not be considered as having endocrine disrupting properties. However, for the active substance, a current review on ED properties is taking place at the moment of evaluation of this dossier. Therefore, CA NL concludes that we have to await the discussions at EU level.

For none of the co-formulants an ED alert was identified. See the confidential annex for more specific information.

In conclusion, based on available information, it is not possible to conclude whether the active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties the active substance is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

2.1.2.6 Type of formulation

AE = aerosol dispenser (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aerosol category 1 STOT single exposure category 3 Aquatic chronic 2
Hazard statement	H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated H336: May cause drowsiness or dizziness H411: Toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated H336: May cause drowsiness or dizziness H411: Toxic to aquatic life with long lasting effects
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P210 : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after use. P261: Avoid breathing spray. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor/.../if you feel unwell. P391 Collect spillage P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C. P501: Dispose of contents/container to hazardous or special waste collection point.
Note	**GHS02: flame** **GHS07: exclamation mark** **GHS09: environmental hazard**

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Urban pest control, professional and trained professional use

Product Type	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies - adults
Field of use	Indoor: Industrial/commercial premises Households/private areas Public buildings e.g., hospitals, nursing homes
Application method(s)	Spot treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter. Residual efficacy is up to 6 weeks. Maximum of 11 applications per year
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	250, 300, 350, 400, 500 and 600 mL Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated.

Table 2. Use # 2 – Urban pest control, non-professional use

Product Type	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies - adults
Field of use	Indoor: Domestic buildings/households/private areas
Application method(s)	Spot treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter. Residual efficacy is up to 6 weeks. Maximum of 11 applications per year
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100, 150, 200 and 250 mL

	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated.

Table 3. Use # 3 – Rural hygiene (animal buildings on farms), professional and trained professional use

Product Type	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies – adults *Stomoxys calcitrans* – Stable fly – adults
Field of use	Indoor: Animal buildings on farms
Application method(s)	Spot treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter Treat up to a maximum of 10 % of the walls and ceiling area depending on the level of infestation at locations where flies often reside. Residual efficacy is up to 6 weeks. Maximum of 6 applications per year.
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	250, 300, 350, 400, 500 and 600 mL Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated.

Table 4. Use # 4 – Rural hygiene (animal buildings on farms), non-professional use

Product Type	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies – adults *Stomoxys calcitrans* – Stable fly – adults
Field of use	Indoor: Animal buildings on farms
Application method(s)	Spot treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter Treat up to a maximum of 10 % of the walls and ceiling area depending on the level of infestation at locations where flies often reside. Residual efficacy is up to 6 weeks.

	Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100, 150, 200 and 250 mL Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated.

2.1.4.2 Use-specific instructions for use

Use #1 & 2: A number of 11 application(s) per year shall not be exceeded

Use #3 & 4: The treated wall and ceiling surface shall not exceed 10%, which corresponds with 20 m² treated surface per 100 m² floor size depending on the level of infestation at locations where flies often reside. A number of 6 application(s) per year shall not be exceeded.

2.1.4.3 Use-specific risk mitigation measures

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Use #3 & 4: Do not use in animal housings where exposure to a STP or direct emission to surface water cannot be prevented.

Use #3 & 4: Do not use in veal calf animal housing.

Please see general risk mitigation measures.

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

Please see general directions for use.

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

Please see general directions for use.

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

Please see general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use

Seclira Fly Bait (BAS 395 18 I) should be applied indoor throughout the infested area on surfaces on which the flies may settle.
Focus application in areas where flies congregate or settle (warm wall areas, pen partitions, posts, window frames, pipes, outside of feeding troughs, windows, doors, roof beams, edge of beams, eaves, door frames, electrical conduit, sprinklers etc.).

The product is applied at a distance of 30 cm from the surface to be treated.

Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter.

Treated areas should be re-inspected after 2 – 3 weeks. Where initial infestation was severe a second application may be required, particularly if the first treatment has been disturbed or some harbourages/landing sites were missed in the initial application.
Allow the applied solution to dry before re-entry into the treated areas by either humans or animals.

Residual activity: the residual life of the deposit will vary depending upon the cleanliness and nature of the surface to which it is applied, and the extent to which the residue remains undisturbed. For residual activity up to 6 weeks, treated surfaces should not be (wet) cleaned during this time period, but removal of dead flies on a regular basis is recommended. Wet cleaning of surfaces is recommended only after the desired efficacy is achieved.

Apply only on non-porous surfaces

For professional and trained professional use:
Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.

For general public (non-professional use):
If the infestation persists contact a professional.

To avoid the build-up of resistance:

- Always read the label or leaflet before use and follow all the instructions provided.
- Do not [use/apply] the product in areas where resistance to the active substance contained in this product is suspected or established.
- 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 authorisation holder if the treatment is ineffective.

Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population)

2.1.5.2 Risk mitigation measures

Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Avoid breathing spray.
Provide adequate ventilation (industrial ventilation or keeping windows and doors open). The stay in the treated area should be minimised.
Do not apply directly on animals.
For use only in areas that are inaccessible to children, pets and non-target animals.
Do not use near domestic animals or livestock

Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.

Wet cleaning of surfaces is recommended only after the desired efficacy is achieved.
This biocidal product contains dinotefuran which is dangerous to bees

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
Call a POISON CENTER or doctor/physician if you feel unwell.
If medical advice is needed, have product container or label at hand

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of container to hazardous or special waste collection point.

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

Shelf-life is 3 years.

Store in a well-ventilated place.
Protect from sunlight. Do not store above 40°C.

Keep out of reach of children and non-target animals/pets
Do not store near food, drink and feed.

2.1.6 Other information

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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)
Self-pressurised low pressure aerosol can	250, 300, 350, 400, 500 and 600 mL	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated can	Plastic Actuator	Professional, Trained professional	Yes
	100, 150, 200 and 250 mL			Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New data on the active substance and data on the biocidal product are submitted in support of this application for product authorisation. The list of new submitted studies can be found in the list of references in Annex 3.

2.1.8.2 Access to documentation

A letter of access to active substance data which supports the active substance approval and to new active substance data is provided to eCA NL to evaluate on behalf of the applicant for authorisation, BASF Nederland B.V. The active substance data are proprietary and the new active substance data will be provided directly to eCA NL by the representative of the data owner (detailed in the letter of access, Doc ID2021/2043744).

The relationship between the active substance data submitter and the active substance data owner/manufacturer is described in a Letter of Appointment (Doc ID 2018/1233874).

A list of the new active substance data can be found in Annex 3.3.

2.2 Assessment of the biocidal product

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

The uses below are the ones applied for by the applicant, without any changes by the eCA. These uses are assessed in the following chapters.

See 2.1.4. for the authorised uses, after assessment of the dossier.

Table 5. Intended use # 1 – Urban pest control, professional and trained professional use

Product Type(s)	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies - adults
Field of use	Indoor: Industrial/commercial premises Households/private areas Public buildings e.g., hospitals, nursing homes
Application method(s)	Barrier treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter Maximum of 11 applications per year
Category(ies) of user(s)	Professional and trained professional
Pack sizes and packaging material	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated or Tinplate can.

Table 6. Intended use # 2 – Urban pest control, non-professional use

Product Type(s)	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies - adults
Field of use	Indoor: Domestic buildings/households/private areas
Application method(s)	Barrier treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter

	Maximum of 11 applications per year
Category(ies) of user(s)	General public (non-professiona)l
Pack sizes and packaging material	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated or Tinplate can.

Table 7. Intended use # 3 – Rural hygiene (animal buildings on farms), professional and trained professional use

Product Type(s)	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies – adults *Stomoxys calcitrans* – Stable fly – adults
Field of use	Indoor: Animal buildings on farms
Application method(s)	Barrier treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter Maximum of 6 applications per year.
Category(ies) of user(s)	Professional and trained professional
Pack sizes and packaging material	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated or Tinplate can.

Table 8. Intended use # 4 – Rural hygiene (animal buildings on farms), non-professional use

Product Type(s)	PT18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Musca domestica* – House flies – adults *Stomoxys calcitrans* – Stable fly – adults
Field of use	Indoor: Animal buildings on farms
Application method(s)	Barrier treatment with a ready to use aerosol dispenser at a distance of 30 cm from the surface to be treated.
Application rate(s) and frequency	Apply 16 g product / m² which is equivalent to spraying for 3 seconds per linear meter Maximum of 6 applications per year.
Category(ies) of user(s)	General public (non-professional)

Pack sizes and packaging material	Metal can PP (Polypropylene) coated or PE (polyethylene) coated or PET (Polyethylene terephthalate) coated or Tinplate can.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual	0.5% dinotefuran Batch #: 2017-002B	Liquid	[redacted] (2018) DocID: 2018/7005854
21Colour at 20 °C and 101.3 kPa	visual	0.5% dinotefuran Batch #: 2017-002B	Colourless	[redacted] (2018) DocID:2018/7005854
Odour at 20 °C and 101.3 kPa	olfactory	0.5% dinotefuran Batch #: 2017-002B	Solvent like	[redacted] (2018) DocID: 2018/7005854
Acidity / alkalinity	CIPAC MT 75.3 OPPTS 830.7000	0.5% dinotefuran Batch #: 2017-002B	pH 10% v/v dilution: 6.25 Temperature: 24.5°C	[redacted] (2018) DocID: 2018/7005854
	OPPTS 830.7000	0.5% dinotefuran Batch #: 19317PZ5	pH neat product: 5.926 ± 0.003 Temperature: 24.9°C	[redacted] (2021) DocID: 2021/2047539
Relative density / bulk density	OPPTS 830.7300, OECD 109, EU A.3	BAS 395 18 I Batch #: 2017-002B 0.5% dinotefuran	Relative density: $D_4^{20} = 1.008$ at 20 °C	[redacted] (2018) DocID: 2018/7001799
Storage stability test – **accelerated storage**	OPPTS 830.6317 similar to MT 46.3 visual and olfactory inspection	BAS 395 18 I Batch #: 2017-002B 0.5% dinotefuran	Parameter / Before storage / After storage (2 wks) at 54°C in PET coated stainless-steel aerosol can Physical state / liquid / liquid	[redacted] (2018) DocID: 2018/7005854

<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></tr>
<tr><td></td><td>validated HPLC-DAD
CIPAC 75.3
FAO/WHO 8.11.4.2
FAO/WHO 8.11.4.3
FAO/WHO 8.11.4.5</td><td></td><td>
<table>
<tr><td>Colour</td><td>colourless</td><td>Yellow</td></tr>
<tr><td>Odour</td><td>Solvent like</td><td>Solvent like</td></tr>
<tr><td>Weight</td><td>570.59 g</td><td>570.50 g</td></tr>
<tr><td colspan="3">Weight loss: -0.02%</td></tr>
<tr><td>a.s. content</td><td>0.511%</td><td>0.508% (decrease of 0.6%)</td></tr>
<tr><td>pH 10% v/v dilution</td><td>6.250 (T: 24.5°C)</td><td>6.206 (T: 23.3°C) (decrease of 0.7%)</td></tr>
</table>
</td><td></td></tr>
<tr><td></td><td>OPPTS 830.6317</td><td>0.5% dinotefuran
Batch #: 19317PZ5</td><td>
<table>
<tr><th>Parameter</th><th>Before storage</th><th>After storage (8 wks) at 40°C</th></tr>
<tr><td>Discharge rate</td><td>1.273 g/second at 25.0°C</td><td>1.242 g/second at 25.0°C</td></tr>
<tr><td>Internal pressure</td><td>35 psi</td><td>33 psi</td></tr>
<tr><td>Clogging of valves</td><td>No clogging</td><td>No clogging</td></tr>
</table>
</td><td>[redacted] (2021)
DocID: 2021/2039170</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>visual and olfactory inspection

validated HPLC

OPPTS 830.6317
OPPTS 830.6320
OPPTS 830.6302
OPPTS 830.6303</td><td>0.5% dinotefuran
Batch #: 2017-002B</td><td>
<table>
<tr><th>Parameter</th><th>Before storage</th><th>After 24 months storage in PET coated stainless-steel aerosol can</th><th>After 36 months storage in PET coated stainless-steel aerosol can</th></tr>
<tr><td>pH (1 % w/w)</td><td>4.05</td><td>4.54</td><td>4.83</td></tr>
</table>
</td><td>[redacted] (2022)
DocID: 2022/2055142

[redacted] (2021)
DocID: 2021/2037703
-2 yr interim

[redacted] (2021)
Doc ID: 2021/2032895</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	OPPTS 830.6304 OPPTS 830.7000			

Internal pressure (psi)	34.3 ± 0.4	44 ± 1.0	40 ± 0.6
Discharge rate (g/sec)	1.01	1.14	1.01
Clogging of dispenser valves	No clogging observed	No clogging observed	No clogging observed
Spray pattern	Replicates homogenous	Replicates homogenous	Replicates homogenous
a.s. content	0.511% w/w	0.499% w/w (decrease of 2.3%)	0.473% w/w (decrease of 7.4%)
Combined weight of container and test substance	559.21 g	decrease of 0.05% ± 0.03)	decrease of 0.15% ± 0.04
Appearance	clear yellow liquid with sharp pungent odour	clear light-yellow liquid with sharp alcohol-like odour	clear light-yellow liquid with sharp alcohol-like odour

Property	Guideline and Method	Purity of the test substance % (w/w)	Results				Reference
			Reactivity towards the container material	Commercial packaging: PET coated stainless-steel aerosol can	No corrosion of the storage container (PET coated stainless-steel aerosol can) was observed	No corrosion of the storage container (PET coated stainless-steel aerosol can) was observed	

<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></tr>
<tr><td colspan="5">eCA Remark: The measured pH in the long-term storage stability study ranged from 4.05 – 4.83. This pH was determined for 1% water solution. Those values of the pH are unexpectedly low compared to the pH of the neat solution, i.e., 5.926. That unexpected low pH was likely caused by the use of deionized water. Since the Seclira Fly Bait biocidal product is not intended to be diluted with water, this is unrealistic situation and cannot suggest issues with the stability of the biocidal product. Therefore, eCA considers the long-term storage stability study acceptable.</td></tr>
<tr><td colspan="5">eCA Remark: The MMAD has to be determined before and after the storage. The applicant determined the MMAD only for the fresh product. Since the other spray characteristics after the storage were acceptable, we expect that the MMAD will not be dramatically different from the measured values for the fresh product. Moreover, the other aspects do not use the MMAD values.</td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 39.3</td><td>0.5% dinotefuran Batch #: 2017-002B</td><td><table><tr><th>Parameter</th><th>Before storage</th><th>After storage (7 days at 0 °C)</th></tr><tr><td>Physical state</td><td>liquid</td><td>liquid</td></tr><tr><td>Colour</td><td>colourless</td><td>colourless</td></tr><tr><td>Separation</td><td>Homogeneous</td><td>Homogeneous (No separation of phase observed)</td></tr></table></td><td>[redacted] (2017)
Doc ID: 2017/7016032</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td>-</td><td>-</td><td colspan="2">Data waiving since the product is packed in a stainless-steel PP or PE or PET coated can which is light impervious.</td><td>Data waiver provided</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product –</td><td>OPPTS 830.6317 similar to CIPAC MT46.3</td><td>0.5% dinotefuran Batch #: 2017-002B</td><td colspan="2">Temperature: The test item was found stable under the accelerated storage conditions (54°C). No changes in physical state, odour, pH, and active ingredient content were observed. No corrosion of the stainless-steel aerosol can was noticed.</td><td>[redacted] (2018)
DocID: 2018/7005854</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
temperature and humidity			**Humidity**: Data waiving since the product is packed in a stainless steel can protected from humidity.	
eCA remark: From a significant part the product consists of water and therefore it is expected that the effect of humidity will be negligible.				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	OPPTS 830.6320	0.5% dinotefuran Batch #: 2017-002B	After the accelerated storage conditions and 3year storage, no corrosion of the stainless-steel PET coated aerosol can was noticed.	[redacted] (2018) DocID: 2018/7005854 [redacted] (2018) Doc ID: 2021/2032895 (replaces 1 yr interim report DocID 2018/7007503)
Wettability	-	-	Not applicable to the formulation	Data waiver provided
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable to the formulation	Data waiver provided
Wet sieve analysis and dry sieve test	-	-	Not applicable to the formulation	Data waiver provided
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable to the formulation	Data waiver provided
Disintegration time	-	-	Not applicable to the formulation	Data waiver provided
Particle size distribution, content of dust/fines, attrition, friability	OPPTS 830.7520 CIPAC MT 187	0.5% dinotefuran Batch #: 19317PZ5	Particle size analysis using small volume (wet) module (SVM) / Average (µm) Volume weighted mean: 108 Median (d.50): 112	[redacted] (2021) DocID 2021/2047539

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Mode 141 10 % of material is < 13.6 50 % of material is < 112 90 % of material is < 188 By volume of sample was seen to be < 10.00 µm 5.95%	
Persistent foaming	-	-	Not applicable to the formulation	Data waiver provided
Flowability/Pourability/Dustability	-	-	Not applicable to the formulation	Data waiver provided
Burning rate — smoke generators	-	-	Not applicable as the test item is not a smoke generator	Data waiver provided
Burning completeness — smoke generators	-	-	Not applicable as the test item is not a smoke generator	Data waiver provided
Composition of smoke — smoke generators	-	-	Not applicable as the test item is not a smoke generator	Data waiver provided
Spraying pattern — aerosols	European Aerosol Foundation, FEA 644E	0.5% dinotefuran Batch #: 2017-002B	The spray patters were recorded in 30cm distance by continuous spraying for 3 seconds. The 3 replicates of spray pattern were homogeneous.	[redacted] (2018) Doc ID: 2018/7005408
Physical compatibility	-	-	Not applicable as the product will be used as a standalone product	Data waiver provided
Chemical compatibility	-	-	Not applicable as the product will be used as a standalone product	Data waiver provided
Degree of dissolution and dilution stability	-	-	Not applicable to the formulation	Data waiver provided
Surface tension	EU A.5	0.5% dinotefuran	Surface tension (of 1g/L dilution) determined by ring method was 71.8 mN/m (corrected mean surface tension) at 20 °C.	[redacted] (2018) Doc ID: 2018/7005408

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Batch #: 2017-002B		
	OECD 115	0.5% dinotefuran Batch #: 19317PZ5	Mean surface tension of three replicates of neat product was determined to be 37.3 ± 0.5 mN/m at 19.9 ± 0.1°C.	[redacted] (2021) DocID: 2021/2047539
Viscosity	ASTM D445, OPPTS 830.7100 and CIPAC MT 22 (similar to OECD 114)	0.5% dinotefuran Batch #: 2017-002B	2.264 ×10^{-6} m²/s at 20 °C and 1.322 ×10-6 m²/s at 40 °C * Values converted from centistokes, as reported in the study report, to m²/s (1 cSt = 0.000001 m²/s).	[redacted] (2018) DocID: 2018/7001799
	OECD 114 CIPAC MT 192	0.5% dinotefuran Batch #: 19317PZ5	Newtonian behaviour under both (cone and plate) and (Double Gap) geometries was observed.	[redacted] (2021) DocID: 2021/2032687

Conclusion on the physical, chemical and technical properties of the product
The biocidal product SECLIRA FLY BAIT has supported shelf life of 3 years in PP or PE or PET coated metal can. The product should not be stored above 40°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	EU A.14	0.5% dinotefuran Batch #: 2017-002B	Data waiving since the DSC screening test conducted in closed high-pressure (Si-coated) crucible, with a heating rate of 2.5 K/min ran from 30°C up to 500°C showed an exothermic peak of 60 J/g with onset of 420°C. Further Koenen test and Impact hammer apparatus tests were negative.	[redacted] (2017) DocID: 2017/7012284 [redacted] (2022) DocID 2022/2025348
Flammable gases	-	-	Data waiving since the product is not a gas	
Flammable aerosols	UN Manual of Tests and Criteria: Part III, section 31.4, ignition distance test for spray aerosols	0.5% dinotefuran Batch #: 2017-002B	Ignition distance of 90 cm, categorised as Category 1 (extremely flammable aerosols)	[redacted] (2018) DocID: 2018/7001799
Oxidising gases	-	-	Data waiving since the product is not a gas	
Gases under pressure	-	-	Data waiving since the product is not a gas and aerosols shall not be classified as gases under pressure.	Data waiver provided
Flammable liquids	-	-	Data waiving since aerosols shall not be classified as flammable liquids.	Data waiver provided
Flammable solids	-	-	Data waiving since the product is not a solid.	Data waiver provided
Self-reactive substances and mixtures	-	-	Data waiving since the DSC screening test conducted in high-pressure crucible showed an exothermic peak of60 J/g with onset of 420°C.	[redacted] (2022) DocID 2022/2025348
Pyrophoric liquids	-	-	Data waiving since experience in manufacture and handling shows that the liquid does not ignite spontaneously on coming into contact with air at	Data waiver provided

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			normal temperatures (authorised in other geographies).	
Pyrophoric solids	-	-	Data waiving since the product is not a solid	Data waiver provided
Self-heating substances and mixtures	-	-	Data waiving since the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating.	Data waiver provided
Substances and mixtures which in contact with water emit flammable gases	-	-	Data waiving since the product contains water.	Data waiver provided
Oxidising liquids	EU method A21, UN Manual of Tests and criteria: O.2 (test for oxidising liquids)	0.5% dinotefuran Batch #: 2017-002B	The mean pressure rise time for a 1:1 product with cellulose mixture was 29.0 s, and for 1:1 reference mixture of cellulose and 65% aqueous nitric acid was 5.0 s. The results fall within the Not.Div. 5.1 group. In conclusion, the biocidal product was found to be not oxidising.	[redacted] (2017) Doc ID: 2017/7012284)
Oxidising solids	-	-	Data waiving since the product is not a solid.	
Organic peroxides	-	-	Not applicable as the test item does not contain organic peroxides	Data waiver provided
Corrosive to metals	OPPTS 830.6320	0.5% dinotefuran	The product fulfils the waiving options for not performing the corrosive to metals test, i.e., the product is halogen-free, no acid, no base, and no complexing agents, and it is pH neutral. The product is not corrosive to metals.	Data waiver provided
Auto-ignition temperatures of	EU method A15	0.5% dinotefuran	No ignition was observed below or at 400 °C at an atmospheric pressure of 1023 mbar.	[redacted] (2017) Doc ID: 2017/7012284

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
products (liquids and gases)		Batch #: 2017-002B		
Relative self-ignition temperature for solids	-	-	Data waiving since the product is not a solid.	Data waiver provided
Dust explosion hazard	-	-	Data waiving since the product does not produce dust.	Data waiver provided

Conclusion on the physical hazards and respective characteristics of the product
SECLIRA FLY BAIT is non-explosive, not self-reactive and not oxidising. The auto-ignition temperature of the product > 400ºC. The product is a flammable aerosol with an ignition distance of 90 cm. According to CLP regulation, the product will be classified with H222 Extremely flammable aerosol and H229 Pressurized contained. May burst if heated.

2.2.4 Methods for detection and identification

The HPLC/dad method for the determination of active ingredient content in SECLIRA FLY BAIT was found to be linear with correlation co-efficient 1.000 in the range of 10.09-50.28 µg/mL, precise with RSD of 0.08% and accuracy of 100.9%.

Analytical methods for the analysis of the product as such including the active substance									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance (Dinotefuran)	HPLC-DAD	105%, and 175% of nominal concentration, measured in duplicate	10.09-50.28 µg/mL, n = 6, y = 84022.47x +8142.52 r^2= 1.000	Chromatograms of standards, test item and blank were well defined and symmetrical. No interference ≥3% from matrix was detected.	105% – 175%	**105%:** 100.9% **175%:** 100.9%	Precision: n=6 dinotefuran content = 0.511% (mean) RSD= 0.08% this complies with Horwitz criterion	Not required; confirmatory method for determining a.s. content in formulated product	[redacted] (2017) DocID: 2017/7012220

1. Preparation of standards
   Stock Standard Preparation: Prepare duplicate stock standard solutions (designated as STD 1 and STD 2) by accurately weighing -25 mg of the reference standard into separate 100 mL volumetric flasks and adding -80 mL of diluent (acetonitrile : 0.1 % phosphoric acid in deionized water (8.4:91.6)). Sonicate the solutions for two minutes, allow the solutions to equilibrate to room temperature, and dilute to volume with diluent.
   Linearity Solution Preparation: Prepare six linearity solutions with target concentrations 10, 15, 20, 30, 40 and 50 µg/mL by accurately pipetting appropriate amounts of stock standard solutions into volumetric flasks, bringing to volume with diluent and mixing well.
   Accuracy solution preparation: Two spike solutions were prepared with concentration 18.3 µg/mL (low spike) and 30.5 µg/mL (high spike).
2. Analytical techniques and conditions:
   Analysis of the samples were performed on a HPLC-DAD with Thermo Scientific Hypersil GOLD, 100 x 4.6 mm column and ACN/(ACN+0.1% phosphoric acid) as mobile phase and detection wavelength at 225 nm.

Analytical methods for monitoring – surface and ground water									
Surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	QuEChERs, LC-MS/MS	0.10-1.0 5 measurements	Linear r^2= 0.999 in the range of 0.03 µg/L to 1.54 µg/L	Chromatograms of standards, test item and blank showed no interference at the retention time of interest.	104-105	105	1.7	0.1 µg/L	* [redacted] (2017) (refer to letter of access, Doc ID 2021/2043744)
Groundwater									
Active substance	QuEChERs, LC-MS/MS	0.10-1.0 5 measurements	Linear r^2= 0.999 in the range of 0.03 µg/L to 1.54 µg/L	Chromatograms of standards, test item and blank showed no interference at the retention time of interest.	103-105	104	2.0	0.1 µg/L	* [redacted] (2017) (refer to letter of access, Doc ID 2021/2043744)

eCA remark: The analytical method for dinotefuran in water was submitted and evaluated after the active substance authorization. The eCA of the active substance, BE, confirmed that the method validation is acceptable (private communications, April 2022).

1. Preparation of standard solution:
   Stock solution: Four stock solution of dinotefuran were prepared. One solution was used for tuning. Second stock solution was used to prepare working solution and calibration solution. The third was used for comparing with the first at two different concentrations. The fourth solution was used for stability testing. A stock solution of dinotefuran was prepared in a volumetric dlask by dissolving 10.32 mg of dinotefuran in 10 mL of ACN/water (90/10 v/v) resulting a concentration of 1.03 mg/mL.
   Fortification solution: Diluting the stock solution following fortification solutions were prepared: 0.01 µg/mL and 0.1 µg/mL
   Calibration solution: Fortification solution of the concentration 10.3 ng/mL was dissolved in ACN/H2O (5/95, v/v) to concentrations ranging from 0.03 ng/mL to 1.54 ng/mL which were used for calibration purposes.
2. Analytical techniques and conditions: 10 g (= 10 mL) specimen was weighed into a 15 mL centrifuge tube. In the case of recovery specimens fortification took place at this point and shaken by hand afterwards. Specimens were then centrifuged for 3 min at 5000 rpm and the clear supernatant was filled in a vial for measurement. Specimens with high concentrations of dinotefuran should be diluted with ultra pure water before measurement with LC-MS/MS.
3. Analysis of the samples were performed on a HPLC with C18 column and 0.1% formic acid in water/0.1% formic acid in acetonitrile as mobile phase and detection performed using mass spectra for two ion transitions-Primary ion transition (203>157) and secondary ion transition (203>129).

* These data were not evaluated for the approval of dinotefuran PT18.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

An acceptable monitoring method for the determination of residues of dinotefuran in soil is available from the evaluation of the active substance approval. At the same time a method was submitted and evaluated for water, but it was considered acceptable for one ion transition only and the following was stated in the Dinotefuran PT18 Assessment Report (2014) "Validation data for a second ion transition would be required in order to fully meet the requirements. The method is considered suitable as a monitoring method subject to the submission of validation data for a second ion transition." An overview of the newly submitted method is provided for in the table above.

A method is not required for air as the vapour pressure of dinotefuran was estimated to be 5.0×10^{-5} Pa at 25°C .

Methods for the detection of dinotefuran in matrices of plant and animal origin are not required based upon the intended use pattern of the product which will not result in contact with food or feedstuffs.

The product is intended for professional, trained professional and non-professional (amateur) use via crack & crevice and spot applications and the label states 'Do not place product where food, feed or water could become contaminated'. Therefore, an analytical method to determine residues in food of plant and animal origin is considered unnecessary.

Dinotefuran is not classified as toxic or very toxic and hence a monitoring method for residues in body fluids and tissues is not required.

Conclusion on the methods for detection and identification of the product
The method is satisfactorily validated in accordance with the EU guidance document SANCO/3030/99 rev. 4. According to the Implementing Regulation 2015/416 there are no relevant impurities associated with dinotefuran, therefore no further consideration is required from a chemistry perspective.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

SECLIRA FLY BAIT is an insecticide belonging to PT18 and its function is to control flies (reduction of population) in industrial, domestic, public buildings and animal buildings. The product is based on the active substance Dinotefuran.

The product is for use indoors in urban and rural buildings and is applied as a barrier treatment. The operator applies a band of product on surfaces where flies congregate or settle (warm wall areas, pen partitions, posts, windows frames, pipes, outside of feeding troughs, windows, doors, roof beams).

The product is intended for use by professionals, trained professionals, and the general public (non-professional users).

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

SECLIRA FLY BAIT is a bait product used to control House flies and Stable flies.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product aims to control flies. The active substance in the product, Dinotefuran, is a contact and stomach poison that kills insects. As the target organisms are invertebrates, animal welfare is not assessed.

2.2.5.4 Mode of action, including time delay

Contact and ingestion: Dinotefuran is a neonicotinoid in the nitroguanidine class.
It appears that dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides. Please see the confidential annex for further details.

2.2.5.5 Efficacy data

Stable flies

- **Laboratory testing**

A laboratory bioassay to test the efficacy of SECLIRA FLY BAIT at 2 rates in a no-choice test with Stable flies on porous and non-porous surfaces. Exposure was for 6 hours to 1 day and 45 day aged product, for a 72 hour observation period. Assessments of knock-down and mortality were made at 30 minutes, 1, 2, 4, 6, 24, 48 and 72 hours.

A laboratory bioassay to test the efficacy and palatability of 1 year stored SECLIRA FLY BAIT at 1 rate in a no-choice test with Stable flies on non-porous surfaces. Exposure was for up to 24 hours to 1 day and 84 day aged product, for the 24 hour observation period. Assessments of combined knock-down and mortality were made at 30 minutes, 1, 2, 4 hours and 1 day, assessments of mortality were made at 1 day.

A laboratory/simulated use bioassay to test the efficacy of SECLIRA FLY BAIT at 3 rates in a choice test with Stable flies on porous and non-porous surfaces. Exposure was for up to 72 hours to 1 day and 45 day aged product, for a 72 hour observation period. Assessments of knock-down and mortality were made at 30 minutes, 1, 2, 4, 24, 48 and 72 hours.

A laboratory test to assess the efficacy and palatability of SECLIRA FLY BAIT at one rate in a choice test with Stable flies on non-porous surfaces, following three years of product storage. Exposure was for 48 hours to 1-day aged product. Assessments of knock-down plus mortality were made at 0.5, 1, 2, 4, 24 and 48 hours, and assessments of mortality were made at 24 and 48 hours.

Although efficacy on porous surfaces was tested in the laboratory tests, efficacy proved to be insufficient for authorization. As use on porous surfaces is not claimed, the results for the laboratory tests on porous surfaces have not been included in the efficacy study summary table below.

- **Field testing**

A field trial was conducted to assess the efficacy of SECLIRA FLY BAIT against Stable flies in terms of population reduction. SECLIRA FLY BAIT was applied at a use rate of 80 mg as/m² as a barrier treatment where flies congregate or settle to 10% of the walls and ceiling surface of the animal building during high pressure conditions, to an animal stable with historical natural infestation of flies.

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Insecticide</td>
<td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 395 18I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td>
<td>Stable fly (Stomoxys calcitrans) adults</td>
<td>Laboratory:
No-choice test. Ten flies were confined on treated tiles (ceramic tiles/ cement board) within upturned plastic cups for the exposure duration.</td>
<td>Three replicates (x3) were conducted for each treatment (3x), for each surface type (x1), for each ageing interval (x2)
Treatment rates: control, 80, 120 mg a.i./m².

1 day and 45 day aged product.

Exposure time: 6 hours

Test conditions:
22.7 – 27.2 ºC
31.3 -86.9 % humidity</td>
<td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="4">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">Fresh product</th><th colspan="2">45-day aged product</th></tr>
<tr><th>KD</th><th>D</th><th>KD</th><th>D</th></tr>
<tr><td rowspan="8">80 mg a.i./m²</td><td>30 min</td><td>66.7</td><td>3.3</td><td>86.7</td><td>6.7</td></tr>
<tr><td>1 h</td><td>93.3</td><td>0.0</td><td>86.7</td><td>6.7</td></tr>
<tr><td>2 h</td><td>96.7</td><td>0.0</td><td>90.0</td><td>6.7</td></tr>
<tr><td>4 h</td><td>96.7</td><td>0.0</td><td>90.0</td><td>10.0</td></tr>
<tr><td>6 h</td><td>100</td><td>0.0</td><td>90.0</td><td>10.0</td></tr>
<tr><td>24 h</td><td>13.3</td><td>86.7</td><td>0.0</td><td>100</td></tr>
<tr><td>48 h</td><td>10.0</td><td>90.0</td><td>0.0</td><td>100</td></tr>
<tr><td>72 h</td><td>0.0</td><td>100</td><td>0.0</td><td>100</td></tr>
<tr><td rowspan="8">120 mg a.i./m²</td><td>30 min</td><td>93.3</td><td>0.0</td><td>83.3</td><td>10.0</td></tr>
<tr><td>1 h</td><td>96.7</td><td>0.0</td><td>93.3</td><td>3.3</td></tr>
<tr><td>2 h</td><td>100</td><td>0.0</td><td>93.3</td><td>3.3</td></tr>
<tr><td>4 h</td><td>100</td><td>0.0</td><td>93.3</td><td>3.3</td></tr>
<tr><td>6 h</td><td>100</td><td>0.0</td><td>96.7</td><td>3.3</td></tr>
<tr><td>24 h</td><td>3.3</td><td>96.7</td><td>0.0</td><td>100</td></tr>
<tr><td>48 h</td><td>0.0</td><td>100</td><td>0.0</td><td>100</td></tr>
<tr><td>72 h</td><td>0.0</td><td>100</td><td>0.0</td><td>100</td></tr>
</table>
KD=knockdown, D=mortality

Untreated controls typically showed 0% KD and D except 6.7 and 10.0 % D at 48 and 72 h respectively to fresh product; and 6.7 and 10.0 % D at 48 and 72 h respectively to aged product.
</td>
<td>Doc ID: 2018/1093863

[redacted] (2018a) Laboratory bioassay to determine the residual efficacy of an aerosol product against stable flies, Stomoxys calcitrans.</td>
</tr>
</table>

<table>
<tr>
<td>Insecticide</td>
<td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 395 KL I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT

1 year stored product</td>
<td>Stable fly (Stomoxys calcitrans) adults</td>
<td>Laboratory: Palatability and efficacy. Twenty flies were confined on treated tiles beneath lids for the exposure duration.</td>
<td>Three replicates (x3) were conducted for each treatment (x2), for each surface type (x1), for each aging interval (x2) and for each species (x20).

Treatment rates: control, 80 mg a.i./m².

1 day and 84 day aged product.

Exposure time: up to 1 day

Test conditions: 28 ºC
Relative humidity: 50 %</td>
<td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="4">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">Fresh product</th><th colspan="2">84-day aged product</th></tr>
<tr><th>KD+D</th><th>D</th><th>KD+D</th><th>D</th></tr>
<tr><td rowspan="5">80 mg a.i./m²</td><td>30 min</td><td>32.6</td><td></td><td>18.8</td><td></td></tr>
<tr><td>1 h</td><td>52.1</td><td></td><td>40.6</td><td></td></tr>
<tr><td>2 h</td><td>79.0</td><td></td><td>59.0</td><td></td></tr>
<tr><td>4 h</td><td>92.7</td><td></td><td>71.2</td><td></td></tr>
<tr><td>1 d</td><td>100.0</td><td>98.4</td><td>98.2</td><td>94.4</td></tr>
</table>
KD=knockdown, D=mortality
Not measured

Untreated controls typically showed 0% KD+D except 1.8 and 5.3 % KD+D at 4 h and 1 d respectively, to fresh product and 5.3 % D to aged product; and 8.7 % KD+D at 1 day and 8.7 % D to aged product.
</td>
<td>DocID: 2018/1121174

[redacted] (2018a) Insecticidal efficacy of BAS 395 KL I pressurized fly bait, one year after manufacture, against adult stable flies (Stomoxys calcitrans) as aged (1 and 84 days) applications in laboratory assays.</td>
</tr>
</table>

<table>
<tr>
<td>Insecticide</td>
<td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 395 18 I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td>
<td>Stable fly (Stomoxys calcitrans) adults</td>
<td>Laboratory test:
Choice test. Ten flies were confined within cages. Half of the floor was lined with treated tiles (ceramic tiles/ cement board) and the other half with untreated tiles. A sugar water saturated cotton wool pad was placed on each half of the floor as sustenance.</td>
<td>Three replicates (x3) were conducted for each treatment (4x), for each surface type (x1), for each ageing interval (2x)
Treatment rates: control, 80, 120, 160 mg a.i./m²

1 day and 45 day aged product.

Exposure time: up to 24 hours

Test conditions:17.7 C - 24.7 C
Relative humidity: 34%-64.9%</td>
<td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="4">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">Fresh product</th><th colspan="2">45-day aged product</th></tr>
<tr><th>KD</th><th>D</th><th>KD</th><th>D</th></tr>
<tr><td rowspan="8">80 mg a.i./m²</td><td>30 min</td><td>50</td><td>0</td><td>6.7</td><td>0</td></tr>
<tr><td>1 h</td><td>43.3</td><td>0</td><td>33.3</td><td>0</td></tr>
<tr><td>2 h</td><td>63.3</td><td>0</td><td>50</td><td>0</td></tr>
<tr><td>4 h</td><td>80</td><td>0</td><td>70</td><td>0</td></tr>
<tr><td>24 h</td><td>93.3</td><td>0</td><td>96.7</td><td>0</td></tr>
<tr><td>48 h</td><td>6.7</td><td>86.7</td><td>6.7</td><td>93.3</td></tr>
<tr><td>72 h</td><td>0</td><td>100.0</td><td>0</td><td>100</td></tr>
<tr><td rowspan="8">120 mg a.i./m²</td><td>30 min</td><td>16.7</td><td>0</td><td>14.1</td><td>0</td></tr>
<tr><td>1 h</td><td>36.7</td><td>0</td><td>24.4</td><td>0</td></tr>
<tr><td>2 h</td><td>56.7</td><td>0</td><td>34.8</td><td>0</td></tr>
<tr><td>4 h</td><td>80</td><td>0</td><td>55.2</td><td>0</td></tr>
<tr><td>24 h</td><td>96.7</td><td>0</td><td>89.6</td><td>0</td></tr>
<tr><td>48 h</td><td>10</td><td>90</td><td>10.4</td><td>79.3</td></tr>
<tr><td>72 h</td><td>0</td><td>100</td><td>10.7</td><td>82.6</td></tr>
<tr><td rowspan="8">160 mg a.i./m²</td><td>30 min</td><td>25.2</td><td>0</td><td>10.7</td><td>0</td></tr>
<tr><td>1 h</td><td>68.5</td><td>0</td><td>25.6</td><td>0</td></tr>
<tr><td>2 h</td><td>86.3</td><td>0</td><td>33.0</td><td>0</td></tr>
<tr><td>4 h</td><td>96.7</td><td>0</td><td>60.4</td><td>0</td></tr>
<tr><td>24 h</td><td>100</td><td>0</td><td>96.7</td><td>0</td></tr>
<tr><td>48 h</td><td>14.1</td><td>85.9</td><td>3.3</td><td>96.7</td></tr>
<tr><td>72 h</td><td>0</td><td>100</td><td>0</td><td>100</td></tr>
</table>
KD=knockdown, D=mortality
Untreated controls typically showed 0% KD and D except 9.3 % D at 72 h after exposure to fresh product; 3.3 % KD at 72 h and 10, 13.3 and 30 % D at 24, 48 and 72 h respectively to aged product.
</td>
<td>DocID: 2018/1062029

[redacted] (2017) Laboratory bioassay to determine the residual efficacy of a pressurised fly bait product (BAS 395 18 I) against stable flies, Stomoxys calcitrans.</td>
</tr>
</table>

<table>
<tr>
<td>Insecticide</td>
<td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 395 KL I (containing 0.5% w/w dinotefuran)= SECLIRA FLY BAIT

3 year old product</td>
<td>Stable fly (Stomoxys calcitrans) adults</td>
<td>Laboratory test: Palatability and efficacy of 3-year stored product. Choice test. Twenty flies were confined within clear plastic containers (3.55 L) with a ventilated lid and which contain 4 treated ceramic tiles (5.08 x 5.08 cm each). A 10 % sugar solution 5 mL centrifuge tube was plugged with cotton and placed on each set of 4 tiles.</td>
<td>Three replicates (x3) were conducted for each treatment (1x), for each surface type (1x), for each ageing interval (1x)
Treatment rates: control, product applied from 30.5
cm at 61 linear cm per second (=80 mg a.i./m²).

1 day aged product.

Assessments of knockdown and mortality at 0.5, 1, 2, 4, 24, 48 hours and of mortality at 24, 48 hours.

Exposure time: 48 hours

Test conditions: 21.2-24.0 ºC, relative humidity 52-66%, ambient room and window lighting.</td>
<td>
<table>
<tr><th rowspan="2">Application rate</th><th rowspan="2">Time to effect</th><th colspan="2">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">1-day aged product (following 3 years of storage)</th></tr>
<tr><th></th><th></th><th>KD+D</th><th>D</th></tr>
<tr><td rowspan="6">80 mg a.i./m²</td><td>30 min</td><td>3.1</td><td>-</td></tr>
<tr><td>1 h</td><td>3.1</td><td>-</td></tr>
<tr><td>2 h</td><td>3.0</td><td>-</td></tr>
<tr><td>4 h</td><td>12.3</td><td>-</td></tr>
<tr><td>24 h</td><td>84.4</td><td>67.1</td></tr>
<tr><td>48 h</td><td>95.8</td><td>92.9</td></tr>
</table>
KD=knockdown, D=mortality
Untreated controls typically showed 0% KD plus D except 3.8 % at 48 h, and showed 0.0 % and 3.8 % mortality at 24 h and 48 h respectively, after exposure to fresh product following 3 years of storage.
</td>
<td>DocID: 2021/2039678

[redacted] (2021)

Insecticidal efficacy of BAS 395 KL I (BAS 395 18 I) pressurized fly bait, three years after manufacture, against stable flies as 1-day aged applications in laboratory assay</td>
</tr>
</table>

<table>
<tr>
<td>Insecticide</td>
<td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 318 18I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td>
<td>Stable fly (Stomoxys calcitrans)

Natural population</td>
<td>Field test:
For two days prior to treatment, infestation levels were determined via counting spots which remained consistent for the duration of the test. Efficacy assessments were made 1, 7, 14, 21, 28, 35 and 42 days after treatment.</td>
<td>The site is located in an animal building in Spain known to have historical natural fly infestations.

The sitewas divided into 6 equal sections (rooms) which were completely separated from each other, 3 as treatment replicates, and 3 as control replicates.

Treatment rate: 80 mg a.i./m² to 10% of walls and ceiling area, onto non-porous surfaces.

Total surface of walls and ceiling = ca. 85 m² per section.
10% of treated area = 8.5 m² per section.

Exposure time: up to 42 days

4 squared counting spots per section on walls and ceiling (0.5 x 0.5 m each)

Test conditions:
Temperature: 19.2 ºC
Relative humidity: 48 %</td>
<td>
<table>
<tr><th rowspan="2">Time to effect</th><th rowspan="2">Mean % reduction</th><th colspan="4">Average flies per spot</th></tr>
<tr><th>Control</th><th>TR1</th><th>TR2</th><th>TR3</th></tr>
<tr><td>Day -1</td><td>-</td><td rowspan="2">5.7</td><td>4.0</td><td>3.8</td><td>4.3</td></tr>
<tr><td>Day 0</td><td>-</td><td>4.0</td><td>6.5</td><td>6.0</td></tr>
<tr><td>Day 1</td><td>97.9</td><td>4.7</td><td>0.3</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 7</td><td>97.9</td><td>6.8</td><td>0.3</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 14</td><td>100.0</td><td>7.3</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 21</td><td>98.4</td><td>4.7</td><td>0.0</td><td>0.0</td><td>0.3</td></tr>
<tr><td>Day 28</td><td>98.4</td><td>4.3</td><td>0.0</td><td>0.0</td><td>0.3</td></tr>
<tr><td>Day 35</td><td>95.8</td><td>7.7</td><td>0.5</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 42</td><td>82.1</td><td>5.5</td><td>0.0</td><td>1.8</td><td>1.0</td></tr>
</table>
% reduction Stomoxys calcitrans is compared against the pre-treatment levels on Day -1 and Day 0.
</td>
<td>DocID: 2021-2047841

[redacted] (2021)

Efficacy evaluation of the insecticide “BAS 395 18 I” against Musca domestica and Stomoxys calcitrans in livestock premises (application rate: 10% of all walls and ceiling surface)</td>
</tr>
</table>

House flies

- **Laboratory testing**

A laboratory bioassay to test the efficacy of SECLIRA FLY BAIT at 2 rates in a no-choice test with House flies on porous and non-porous surfaces. Exposure was for 6 hours to 1 day and 45 day aged product, for a 72 hour observation period. Assessments of knock-down and mortality were made at 30 minutes, 1, 2, 4, 6, 24, 48 and 72 hours.

A laboratory bioassay to test the efficacy and palatability of 1 year stored SECLIRA FLY BAIT at 1 rate in a no-choice test with House flies on non-porous surfaces. Exposure was for up to 24 hours to 1 day and 55 day aged product, for the 24 hour observation period. Assessments of combined knock-down and mortality were made at 30 minutes, 1, 2, 4 and 1 day, assessments of mortality were made at 1 day.

A laboratory/simulated use bioassay to test the efficacy of SECLIRA FLY BAIT at 3 rates in a choice test with House flies on porous and non-porous surfaces. Exposure was for up to 72 hours to 1 day and 45 day aged product, for a 72 hour observation period. Assessments of knock-down and mortality were made at 30 minutes, 1, 2, 4, 24, 48 and 72 hours.

A laboratory test to assess the efficacy and palatability of SECLIRA FLY BAIT at one rate in a choice test with House flies on non-porous surfaces, following three years of product storage. Exposure was for 24 hours to 1-day aged product. Assessments of knock-down plus mortality were made at 0.5, 1, 2, 4, 24 hours, and assessments of mortality were made at 24 hours.

Although efficacy on porous surfaces was tested in the laboratory tests, efficacy proved to be insufficient for authorization. As use on porous surfaces is not claimed, the results for the laboratory tests on porous surfaces have not been included in the efficacy study summary table below.

- **Simulated use testing**

A simulated-use test to assess the efficacy of SECLIRA FLY BAIT at one rate in a choice test with House flies on non-porous surfaces. Exposure was for 24 hours to 1-, 28- and 42-day aged product, for a 24 hour exposure period. Assessments of knock-down and mortality were made at 8 and 24 hours, respectively.

- **Field testing**

A field trial was conducted to assess the efficacy of SECLIRA FLY BAIT against House flies in terms of population reduction. SECLIRA FLY BAIT was applied at a use rate of 80 mg as/m² as a barrier treatment where flies congregate or settle to 10% of the walls and ceiling surface of the animal building during high pressure conditions, to an animal stable with historical natural infestation of flies.

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system/ concentrations applied/ exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Insecticide</td>
<td>Indoor use in urban and rural buildings by professionals, trained professionals and non-professionals</td>
<td>BAS 395 18I

(containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td>
<td>House fly (Musca domestica) adults</td>
<td>Laboratory test: No-choice test. Ten flies were confined on treated tiles within upturned plastic cups for the exposure duration.</td>
<td>Three replicates (x3) were conducted for each treatment (x3), for each surface type (x1), for each ageing interval (x2)
Treatment rates: control, 80, 120 mg a.i./m².

1 day and 45 day aged product.

Exposure time: 6 hours

Test conditions: 22.7 – 27.2 ºC 31.3 -86.9 % humidity</td>
<td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="4">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">Fresh product</th><th colspan="2">45-day aged product</th></tr>
<tr><th>KD</th><th>D</th><th>KD</th><th>D</th></tr>
<tr><td rowspan="8">80 mg a.i./m²</td><td>30 min</td><td>30.0</td><td>0.0</td><td>16.7</td><td>50.0</td></tr>
<tr><td>1 h</td><td>63.3</td><td>0.0</td><td>20.0</td><td>66.7</td></tr>
<tr><td>2 h</td><td>96.7</td><td>0.0</td><td>76.7</td><td>13.3</td></tr>
<tr><td>4 h</td><td>100.0</td><td>0.0</td><td>100.0</td><td>0.0</td></tr>
<tr><td>6 h</td><td>100.0</td><td>0.0</td><td>100.0</td><td>0.0</td></tr>
<tr><td>24 h</td><td>16.7</td><td>83.3</td><td>46.7</td><td>46.7</td></tr>
<tr><td>48 h</td><td>3.3</td><td>96.7</td><td>13.3</td><td>73.3</td></tr>
<tr><td>72 h</td><td>0.0</td><td>100.0</td><td>10.0</td><td>76.7</td></tr>
<tr><td rowspan="9">120 mg a.i./m²</td><td>30 min</td><td>16.7</td><td>0.0</td><td>3.3</td><td>63.3</td></tr>
<tr><td>1 h</td><td>73.3</td><td>0.0</td><td>10.0</td><td>86.7</td></tr>
<tr><td>2 h</td><td>96.7</td><td>0.0</td><td>70.0</td><td>26.7</td></tr>
<tr><td>4 h</td><td>100.0</td><td>0.0</td><td>100.0</td><td>0.0</td></tr>
<tr><td>6 h</td><td>100.0</td><td>0.0</td><td>100.0</td><td>0.0</td></tr>
<tr><td>24 h</td><td>20.0</td><td>80.0</td><td>33.3</td><td>63.3</td></tr>
<tr><td>48 h</td><td>3.3</td><td>96.7</td><td>3.3</td><td>86.7</td></tr>
<tr><td>72 h</td><td>0.0</td><td>100.0</td><td>6.7</td><td>93.3</td></tr>
</table>
KD=knockdown, D=mortality
Untreated controls typically showed 0% KD and D except 3.3 % KD at 6h, and 3.3, 3.3, 10 % D at 24, 48 and 72 h respectively to fresh product; and 72 h respectively to aged product.
</td>
<td>Doc ID: 2018/1093862

[redacted] (2018b) Laboratory bioassay to determine the residual efficacy of an aerosol product against Houseflies, Musca domestica</td>
</tr>
<tr>
<td>Insecticide</td>
<td>Indoor use in urban and rural buildings by professionals, trained professionals</td>
<td>BAS 395 KL I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td>
<td>House fly (Musca domestica) adults</td>
<td>Laboratory test: Palatability and efficacy. Twenty flies were confined on</td>
<td>Three replicates (x3) were conducted for each treatment (x2), for each surface type (x1), for each aging interval (x1)</td>
<td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="4">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">Fresh product</th><th colspan="2">55-day aged product</th></tr>
<tr><th>KD+D</th><th>D</th><th>KD+D</th><th>D</th></tr>
<tr><td></td><td>30 min</td><td>98.6</td><td></td><td>100.0</td><td></td></tr>
</table>
</td>
<td>DocID: 2018/1186617

[redacted] (2018b) Insecticidal efficacy of BAS 395 KL I pressurized fly bait, one year after</td>
</tr>
</table>

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 time	Test results: effects	Reference
	and non-professionals	1 year stored product		treated tiles beneath lids for the exposure duration.	and for each species (x20). Treatment rates: control, 80 mg a.i./m². 1 day and 55 day aged product. Exposure time: up to 1 day Test conditions: 25 ºC and relative humidity 55 %	80 mg a.i./m²: 1 h 100.0 / 100.0; 2 h 100.0 / 100.0; 4 h 100.0 / 100.0; 1 d 100.0 / 100.0 / 100.0 / 98.5 KD=knockdown, D=mortality Not measured Untreated controls typically showed 0% KD+D except 1.5, 4.5 and 12.1 % KD+D at 2h, 4 h and 1 d respectively and 12.1 % D to fresh product; and 4.0 % KD+D at 1 d; and 2.8 % D to aged product.	manufacture, against adult house flies as aged (1 and 55 days) applications in laboratory assays.
Insecticide	Indoor use in urban and rural buildings by professionals, trained professionals and non-professionals	BAS 395 KL I (containing 0.5% w/w dinotefuran)= SECLIRA FLY BAIT	House fly (*Musca domestica*) adults	**Laboratory test:** Choice test. Ten flies were confined within cages. Half of the floor was lined with treated tiles and the other half with untreated tiles. A sugar water saturated cotton wool pad was placed on each half of the floor as sustenance.	Three replicates (x3) were conducted for each treatment (4x), for each surface type (2x), for each ageing interval (2x) Treatment rates: control, 80, 120, 160 mg a.i./m² 1 day and 45 day aged product. Exposure time: 24 hours Test conditions: 16.1-25.5 ºC, relative humidity 28.9-66.8%	**Effect on non-porous surfaces** **Fresh product** / **45-day aged product** KD / D / KD / D 80 mg a.i./m²: 30 min 23.33 / 0.00 / 20.00 / 0.00; 1 h 36.67 / 0.00 / 53.33 / 0.00; 2 h 66.67 / 0.00 / 70.00 / 0.00; 4 h 93.33 / 0.00 / 100.00 / 0.00; 24 h 36.67 / 93.33 / 40.00 / 93.33; 48 h 0.00 / 100.00 / 6.67 / 93.33; 72 h na / na / 3.33 / 96.67 120 mg a.i./m²: 30 min 3.33 / 0.00 / 20.00 / 0.00; 1 h 30.00 / 0.00 / 53.33 / 0.00; 2 h 56.67 / 0.00 / 70.00 / 0.00; 4 h 80.00 / 0.00 / 100.00 / 0.00	DocID: 2017/1136552 [redacted] (2017) Laboratory bioassay to determine the residual efficacy of a pressurized fly bait product(BAS 395 KL I) against houseflies, *Musca domestica*.

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system/ concentrations applied/ exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>24 h</td><td>33.33</td><td>100.00</td><td>40.00</td><td>93.33</td></tr>
<tr><td></td><td>48 h</td><td>0.00</td><td>100.00</td><td>6.67</td><td>93.33</td></tr>
<tr><td></td><td>72 h</td><td>na</td><td>na</td><td>3.33</td><td>96.67</td></tr>
<tr><td rowspan="7">160 mg a.i./m²</td><td>30 min</td><td>10.00</td><td>0.00</td><td>26.67</td><td>0.00</td></tr>
<tr><td>1 h</td><td>26.67</td><td>0.00</td><td>50.00</td><td>0.00</td></tr>
<tr><td>2 h</td><td>73.33</td><td>0.00</td><td>73.33</td><td>0.00</td></tr>
<tr><td>4 h</td><td>96.67</td><td>0.00</td><td>96.67</td><td>0.00</td></tr>
<tr><td>24 h</td><td>3.33</td><td>90.00</td><td>13.33</td><td>86.67</td></tr>
<tr><td>48 h</td><td>0.00</td><td>100.00</td><td>0.00</td><td>100.00</td></tr>
<tr><td>72 h</td><td>na</td><td>na</td><td>0.00</td><td>100.00</td></tr>
</table>
KD=knockdown, D=mortality
na: assessments terminated at 48 hours due to 100% mortality in treatments.
Untreated controls typically showed 0% KD and D except 3.33 and 6.67 % D at 24 and 72 h after exposure to fresh product and; 3.3 % KD at all time points to aged product.
</td><td></td></tr>
<tr><td>Insecticide</td><td>Indoor use in urban and rural buildings by professionals, trained professionals and non-professionals</td><td>BAS 395 KL I (containing 0.5% w/w dinotefuran)= SECLIRA FLY BAIT

3 year old product</td><td>House fly (Musca domestica) adults</td><td>Laboratory test: Palatability and efficacy of 3-year stored product. Choice test. Twenty flies were confined within clear plastic containers (3.55 L) with a ventilated lid and which</td><td>Three replicates (x3) were conducted for each treatment (1x), for each surface type (1x), for each ageing interval (1x)
Treatment rates: control, product applied from 30.5 cm at 61 linear cm per second (=80 mg a.i./m²).

1 day aged product.</td><td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="2">Effect on non-porous surfaces</th></tr>
<tr><th colspan="2">1-day aged product (following 3 years of storage)</th></tr>
<tr><th>KD+D</th><th>D</th></tr>
<tr><td rowspan="7">80 mg a.i./m²</td><td>30 min</td><td>89.9</td><td>-</td></tr>
<tr><td>1 h</td><td>97.3</td><td>-</td></tr>
<tr><td>2 h</td><td>95.8</td><td>-</td></tr>
<tr><td>4 h</td><td>95.8</td><td>-</td></tr>
<tr><td>24 h</td><td>100</td><td>100</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
KD=knockdown, D=mortality
Untreated controls typically showed 0% KD plus D except 1.4 and 9.3 % at 4 and 24 h, and showed 9.3% mortality at
</td><td>DocID: 2021/2039673

[redacted] (2021)

Insecticidal efficacy of BAS 395 KL I (BAS 395 18 I) pressurized fly bait, three years after manufacture, against house flies as 1-day aged applications in laboratory assay</td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system/ concentrations applied/ exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>contain 4 treated ceramic tiles (5.08 x 5.08 cm each). A 10 % sugar solution 5 mL centrifuge tube was plugged with cotton and placed on each set of 4 tiles.</td><td>Assessments of knockdown and mortality at 0.5, 1, 2, 4, 24 hours and of mortality at 24 hours.

Exposure time: 24 hours

Test conditions: 21.2-24.0 ºC, relative humidity 52-66%, ambient room and window lighting.</td><td>24 h, after exposure to fresh product following 3 years of storage.</td><td></td></tr>
<tr><td>Insecticide</td><td>Indoor use in urban and rural buildings by professionals, trained professionals and non-professionals</td><td>BAS 395 18 I (containing 0.5% w/w dinotefuran)= SECLIRA FLY BAIT</td><td>House fly (Musca domestica) adults</td><td>Simulated use: Choice test. Testing conducted in a 20 m³ test chamber. Treated cardboards with aluminium foil (0.925 m²) were placed around windows of test chamber. 100 flies were released free flying in the test chamber. A 10 % sugar solution-soaked sponge was placed in two</td><td>Four replicates (4x) were conducted for each treatment (1x), for each ageing interval (3x).

Treatment rates: control, 80 mg a.i./m².

1 day, 28 day and 42 day aged product.

Treated surfaces (aluminium foil cardboards) represented 2.5 % of wall plus ceiling of the test chamber.

Assessments of knockdown at 8 hours and of mortality at 28 hours.

Exposure time: 24 hours</td><td>
<table>
<tr><th rowspan="3">Application rate</th><th rowspan="3">Time to effect</th><th colspan="6">Age (after treatment)</th></tr>
<tr><th colspan="2">1-day</th><th colspan="2">28-day</th><th colspan="2">42-day</th></tr>
<tr><th>KD</th><th>D</th><th>KD</th><th>D</th><th>KD</th><th>D</th></tr>
<tr><td rowspan="2">80 mg a.i./m²</td><td>8 h</td><td>92</td><td>-</td><td>99</td><td>-</td><td>99</td><td>-</td></tr>
<tr><td>24 h</td><td>-</td><td>100</td><td>-</td><td>100</td><td>-</td><td>100</td></tr>
</table>
KD=knockdown, D=mortality
Untreated controls showed 0% KD and D.</td><td>DocID: 2021/2036486

[redacted] (2021)

Simulated-use test to determine the biological efficacy of the aerosol product “BAS 395 18 I” applied on cardboards wrapped in aluminium foil (to simulate non-porous surfaces) applied to a surface corresponding to 2.5 % of the wall plus ceilings area of the test chamber, at different test days against House flies, Musca domestica tested in a 20 m³ chamber.</td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system/ concentrations applied/ exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>beakers and placed in the test chamber as sustenance.</td><td>Test conditions: 21-24 ºC, relative humidity 38-72 %, artificial light during testing</td><td></td><td></td></tr>
<tr><td>Insecticide</td><td>Indoor use in rural buildings by professionals, trained professionals and non-professionals</td><td>BAS 318 18I (containing 0.5% w/w dinotefuran) = SECLIRA FLY BAIT</td><td>House fly (Musca domestica)

Natural population</td><td>Field test: For two days prior to treatment, infestation levels were determined via counting spots which remained consistent for the duration of the test. Efficacy assessments were made 1, 7, 14, 21, 28, 35 and 42 days after treatment.</td><td>The site is located in an animal building in Italy known to have historical natural fly infestations.

The site was divided into 6 equal sections (rooms) which were completely separated from each other, 3 as treatment replicates, and 3 as control replicates.

Treatment rate: 80 mg a.i./m² to 10% of walls and ceiling area, onto non-porous surfaces.

Total surface of walls and ceiling = ca. 85 m² per section.
10% of treated area = 8.5 m² per section.

Exposure time: up to 42 days

4 squared counting spots per section on walls and</td><td>
<table>
<tr><th rowspan="2">Time to effect</th><th rowspan="2">Mean % reduction</th><th colspan="4">Average flies per spot</th></tr>
<tr><th>Control</th><th>TR1</th><th>TR2</th><th>TR3</th></tr>
<tr><td>Day -1</td><td>-</td><td rowspan="2">7.0</td><td>6.3</td><td>4.8</td><td>6.8</td></tr>
<tr><td>Day 0</td><td>-</td><td>7.8</td><td>6.0</td><td>5.3</td></tr>
<tr><td>Day 1</td><td>98.6</td><td>5.7</td><td>0.0</td><td>0.0</td><td>0.3</td></tr>
<tr><td>Day 7</td><td>100.0</td><td>6.3</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 14</td><td>97.4</td><td>7.3</td><td>0.3</td><td>0.0</td><td>0.3</td></tr>
<tr><td>Day 21</td><td>100.0</td><td>8.7</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 28</td><td>97.6</td><td>5.5</td><td>0.5</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Day 35</td><td>97.3</td><td>4.3</td><td>0.3</td><td>0.3</td><td>0.0</td></tr>
<tr><td>Day 42</td><td>92.5</td><td>6.5</td><td>1.3</td><td>0.3</td><td>0.0</td></tr>
</table>
% reduction Musca domestica is compared against the pre-treatment levels on Day -1 and Day 0.
</td><td>DocID: 2021-2047841

[redacted] (2021)

Efficacy evaluation of the insecticide "BAS 395 18 I" against Musca domestica and Stomoxys calcitrans in livestock premises (application rate: 10% of all walls and ceiling surface)</td></tr>
</table>

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 time**	**Test results: effects**	**Reference**
					ceiling (0.5 x 0.5 m each) Test conditions: Temperature: 19.2 ºC Relative humidity: 48 %		

Conclusion on the efficacy of the product
To demonstrate efficacy of the product 8 laboratory studies, 1 simulated-use test and 1 field study were provided. Tests were performed with products with various names, all of which are identical in composition to the product to be authorised. For a full evaluation of the label claims, please refer to section 2.2.5.8.

2.2.5.6 Occurrence of resistance and resistance management

Dinotefuran is a nitroguanidine compound included with other insect nicotinic acetylcholine receptor (nAChRs) agonists in the Insect Resistance Action Committee (IRAC) group 4A. Detailed mode of action studies suggest that dinotefuran binds to the acetylcholine receptor site in a mode that differs to the chlorinated neonicotinic molecules included in IRAC group 4A (see confidential annex **Error! Reference source not found.**). In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted.

According to the Arthropod Pesticide Resistance Database (www.pesticideresistance.org) as of August 2021, resistance to dinotefuran has **not** been noted for House flies and Stable flies, but has been for other arthropods as follows:

Genus Species	Taxonomy (family - order)	Common Name(s)	# Cases
aphis gossypii	aphididae homoptera	melon and cotton aphid	7
bemisia tabaci	aleyrodidae homoptera	sweetpotato whitefly	1
cimex lectularius	cimicidae hemiptera	bed bug	3
leptinotarsa decemlineata	chrysomelidae coleoptera	colorado potato beetle	1
nilaparvata lugens	delphacidae homoptera	brown planthopper	25
sogatella furcifera	delphacidae homoptera	white-backed planthopper	3

Furthermore, a literature review on resistance of dinotefuran was conducted and revealed the following information:

- ([redacted], 2011a). Dinotefuran is more effective than thiamethoxam, clothianidin, nitenpyram, thiacloprid and acetamiprid against imidacloprid-resistant *Aphis gossypii*, therefore reduces further resistance development.
- ([redacted], 2011b). No cross-resistance to dinotefuran of the laboratory-generated imidacloprid-resistant *Aphis gossypii.*
- ([redacted] 2012). All of the neonicotinoids examined, except dinotefuran showed reduced insecticidal efficacy on larvae of the laboratory-generated Dα1 mutant of *Drosophila melanogaster*. This observation suggests that the specific Dα1 subunit mutation examined in the study does not affect the action of dinotefuran, and/or perhaps that the Dα1 subunit (or Dα1 subunit containing nAChR subtypes) may not be involved in the insecticidal activity of dinotefuran.

- ([redacted], 2012). No or little level cross-resistance to dinotefuran of Q biotype strains of *Bemisia tabaci* compared with imidacloprid, thiamethoxam and acetamiprid. Resistance in the Q biotype strains was associated with over-expression of a cytochrome P450 monooxygenase gene, CYP6CM1, whose substrate specificity presumably accounts for the observed cross-resistance profiles.
- ([redacted], 2013). Lower resistance to dinotefuran of biotype B whiteflies (*Bemisia tabaci*) compared to imidacloprid and thiamethoxam.
- ([redacted], 2014). Low level of resistance to dinotefuran by thiamethoxam-resistant *Frankliniella occidentalis* strain (TH-R) selected under the laboratory conditions.
- ([redacted], 2014). Cross-resistance to dinotefuran of house fly (*Musca domestica*) strains selected with imidacloprid for three/five generations under the laboratory conditions.
- ([redacted], 2014). Relatively lower resistance ratios to dinoterfuran compared with the other neonicotinoids acetamiprid, clothianidin, imidacloprid, thiacloprid in *Aphis gossypii.*
- ([redacted] 2014). Dinotefuran is important for use in rotation of different modes of action in pest management programs, particularly against *Bremisia toabaci* crypic species. Out of 18 active ingredients tested, dinotefuran (applied as a soil drench) was the most efficacious against both MEAM1 and MED cryptic species (commonly known as biotypes B and Q respectively) compared with the other chemical or biorational insecticides evaluated.
- ([redacted] 2016). Resistance to dinotefuran in the common bed bug.
- ([redacted], 2016). The bioassay results showed that the Q-biotype field strains in eastern China have developed low to moderate levels of resistance to imidacloprid, nitenpyram and thiamethoxam, however, no resistance to dinotefuran was detected.
- ([redacted], 2017). Results revealed lowest resistance of field strains of German cockroaches to dinotefuran and other AIs (including boric acid, abamectin, clothianidin, thiamethoxam and chlorfenapyr).
- ([redacted] 2017). Moderate cross-resistance to dinotefuran in chlorpyrifos-methyl resistant cowpea aphids (*Aphis cracivora*) strain which was selected under the laboratory conditions.
- ([redacted], 2018). Comparatively low levels of cross-resistance to dinotefuran of *Aphis gossypii* strain selected with acetamiprid under the labolatory conditions compared with thiacloprid and imidacloprid.
- ([redacted] 2018). Moderate tolerance to dinotefuran in Whitefly (*Bemisia tabaci* Gennadius) in field strains in India.
- ([redacted], 2019). The P450 monooxygenase enzyme CYP6CM1, whose overexpression in *Bemisia tabaci* confers resistance to imidacloprid, metabolized imidacloprid but not dinotefuran in the *in vitro* test, suggesting that no or low level of cross-resistance of dinotefuran.
- ([redacted] 2019). Possible weak cross-resistance to dinotefuran in pyriproxyfen-resistant Silverleaf whitefly (*Bemisia tabaci* (Gennadius)) strain AY09-1R selected under the laboratory conditions. All three insecticides (spirotetramat, cyantraniliprole and dinotefuran) demonstrated good efficacy against silverleaf whitefly, and for the Australian cotton industry, they add three modes of action to the insecticide resistance management strategy, providing greater flexibility in control options.
- ([redacted] 2019). The P450 monooxygenase enzyme CYP6CY3, whose overexpression in *Myzus persicae* confers resistance to imidacloprid, showed

metablic activity against imidacloprid, acetamiprid, clothianidin and thiacloprid, but had no activity against dinotefuran in the *in vitro* test, suggesting that no or low level of cross-resistance of dinotefuran.

Conclusion:

No resistance has yet been noted for house and stable flies (expect a cross-resistance observed in the laboratory by [redacted] 2014). However, based on observations in other insects, most of which are crop pests and therefore not controlled with biocidal products, the development of resistance/cross-resistance cannot be excluded.

To avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Alternate products containing active substances with different modes of action.
- 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 need be, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.
- Do not use the product in areas where resistance is suspected or established.
- Inform the authorisation holder if the treatment is ineffective.
- Avoid continuous use of products.

2.2.5.7 Known limitations

For use on non-porous surfaces only. To ensure residual efficacy, applied product should be left undisturbed (e.g., no (wet) cleaning of treated areas). Do not use in veal calf animal housing and animal housing connected to the STP. For animal buildings on farms, applications up to 10% of the wall and ceiling area are permissible.

2.2.5.8 Evaluation of the label claims

The label claim "control of flies at 16 g product /m² (= 80 mg as/m²) with a residual efficacy of 6 weeks" is supported by several studies conducted with House flies (*Musca domestica*) and Stable flies (*Stomoxys calcitrans*).

For the end-user, and in order to avoid insufficient dose application, the discharge rate observed in efficacy trials is applied to describe the way of application. An average of 0.862 g/s was used to convert the weight of product / m² into number of seconds discharged per linear meter for the label claim (Doc ID 2018/1099481). 16 g product / m² is equivalent to spraying for 3 seconds per linear meter.

STABLE FLIES:

Laboratory test (no-choice test), 6-hour exposure ([redacted] 2018a):

• a knockdown of 96.7% was demonstrated within 4 hours following exposure to 1-day aged residues and 90.0% for 45-day aged residues on ceramic tiles at an application rate of 80 mg a.s./m². Mortality was 86.7 % within 24 hours and 90% within 48 hours following exposure to 1-day aged residues and 100% within 24 hours exposure to 45-day aged residues.

Laboratory test (choice test), 24-hour exposure ([redacted], 2017):

• a knockdown of 80% was demonstrated within 4 hours following exposure to 1-day aged residues and 96.7% for 45-day aged residues on ceramic tiles at an application rate of 80 mg a.s./m². Mortality was 0% within 24 hours, 86.7% within 48 hours and 100% within 72 hours exposure to 1-day residues and 0% at 24 hours, 93.3% at 48 hours and 100% at 72 hours to 45-day aged residues.

Laboratory test (Palatability test, 1 year old product) ([redacted], 2018a):

• at a rate of 80 mg a.s./m² on ceramic tiles, 92.7% knockdown was demonstrated after 4 hours for 1-day aged residue and 98.2% knockdown after 24 hours for 84-day aged residues. Mortality after 24 hours for 1-day aged residues was 98.4% and 94.4 % for 84-day aged residues.

Laboratory test (Palatability test, 3 year old product) ([redacted] 2021):

• at a rate of 80 mg a.s./m² on ceramic tiles, 84.4 % and 95.8 % mortality plus knockdown was demonstrated after 24 and 48 hours, respectively to 1-day aged residues. Mortality after 24 and 48 hours to 1-day aged residues was 67.1 % and 92.9 %, respectively.

Field test ([redacted] 2021):

• A field test conducted at 80 mg ai/m² with product applied on 10% of the walls and ceiling surface demonstrated sufficient efficacy >95% population reduction within 1 day after exposure, which was maintained for 35 days. At the 42-day assessment, efficacy was maintained at >80% population reduction.

HOUSEFLIES (*Musca domestica*):

Laboratory test (no-choice test), 6-hour exposure ([redacted] 2018b):

• a knock-down of 100% was demonstrated within 4 hours following exposure to both 1-day aged residues and 45-day aged residues on ceramic tiles at an application rate of 80 mg a.s./m². Mortality after 24 hours for 1-day aged residues is 83.3% and 96.7% after 48 hours. For 45-days aged residues mortality after 24 hours is 46.7% and 76.7% after 72 hours.

Laboratory test (choice test) ([redacted], 2017):

• a knock-down of 93.3% was demonstrated within 4 hours following exposure to 1-day aged residues and 100% knock-down within 4 hours exposure to 45-day aged residues on ceramic tiles at an application rate of 80 mg a.s./m². Mortality after 24 hours for 1-day aged residues is 93.3% and 100% after 48 hours. For 45-days aged residues mortality after 24 hours is 93.3% and 96.67% after 72 hours.

Simulated-use (choice test) ([redacted], 2021):

• at a rate of 80 mg a.s./m² on aluminium foil covered cardboards representing 2.5% of the wall + ceiling surface,>90 % (92%, 99%, 99%) knockdown was demonstrated within 8 hours for 1-, 28- and 42-day aged residues. Mortality at 24 hours for 1-, 28- and 42-day residues was 100%.

Laboratory test (Palatability test, 1 year old product) ([redacted], 2018b):

• at a rate of 80 mg a.s./m² on ceramic tiles, >95% knockdown was demonstrated within 30 minutes for both 1-day and 55-day aged residues. Mortality after 24 hours for both 1-day and 55-day aged residues is also >95%.

Laboratory test (Palatability test, 3 year old product) ([redacted], 2021):

• at a rate of 80 mg a.s./m² on ceramic tiles, 100 % mortality plus knockdown was demonstrated after 24 hours to 1-day aged residues. Mortality after 24 hours to 1-day aged residues was 100 %.

Field test ([redacted], 2021):

• A further field test conducted at a rate of 80 mg as/m² and a surface treated representing 10% of the walls and ceiling surface demonstrated sufficient efficacy of >95% infestation reduction within 1 day after exposure, which was maintained for 35 days. At the 42-day assessment, efficacy was maintained at >90% population reduction.

Use in houses (use 1 & 2):

A simulated use test was provided with *Musca domestica*, showing sufficient efficacy, i.e., > 80% knockdown and after 24 hours > 90% mortality. In addition, laboratory tests show that efficacy is still sufficient with 3 year old product.

Therefore, use 1 & 2 in houses against *Musca domestica* can be authorised with a shelf life of 3 years.

For the use in stables (use 3 & 4):

Musca domestica

For use in stables a laboratory test and a field test showing sufficient efficacy are required. For houseflies 4 laboratory tests and one field test were provided. In all four laboratory tests sufficient knockdown (>80%) was demonstrated within 24 hours. This was found for 1-day and 45-day old residue of fresh product, for 1-day and 55-day old residue of 1 year old product and for 1-day old residue of 3 year old product. However, sufficient mortality (90% after 24 hours) was only demonstrated for three of the laboratory tests. For the other laboratory test ([redacted] 2018b) 1-day old residue provided 83.3 % efficacy after 24 hours and >90% efficacy after 48 hours. For 45-days old residue efficacy was only 76.7% after 72 hours.

One field test conducted at 80 mg as/m² with a treated surface representing 10% of the walls and ceiling surface showed a reduction of the flies population greater than 95% one day after exposure, which was maintained for 35 days. At the 42-day assessment, efficacy was maintained at >90% population reduction, allowing to support the claimed residuality of 6 weeks. This trial fulfils the validity criteria defined in the EFF TAB (version 2.2) Entry 18 and supports the efficacy claimed for House flies.

Stomoxys calcitrans

For stable flies 4 laboratory tests and one field test were provided. In all four laboratory tests sufficient knockdown (>80%) was demonstrated within 24 hours (see more detailed description above with use 1 & 2). This was found for 1-day and 45-day old residue of fresh product, for 1-day and 84-day old residue of 1 year old product and for 1-day old residue of 3 year old product.

Not all laboratory tests demonstrated >90% mortality after 24 hours, but all laboratory tests demonstrated 90-100% mortality within 72 hours. In the palatability test ([redacted],

2018a) with 1 year old product >90% mortality was found within 24 hours for both 1-day and 84-day aged residue and 100% mortality was demonstrated after 24 hours for 45-day aged residue of fresh product ([redacted] 2018a). The other results were 90% mortality within 48 hours for 1-day aged residue of fresh product and 100% mortality within 72 hours for both 1-day and 45-day aged residue of fresh product ([redacted] 2018a) and >90% mortality after 48 hours for 1-day aged residue of 3 year old product ([redacted], 2021)

One field test conducted at 80 mg as/m² with a treated surface representing 10% of the walls and ceiling surface showed a reduction of the fly population greater than 95% infestation reduction 1 day after exposure, which was maintained for 35 days. At the 42-day assessment, efficacy was maintained at >80% population reduction, supporting the claimed residuality of 6 weeks. This trial fulfils the validity criteria defined in the EFF TAB (version 2.2) Entry 18 and supports the efficacy claimed for Stable flies.

Conclusion:

Although not all laboratory tests showed 90% mortality within 24 hours, most of these tests did and all of them showed >90% mortality within 48-72 hours. As the field test showed >95% population reduction within 24 hours for both fly species, the eCA considers efficacy sufficiently shown in the tests and therefore use 3 and 4 of the product against house flies and stable flies can be authorised.

The efficacy test against stable flies with 3 year old product did not show >90% mortality within 24 hours, but within 48 hours. However, in the efficacy guidance there are no specific criteria for a fly bait product defined. The criterium " mortality after 24 hours should be ≥ 90%" is taken from the criteria for products intended for use as general surface treatment. For a bait product, beside the pure efficacy of the active substance, also the attractiveness of the bait matrix is of relevance. When looking in the efficacy guidance for tests with bait product with e.g. cockroaches or ants the required results in laboratory palatability choice test (bait and alternative food) are: at least 95% of the test insects have been killed at a given time point. This result has been achieved in the palatability test with 3 year old product. As such the eCA considers that a shelf life of 3 years can be authorised against.
Therefore, use 3 & 4 in stables against *Musca domestica* and *Stomoxys calcitrans* can be authorised with a shelf life of 3 years.

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

This biocidal product is not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No *in vitro* data are available

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**
Skin irritation. OECD 404, OPPTS 870.2500, GLP, reliability 1	Rabbit, New Zealand White, female, 3	BAS 395 18 I (SECLIRA FLY BAIT), no vehicle, 0.5 mL undiluted, 4 h	The average scores for erythema are 1.0 / 0.3 / 0.0 and for edema 0.3 / 0.0 / 0.0 for each animal at 24, 48 and 72h, respectively. All animals were free of erythema and edema by Hour 1, Hour 48 or Day 10 (study termination)	none	Doc ID 2017/1175881

No human data is available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	SECLIRA FLY BAIT is not corrosive or irritating to the skin.
Justification for the value/conclusion	Based on the results of the study, the mean score for erythema is < 2.3 and the mean score for edema is < 2.3 from gradings at 24, 48 and 72 hours after patch removal. SECLIRA FLY BAIT (BAS 395 18 I) has been developed by BASF with the objective of having it authorized in different parts of the world. In order to comply with global registration requirements, *in vivo* GLP studies for the acute toxicity as well as irritation and sensitization endpoints are necessary. All studies were conducted in 2017 following internationally recognized guidelines, good laboratory practices, and animal welfare regulations.

	Authorizations have been obtained in the US and Australia already and others are pending in Asian countries. Subsequently, the applicant elected to seek registration of the product in the EU.
Classification of the product according to CLP and DSD	No classification

Eye irritation

No *in vitro* data are available.

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**
OECD 405, OPPTS 870.2400, GLP, reliability 1	Rabbit, New Zealand White, female, 3	BAS 395 18 I (SECLIRA FLY BAIT), no vehicle, 0.09-0.24 g undiluted, single application no rinsing	The average scores at 24h, 48h and 72h were 0.0 for corneal opacity, iritis and conjunctiva (redness and chemosis)effects for any animal.	none	DocID 2017/1210724

No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	SECLIRA FLY BAIT is not irritating to the eye.
Justification for the value/conclusion	Based on the results of the study, the mean score for corneal opacity, iritis and conjunctiva (redness and chemosis) at all assessments was 0. SECLIRA FLY BAIT (BAS 395 18 I) has been developed by BASF with the objective of having it authorized in different parts of the world. In order to comply with global registration requirements*, in vivo* GLP studies for the acute toxicity as well as irritation and sensitization endpoints are necessary. All studies were conducted in 2017 following internationally recognized guidelines, good laboratory practices, and animal welfare regulations. Authorizations have been obtained in the US and Australia already and others are pending in Asian countries. Subsequently, the applicant elected to seek registration of the product in the EU.
Classification of the product according to CLP and DSD	No classification

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	No concerns regarding this endpoint
Justification for the conclusion	No hazard triggers from active substance or co-formulants
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Information on respiratory tract irritation
Justification	SECLIRA FLY BAIT is not acutely toxic by the inhalation route. Moreover, based on the hazard information on the active substance and other co-formulants, none are classified for respiratory irritation (H335).

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**
Buehler method, OECD 406, OPPTS 870.2600, GLP, reliability 1	Guinea pig, Hartley albino, male, 20 (test group) 10 (naïve group)	BAS 395 18 I (SECLIRA FLY BAIT), no vehicle, 0.5 mL 100% HNIC (undiluted, topical application) Induction: 5 tenths of a mL of neat test substance applied topically. No. exposures:3 Exposure period: once per week for 3 weeks Neat test substance applied topically Challenge exposure: 5 tenths of a mL of the neat test substance (100% HNIC) was applied topically.	No adverse effects observed for any of test sites 24 and 48 hours after challenge	none	DocID 2017/1189885

No human data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	SECLIRA@FLY BAIT is not a skin sensitiser
Justification for the value/conclusion	No irritation observed at the highest non-irritating concentration. The Buehler method was used instead of the LLNA study as it was an acceptable method to conduct for the purposes of supporting registrations in the USA. Subsequently, the applicant elected to seek registration of the product in the EU. To address concerns of animal welfare, a LLNA study was not conducted for EU authorisation purposes.
Classification of the product according to CLP and DSD	No classification

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No concerns regarding this endpoint
Justification for the value/conclusion	No hazard triggers from active substance or co-formulants
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Information on respiratory sensitisation.
Justification	SECLIRA FLY BAIT is not a respiratory sensitiser, based on the hazard information on the active substance and other co-formulants, none are classified for respiratory sensitisation (H334).

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 toxic class method, OECD 423, OPPTS 870.1100, GLP, reliability 1	Rat, Sprague-Dawley, female, 6	BAS 395 18 I (SECLIRA FLY BAIT), 2000 mg/kg bw, gavage	none	>2000 mg/kg bw	none	DocID 2017/1177624

No human data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	SECLIRA@FLY BAIT is not toxic via the oral route
Justification for the selected value	Based upon the results of the study, LD50 > 2000 mg/kg bw, no adverse effects were observed. SECLIRA FLY BAIT (BAS 395 18 I) has been developed by BASF with the objective of having it authorized in different parts of the world. In order to comply with global registration requirements, *in vivo* GLP studies for the acute toxicity as well as irritation and sensitization endpoints are necessary. All studies were conducted in 2017 following internationall recognized guidelines, good laboratory practices, and animal welfare regulations. Authorizations have been obtained in the US and Australia already and others are pending in Asian countries. Subsequently, the applicant elected to seek registration of the product in the EU.
Classification of the product according to CLP and DSD	No classification

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 403, OPPTS 870.1300, GLP, reliability 1	Rat, Wistar, male/female, 5 per sex	BAS 395 18 I (SECLIRA@FLY BAIT), Aerosol, MMAD 2.42µm, Analytical chamber concentration 7.22 mg/L Nominal chamber concentration 25.02 mg/L Nose-only exposure	Four rats exhibited irregular respiration following exposure and recovered by Day 1 and for the duration of the observation period.	>7.22 mg/L	none	DocID 2017/1177601

No human data are available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	SECLIRA@FLY BAIT is not toxic via the inhalation route
Justification for the selected value	Based upon the results of the study, single exposure acute inhalation LC50 > 7.22 mg/L, no lasting adverse effects were observed. SECLIRA FLY BAIT (BAS 395 18 I) has been developed by BASF with the objective of having it authorized in different parts of the world. In order to comply with global registration requirements, *in vivo* GLP studies for the acute toxicity as well as irritation and sensitization endpoints are necessary. All studies were conducted in 2017 following internationally recognized guidelines, good laboratory practices, and animal welfare regulations. Authorizations have been obtained in the US and Australia already and others are pending in Asian countries. Subsequently, the applicant elected to seek registration of the product in the EU.

Classification of the product according to CLP and DSD	No classification

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**
Fixed dose procedure, OECD 402, OPPTS 870.1200, GLP, reliability 1	Rat, Sprague-Dawley, male/female, 5 per sex	BAS 395 18 I (SECLIRA FLY BAIT), no vehicle, 5000 mg/kg bw, ~5 x 7.5 cm (10%)	Dermal irritation, such as very slight erythema (grade 1), was noted for one animal on Day 1 only.	>5000 mg/kg bw	none	DocID 2017/1186406

No human data are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	SECLIRA@FLY BAIT is not toxic via the dermal route
Justification for the selected value	Based upon the results of the study, LD50 > 5000 mg/kg bw, no adverse effects were observed. SECLIRA FLY BAIT (BAS 395 18 I) has been developed by BASF with the objective of having it authorized in different parts of the world. In order to comply with global registration requirements*, in vivo* GLP studies for the acute toxicity as well as irritation and sensitization endpoints are necessary. All studies were conducted in 2017 following internationally recognized guidelines, good laboratory practices, and animal welfare regulations. Authorizations have been obtained in the US and Australia already and others are pending in Asian countries. Subsequently, the applicant elected to seek registration of the product in the EU.
Classification of the product according to CLP and DSD	No classification

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**
OECD 428, OECD Guidance Document No. 28, GLP, reliability 1	Human split-thickness skin, 200-400 mm thick, from abdomen or breast,	^{14}C-BAS 395 18 I, applied undiluted at 60.2 µg/cm²	Sum receptor samples 0-24 h including wash out: 0.19% Receptor fluid: 0.21% Receptor chamber washing: 0.16% Skin associated dose: 0.72% **Dermal absorption = 1.8%**		DocID 2018/1082979 (study report) DocID 2021/2049817 (supporting document with calculations)

No animal studies are available.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Dinotefuran
Value(s)*	1.8 % of applied dose
Justification for the selected value(s)	Based on EFSA Guidance document 2017 on Dermal Absorption [EFSA Journal 2017;15(6):4873] Calculations are included in the confidential Annex (section 1.1.7)

** please include the concentration range(s) the values are applicable for, if relevant*

Other Toxicological hazards

The product is classified H336: May cause drowsiness or dizziness. This classification is triggered by acetone (which is classified with H336, and as present in the formulation in a concentration above the general classification limit of 20%).

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

Acetone: IOELV of 1210 mg/m^3 (500 ppm) for an 8h (working day) exposure scenario.

Available toxicological data relating to a mixture

Not applicable, none of the co-formulants are mixtures.

Other

Endocrine disruption activity of active substances

For the active substance Dinotefuran no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for Dinotefuran (2014) state that this active substance would not be considered as having endocrine disrupting properties. However, for the active substance, a current review on ED properties is taking place at the moment of evaluation of this dossier. Therefore, CA NL concludes that we have to await the discussions at EU level.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).
According to the Endocrine disruption criteria a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

From this criteria ED screening was performed by the applicant.
For none of the co-formulants an ED alert was identified. The ED assessment for co-formulants can be found in confidential annex.

In conclusion, based on available information, it is not possible to conclude whether the active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties of these co-formulants is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards dinotefuran from its use in Seclira®FlyBait

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	yes	n.a.	yes	yes	no
Dermal	n.a.	yes	yes	n.a.	yes	yes	no
Oral	n.a.	no	no	n.a.	no	yes	yes

Identification of main paths of human exposure towards substances of concern from its use in Seclira®FlyBait

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	yes	n.a.	no	no	no
Dermal	n.a.	yes	yes	n.a.	yes	yes	no
Oral	n.a.	no	no	n.a.	no	no	no

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.	Professional and non-professional application by spraying (urban pest control & rural hygiene)	Primary exposure of operators to the active substance and substances of concern by barrier treatment to surfaces of the product with a ready to-use aerosol dispenser.	Professionals, Non-professionals
2.	Secondary exposure to the Professional in urban & rural pest control	Secondary exposure to the professional operator after application of the product due to cleaning of the work clothes.	Professionals
3.	Secondary exposure to the general public in urban pest control and rural hygiene	Secondary exposure to the general public that could take place via the inhalation route by re-entering a treated room, dermally by accidentally touching a treated surface and for infants and toddlers by the oral route from hand-to-mouth contact from treated surfaces.	General population: Infants, toddlers, children, adults

Industrial exposure

No industrial exposure is foreseen

Professional exposure

The product Seclira®FlyBait is a ready-to-use aerosol provided in spray cans that contains the active substance Dinotefuran at a concentration of 0.5% (w/w) as well the substances of concern Acetone (25.34% w/w). According to the document "37th Meeting of Competent Authorities for REACH and CLP (CARACAL); Doc. CA/58/2020 Final", if the propellant will quickly evaporate (it is liquefied and has a vapour pressure (20ºC) ≥ 10 Kpa), for the classification and labelling of the biocidal product, the concentration of active substance and co-formulant in the product without propellant should be taking into account, as classification of solely the other constituents of the aerosol is more "relevant" within the meaning of Article 6(1) of the CLP Regulation. Therefore, additional composition table of the filling solution has been added in the Confidential annex. Excluding the propellant results in an increase of the active substance and substance of concern, respectively 0.59% Dinotefuran and 29.7% Acetone. These concentrations are considered in the risk assessment.

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Scenario [1] Professional and non-professional application by spraying (urban pest control & rural hygiene)

Description of Scenario [1]

For the urban pest control, the application will be performed in private households, public buildings and large public buildings by professional and non-professional operators, indoors. For the rural hygiene use, the application will be performed in stables on farms. The application is considered to take place at a maximum of 11 times per year in the urban pest control scenario and 6 times per year in the rural hygiene scenario. The technical notes of guidance (version 2002) reports a median duration of 120 minutes application which has been used for the exposure assessment in private households, large public buildings and small stables. For the use in large stables a longer exposure estimate is required, as the application period exceeds 2 hours. Thus, an exposure time of 4 hours has been chosen by estimate for large stables. The task of the operator is restricted to in-use aerosol application, thus no mixing and loading needs to be taken into consideration.

In the ConsExpo pesticide general fact sheet (RIVM Report 320005002) the default room volume for private house used in spot treatment is 20m^3 for an area of 2m^2 treated. This is not considered representative of the area treated with Seclira®FlyBait. According to the technical manual of agreements for biocides (ENV, Version 1.3, August 2017) the treatment area for barrier, which is representative of Seclira®FlyBait in households and professional use is 20 m^2 and 93 m^2 for a domestic house and large commercial building, respectively (Chapter 3.17.1, ENV 142). This has also been considered by the environmental risk assessment (2.2.8.2). It is further specified in the technical manual, that the barrier treated area in a private house is based on a wet cleaned zone (in this case the entire floor area of the treated rooms) of 38.5m^2. Thus, the total volume of the treated area equals 38.5 m^2 x 2.5 m (room height) = 96.25m^3. For a large commercial building, the building volume, which could be a "single room", is specified as 609 m^2 x 4 m equals 2436 m^3 (follow up of WG-I-2018, generic treatment areas). In the rural area, different stable sizes have been reported (ENV/JM/MONO(2006)4). It is considered that 10% of the wall/roof area are maximally treated. Thus, poultry house (Turkey, litter floor) has been considered as the largest building in the exposure assessment (465 m^2 treated area) where-as Cattle (veal calves) occupy the smallest stable building (33 m^2 treated area). Thus, 4 scenarios have been assessed: Private house, large public building, small and large stable.

According to product specific data (BASF DocID 2021/2050294) the flow rate of Seclira®FlyBait from the aerosol can is 1.17 g/s and the time to treat 1 m^2 is 13.67 seconds. Thus, product specific application rates and application times are taken into consideration in the exposure assessment (detailed calculations presented in Annex 3.2).

The airborne fraction, density and initial particle size distribution was assessed according to the RIVM Spray Model (Report 320104005/2009). The product most representative of Seclira®FlyBait is considered to be Flea Spray 1, as it is a pesticidal use applied on surface via a spray can at a distance of 30 cm to an area of 70 x 70 cm. The aerosol size class as reported in table 2 of the RIVM report is considered high and thus the inhalation potential sufficiently conservative for the inhalation exposure assessment of Seclira®FlyBait.

The exposed skin area for an adult applicator wearing a short-shirt, pants, shoes and socks is considered to be 1948 cm^2 (820cm^2 + 1128.8 cm^2) (Adhoc rec 14). As the product

is applied in the ceiling, head and neck can be exposed as well and the exposed skin area is calculated as 3280 cm^2 The following models have been used in the exposure assessment: Dinotefuran: Exposure to spray / spraying (inhalation), direct product contact / constant rate (dermal), non-respirable spray model (oral) Substances of concern: Exposure to vapour / constant rate (inhalation). As these substances are highly volatile and IOELVs for the inhalation route have been defined only, exposure by the dermal/oral route does not have to be assessed.		
	Parameters	Value
Tier 1	Spray duration private house (urban)	8.8 minutes
	Spray duration large building (urban)	21.2 minutes
	Spray duration small stable (rural)	7.5 minutes
	Spray duration large stable (rural)	106 minutes
	Exposure duration[1]	120 minutes
	Exposure duration large stable[2]	240 minutes
	Weight fraction substance	0.5% (w/w)
	Product amount private house (urban)	616 g
	Product amount large building (urban)	1488 g
	Product amount small stable (rural)	528 g
	Product amount large stable (rural)	7437 g
	Room volume house[5]	96.25 m^3
	Room volume large building[5]	2436 m^3
	Room volume small stable[8]	590 m^3
	Room volume large stable[8]	12500 m^3
	Room height private house[2]	2.5 m
	Room height small stable[8] (calculated)	3.69 m
	Room height large stable[8] (calculated)	3.75 m
	Room height large building[2]	4 m
	Ventilation rate[2]	0.6 / hour
	Inhalation rate[3]	20.8 l/min, 1.25 m^3/hr
	Body weight[3]	60kg
	Mass generation rate[4]	1.17 g/s
	Airborne fraction[5]	0.2
	Density non-volatile[5]	2 g/cm^3
	Inhalation cut off diameter[2]	15 µm

	Initial particle size distribution (log normal)[5]	3.6 µm (0.39 µm)
	Maximum diameter[2]	50µm
	Absorption by inhalation (default)	100%
	Exposed Area[7]	3280cm^2
	Contact rate[2]	100 mg/min
	Dermal Absorption[6]	1.8%
	Oral Absorption (default)	100%

[1] Technical Notes for Guidance 2002
[2] RIVM Pesticides General Fact Sheet Default (RIVM Report 320005002)
[3] EU framework biocides
[4] BASF DocID 2021/2050294
[5] RIVM Spray Model (Report 320104005/2009)
[6] BASF DocID 2018/1082979 and assessed according to EFSA 2017
[7] HEAdhoc Recom. no. 14 (2017); adult hand and forearm
[8] OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 14 (ENV/JM/MONO(2006)4)

eCA note: : The Consexpo model "Exposure to Vapour" describes a situation in which a substance evaporates from a liquid product into the room air (i.e. paints). However, it is mentioned that for volatile substances, the Exposure to Vapour model is more appropriate when the substance is released by a spray application. Even though instantaneous release might be used as it is primary exposure (application), instantaneous scenario assumes that all substance is released from the used product at once into the room and is subsequently removed by ventilation. Since the spray duration is long (up to 106 min), NL CA agrees with the use of the option "constant rate inhalation".

Calculations for Scenario [1]

For substances of concern Acetone, occupational exposure limits have been set by the inhalation route. As the IOELV´s are derived for external exposure only, the estimated exposure in mg/m^3 has been assessed here. Single as well as combined exposure against the IOELV is addressed in chapter 2.2.6.3 for risk characterisation.

Summary table: estimated exposure from professional uses					
Exposure scenario:	**Tier/ PPE**	**Estimated inhalation uptake or exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake or exposure**
Scenario [1] Private House Dinotefuran Acetone Large Building	 1 1	 4.56 x 10^{-2} mg/kg bw/d 1080 mg/m^3	 1.56 x 10^{-3} mg/kg bw/d n.a.	 2.61 x 10^{-7} mg/kg bw/d n.a.	 4.71 x 10^{-2} mg/kg bw/d 1080 mg/m^3

Dinotefuran Acetone Small Stable Dinotefuran Acetone Large Stable Dinotefuran Acetone	 1 1 	5.11×10^{-3} mg/kg bw/d 100 mg/m^3 7.41×10^{-3} mg/kg bw/d 152 mg/m^3 5.42×10^{-3} mg/kg bw/d 61.7 mg/m^3	3.75×10^{-3} mg/kg bw/d n.a. 1.33×10^{-3} mg/kg bw/d n.a. 1.88×10^{-2} mg/kg bw/d n.a.	3.89×10^{-8} mg/kg bw/d n.a. 5.28×10^{-8} mg/kg bw/d n.a. 3.57×10^{-8} mg/kg bw/d n.a.	8.86×10^{-3} mg/kg bw/d 100 mg/m^3 8.74×10^{-3} mg/kg bw/d 152 mg/m^3 2.42×10^{-3} mg/kg bw/d 61.7 mg/m^3

n.a. – not applicable

Further information and considerations on scenario [1]

None

Scenario [2] Secondary exposure to the Professional and non-professional operator in urban & rural pest control

Description of Scenario [2]		
Exposure to the professional operator in the urban and/or rural pest control scenario could take place via the dermal route from post-treatment activities (cleaning work clothes at home). The exposure is from handling the contaminated clothing prior to introduction into the washing machine. It is considered to apply for the acute as well as the chronic exposure scenario. The amount of product contaminating the coverall is equivalent to the potential dermal exposure (dermal load) estimated by ConsExpo as calculated in scenario 1. It is assumed that the coverall is washed weekly, after 5 days wear. For an adult, the total area of both palms is 410 cm² (HEEG Opinion 17, 2013). The transfer coefficient for contamination (dried fluid) from cotton, knitwear to wet hands is 30% (ECHA Biocides Human Health Exposure Methodology, p.351). A dermal penetration rate of 1.8% is assumed for dinotefuran. The systemic dose for a 60 kg adult hence can be calculated as (example private house): (a.s. on coverall × 5 day a week x hand surface area × transfer coefficient × dermal absorption rate) / body weight = 1.58 x 10^{-3} mg/cm^2 x 5 x 820 cm^2 x 30% x 1.8% / 60 kg bw = 5.18 x 10^{-4} mg/kg bw/d All calculations are included in the output tables in section 3.2.1.		
	Parameters	Value
Tier 1	Dermal load Private house: Large building Small stable: Large stable:	 1.58 x 10^{-3} mg/cm^2 3.81 x 10^{-3} mg/cm^2 1.35 x 10^{-3} mg/cm^2 1.91 x 10^{-2} mg/cm^2
	Palm area adult[1]	820 cm^2
	Transfer coefficient[2]	30%
	Dermal absorption[3]	1.8%
	Adult body weight	60 kg

[1] HEAdhoc Recom. no. 14 (2017)
[2] ECHA Biocides Human Health Exposure Methodology, p.351
[3] BASF DocID 2018/1082979 and assessed according to EFSA 2017

Calculations for Scenario [2]

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]					
Private House	1	n.a.	5.83×10^{-4} mg/kg bw/d	n.a.	5.83×10^{-4} mg/kg bw/d
Large Building	1	n.a.	1.41×10^{-3} mg/kg bw/d	n.a.	1.41×10^{-3} mg/kg bw/d
Small stable	1	n.a.	4.98×10^{-4} mg/kg bw/d	n.a.	4.98×10^{-4} mg/kg bw/d
Large stable	1	n.a.	7.05×10^{-3} mg/kg bw/d	n.a.	7.05×10^{-3} mg/kg bw/d

Further information and considerations on scenario [2]
None

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1,2] Tier 1				
Private House				
Dinotefuran	4.56×10^{-2} mg/kg bw/d	2.14×10^{-3} mg/kg bw/d	2.61×10^{-7} mg/kg bw/d	4.77×10^{-2} mg/kg bw/d
Acetone	1080 mg/m^3	n.a.	n.a.	1080 mg/m^3
Large Building				
Dinotefuran	5.11×10^{-3} mg/kg bw/d	5.16×10^{-3} mg/kg bw/d	3.89×10^{-8} mg/kg bw/d	1.03×10^{-2} mg/kg bw/d
Acetone	100 mg/m^3	n.a.	n.a.	100 mg/m^3
Small Stable				
Dinotefuran	7.41×10^{-3} mg/kg bw/d	1.83×10^{-3} mg/kg bw/d	5.28×10^{-8} mg/kg bw/d	9.24×10^{-3} mg/kg bw/d
Acetone	152 mg/m^3	n.a.	n.a.	152 mg/m^3
Large Stable				
Dinotefuran	5.42×10^{-3} mg/kg bw/d	2.58×10^{-2} mg/kg bw/d	3.57×10^{-8} mg/kg bw/d	3.13×10^{-2} mg/kg bw/d
Acetone	61.7 mg/m^3	n.a.	n.a.	61.7 mg/m^3

Non-professional exposure

Scenario [1] Professional and non-professional application by spraying (urban pest control & rural hygiene)

The model used and calculations presented for the professional exposure are also applicable to the non-professional scenario. It is considered that the application rate of 11 (urban pest control) and of 6 (rural hygiene scenario) with a re-application interval of 2 to 3 weeks are considered relevant for acute exposure and that no chronic exposure assessment for the non-professional is required. The calculations for the acute exposure assessment can be found in the scenario 1: Summary table: systemic exposure from professional uses.

Further information and considerations on scenario [1]
None

Scenario [2] Secondary exposure to the Professional and non-professional operator in urban & rural pest control

Exposure to the non-professional operator in the urban and/or rural pest control scenario could take place via the dermal route from post-treatment activities (cleaning work clothes at home). The exposure is from handling the contaminated clothing prior to introduction into the washing machine. The calculations for this scenario can be found in scenario 2 of professional exposure.

Combined scenarios

The calculations for the combined exposure assessment can be found in the combined scenarios section for professional exposure.

Exposure of the general public

Scenario [3] Secondary exposure to the general public in urban pest control and rural hygiene

Description of Scenario [3]
Secondary exposure to the general public could take place via the inhalation route by re-entering a treated room, dermally by accidentally touching a treated surface and for infants and toddlers by the oral route from hand-to-mouth contact from accidentally touching/crawling along treated surfaces. According to HEEG opinion 13 (2013), inhalation exposure of volatilized biocide a.s., that is the amount of a.s. volatilizing from surfaces after application with the product, can be considered negligible if the following is true for a toddler (worst-case compared to adults) based on an inhalation rate of 8 m^3/24 h and a bw of 10 kg and using an AEL in mg/kg bw/d: 0.328 x mw x vp / $AEL_{long\text{-}term} \leq 1$, where mw denotes the molecular weight (202.2 g/mol) and vp the vapour pressure in Pa for the toddler (5.0×10^{-5} Pa at 25°C (see active ingredient Biocide Dossier, list of endpoints)). Considering an $AEL_{short\text{-}term}$ of 1.75 mg/kg bw/d, the assessment results in 0.328 x 202.2 g/mol x 5.0×10^{-5} / 1.75 mg/kg bw/d = $1.9 \times 10^{-3} \leq 1$ being true. Therefore, the inhalation risk for toddlers as well as for infants, children and adults is **negligible** in short-term exposure. The same is true when

comparing the $AEL_{long\text{-}term}$ of 0.22 mg/kg bw/d to the assessment results. Thus, inhalation risk for all populations is **negligible** in long-term exposure. As for substance of concern included in the product, no secondary exposure to the general public is expected due to the volatile nature of the compounds. Thus, no exposure assessment for SoC by inhalation, dermal and/or oral route has been conducted for secondary exposure estimates.

For the dermal route, the frequency of exposure is calculated as 11 applications per year times 14 days of exposure post treatment (154 days). The direct product contact and rubbing off model by ConsExpo has been considered for dermal exposure assessment. The dislodgeable amount has been calculated based on the following considerations: As a default 15% of total sprayed will deposit on the ground. The mass generation rate is 1.17 g/sec and spraying time of a private house is 276 seconds. Thus 48g product are deposited. 30% of the product on floor is dislodgeable and the floor surface is 38.5m^2. Thus, the dislodgeable amount is 0.38g/m^2. The respective value for a large building is 0.11 g/m^2 for a small stable 0.15 g/m^2 and a large stable 0.10 g/m^2 based on surface areas of 609 m^2, 160 m^2 and 3330 m^2, respectively. The contacted surface is considered a smaller area than the treated area used in scenario 1, based on the label recommendation that "the product should be applied in areas not accessible to children, companion animals and non-target animals". Thus, contact to a treated area of 2 m^2 is chosen based on default pesticide fact sheet parameters for targeted spot application as a reasonable worst-case consideration. This exposure assessment is applied to all populations under consideration, corrected for body weight.

According to the RIVM Pest Control Fact Sheet (RIVM report 320005002), dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact, which is modelled by the constant rate model in this assessment. The ingestion rate assumed 100% absorption of the mouthed product. It is not considered realistic to anticipate the presence of infants and/or toddlers in other than private house, such as large industrial buildings and stables. Thus, secondary exposure is considered only in the scenario of a domestic home for infants and toddlers.

	Parameters	Value
Tier 1	Molecular weight a.s.[1]	202.2 g/mol
	Vapour pressure[1]	5.0 x 10^{-5} Pa at 25°C
	Frequency of exposure	154 days
	Transfer coefficient dermal[2]	Adult: 0.78 m^2/hr Infant: 0.2 m^2/hr For other children > 12 months the worst-case value of TC for infants should be applied.
	Dislodgeable amount private house	0.38 g/m^2
	Dislodgeable amount large building	0.11 g/m^2
	Dislodgeable amount small stable	0.15 g/m^2
	Dislodgeable amount large stable	0.10 g/m^2

	Contact time[3]	60 minutes
	Contacted surface[3]	2 m^2
	Body weight infant[4]	8 kg
	Body weight toddler[4]	10 kg
	Body weight child (6-<12yr)[4]	23.9 kg
	Body weight adult[4]	60 kg
	Mass generation rate[5]	0.862 g/s
	Hand surface area[4]	Adult 410 cm^2 Child 427.8 cm^2 Toddler 230.4 cm^2 Infant 196.8 cm^2
	Exposed skin area (child; head, arms and hands, legs and feet, neck)	4265.9 cm^2

[1] Active ingredient Biocide Dossier, list of endpoints.
[2] HEADhoc Recom. No. 12 (2016). Default values for indoor Transfer Coefficient.
[3] RIVM Pesticides General Fact Sheet Default (RIVM Report 320005002)
[4] HEAdhoc Recom. no. 14 (2017). Hand surface area: Adult palms; child, infant, toddler palms and back of hands.
[5] BASF DocID 2021/2050294
[6] Dermal load and Ingestion rate: calculations included in 3.2.1

Calculations for Scenario [3]

Summary table: systemic exposure from (non)-professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3] Dinotefuran Private House					
Infant	1	Negligible	1.0×10^{-3} mg/kg bw/d	2.8×10^{-3} mg/kg bw/d	3.8×10^{-3} mg/kg bw/d
Toddler		Negligible	8.1×10^{-4} mg/kg bw/d	2.2×10^{-3} mg/kg bw/d	3.0×10^{-3} mg/kg bw/d
Child		Negligible	3.4×10^{-4} mg/kg bw/d	n.a.	3.4×10^{-4} mg/kg bw/d
Adult		Negligible	5.3×10^{-4} mg/kg bw/d	n.a.	5.3×10^{-4} mg/kg bw/d
Large Building					

Child Adult	1	Negligible Negligible	8.9×10^{-3} mg/kg bw/d 1.5×10^{-4} mg/kg bw/d	n.a. n.a.	8.9×10^{-3} mg/kg bw/d 1.5×10^{-4} mg/kg bw/d
Small stable Child Adult	1	Negligible Negligible	1.3×10^{-4} mg/kg bw/d 2.1×10^{-4} mg/kg bw/d	n.a. n.a.	1.3×10^{-4} mg/kg bw/d 2.1×10^{-4} mg/kg bw/d
Large stable Child Adult	1	Negligible Negligible	8.9×10^{-5} mg/kg bw/d 1.4×10^{-4} mg/kg bw/d	n.a. n.a.	8.9×10^{-5} mg/kg bw/d 1.4×10^{-4} mg/kg bw/d

n.a. – not applicable

Combined scenarios

Combined exposure is possible in case of adults applying the product and having contact with the treated surfaces post-application.

Summary table: estimated combined exposure from non-professional uses (adult)					
Exposure scenario:	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1+3] Private House Dinotefuran Large Building Dinotefuran	1 1	4.56×10^{-2} mg/kg bw/d 5.11×10^{-3} mg/kg bw/d	2.09×10^{-3} mg/kg bw/d 3.90×10^{-3} mg/kg bw/d	2.61×10^{-7} mg/kg bw/d 3.89×10^{-8} mg/kg bw/d	4.77×10^{-2} mg/kg bw/d 9.01×10^{-3} mg/kg bw/d
Small Stable Dinotefuran Large Stable	1	7.41×10^{-3} mg/kg bw/d	1.54×10^{-3} mg/kg bw/d	5.28×10^{-8} mg/kg bw/d	8.95×10^{-3} mg/kg bw/d

Dinotefuran	1	5.42 x 10^{-3} mg/kg bw/d	1.89 x 10^{-2} mg/kg bw/d	3.57 x 10^{-8} mg/kg bw/d	2.44 x 10^{-2} mg/kg bw/d

Further information and considerations on scenario [3]
None

Monitoring data
No monitoring data are available.

Dietary exposure

According to the label, any intentional and unintentional exposure of animals to the biocidal product should be avoided. The product is directed to areas where flies congregate and settle, which is likely a place not too close to the animals. The label instructions for use specify the following:

- Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.
- Do not store near food, drink and feed.
- Do not use near domestic animals or livestock.
- Do not apply directly on animals.

However, it remains a possibility that calves, cattle, pigs and poultry could be exposed via the inhalation route (during product application), and poultry could be further exposed via the oral (consumption of dead flies) and dermal route (it is assumed that poultry will not be removed during product application).

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
1.	Non-professional, (trained) professional use in ruminants (calf, cattle) pigs and poultry stables	Applications applied as spot treatment to 10% of the treatable area (walls + ceilings) at a rate of 80 mg a.s./m²	Inhalation, oral and dermal exposure animals (eggs, meat, fat, liver, kidney and milk).

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Veterinary use	Spot-on treatment for dogs against fleas, ticks, sand flies, mosquitoes and stable flies.	None
2.	Veterinary use	Spot-on treatment for cats against fleas.	None
3.	Plant protection product	Insecticide, dinotefuran is not included in Annex IV to Regulation (EC) No 396/2005	MRL of 0.1 mg/kg for food of animal origin, excluding poultry and eggs that is set at 0.02 mg/kg (Codex MRL) Reg. (EU) No 491/2014 .

Estimating Livestock Exposure to Active Substances used in Biocidal Products and Worst Case Consumer Exposure (WCCE)

Scenario [1] Uptake by animals via oral, dermal and inhalation exposure

Description of Scenario [1]

Inhalation after air space treatment: Although the product is not intended as an air space treatment, it is considered possible that the animal will be exposed to the air containing the biocidal active substance at its saturated vapour concentration (SVC).

The product (0.59% w/w dinotefuran) spray aerosol (AE) formulation is intended for use as PT18 - insecticide by professionals and non-professionals in rural buildings (animal housing). The proposed use is via spot applications to locations where flies congregate and settle, at an application rate of 80 mg a.s./m² to a maximum of 10% of wall plus ceiling area (supported by efficacy testing). For the exposure assessment calculations (included in section 3.2.1), the BfR calculator for estimating livestock exposure to active substances in biocidal products is used.
First a screening assessment was performed to assess whether the trigger value of 0.004 mg/kg bw/d is exceeded (Tier 1). The screening step assumes that the entire amount of biocidal product applied is taken up by animals regardless of the route of exposure. To this end it is assumed that complete wall and floor areas of animal housing (without partitions) are treated with the biocidal product. This is considered worst case for the intendes use, as walls and ceilings will be treated.
If the trigger value is exceeded, a more realistic worst case exposure assessment was performed (Tier 2).
Oral and dermal exposure has been considered to cover the behaviour of animals which can lick, chew and rub in surfaces that can be treated with the product.

According to the label, any intentional and unintentional exposure of animals to the biocidal product should be avoided. The product is directed to areas where flies congregate and settle (which is likely a place not too close to the animals i.e. walls and ceilings). Furthermore, the label instructions for use specify the following:

- Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.
- Do not store near food, drink and feed.
- Do not use near domestic animals or livestock.
- Do not apply directly on animals.

Considering the product is applied by spot treatment and considering that the assigned RMMs exclude direct exposure of the animals, as a worst case exposure assessment exposure to spray drift is considered for oral and dermal exposure. Exposure to spray drift for oral and dermal exposure, is reflected by a value of 11% or 0.11 as refinement factor (derived from the harmonised fraction emitted to floor during surface treatment as depicted in the Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017) is included for the following scenarios:

- "Oral - Animals licking surfaces"
- "Oral - Uptake of feed (treatment of surfaces surrounding through)"
- "Oral - Chewing on wooden stall edgings"
- "Dermal – Rubbing against surfaces"

For the scenario "Oral-Uptake of feed (treatment of surfaces surrounding through)" and "Dermal – Spray treatment" no refinement is included, as the exposure to spray drift reflected by the emission factor is already included in the calculations.

Moreover, the scenario "Oral- Uptake of feed (direct treatment of through)" was not included as the RMM "Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets." excludes direct exposure and the exposure to spray drift is considered covered by scenario "Oral-Uptake of feed (treatment of surfaces surrounding through)".

Furthermore, no refinement factor is included for "Oral – ingestion of dead insects" as the insects themselves can be fully exposed to the product and subsequently eaten by poultry.

In addition, during HH WG 2022 discussion it as agreed that for animal systemic availability after dermal exposure a 50% reduction is considered acceptable, therefore this is also considered in the current exposure calculations.

Moreover, for the scenario " Dermal -Spray treatment" considers exposure to spray drift after full treatment of the walls. This is reflected by the following calculation:

*Exp=AR*Awall*EF*Fcovered/Noanim/bw*RF*

With EF: emission factor for spray application: fraction emitted to floor during surface treatment (default=0,11)

However, considering that the product is applied as spot treatment and dermal exposure is excluded by the included RMMs "Do not use near domestic animals or livestock." and "Do not apply directly on animals." the current dermal exposure to spray is considered too worst case for Seclira Fly Bait. Efficacy studies are based on spot treatment. To this end, 10% of the area is treated, resulting of all (i.e. 75) flies withing 5 minutes. Although the product should not be used near domestic animals or livestock, for the exposure calculations we consider that all of this 10% treatment is available for dermal exposure to spray calculations. Therefore, the calculation is refined by 10%.

In addition, for inhalative exposure the scenario "Inhalative – Saturated Vapour Concentration Model (SVC)" scenario was included, without refinements.

	Parameters	Value
Tier 1 Screening	Concentration active substance in the product	0.59 % w/w/
	Application rate	80 mg/m^2 (field test Efficacy)
Tier 2(Refined) Realistic worst case assessment	Molecular weight (g/mol)[1]	202.2
	Vapour pressure (Pa) at 25 ºC[1]	5E-05
	Temperature (K)[2]	293
	Gas constant (J/K*mol)[2]	8.31451
	Alveolar ventilation) (m^3/d)	defaults from BfR calculator.
	Bodyweight animal (kg)	defaults from BfR calculator.

	Transfer factors[2]	Eggs: 0.03 Milk: 0.02 Muscle: 0.02 Fat: 0.01 Liver: 0.02 Kidney: 0.02
	Spray drift[3]	11%
	Animal systemic availability after dermal exposure[4]	50%
	Spot treatment[5]: Only included for scenario "Dermal – Spray treatment"	10%

[1] Dinotefuran PT18 Assessment Report (2014)
[2] Maximum transfer of external oral dose to livestock edible tissues (see Leeman et al. 2007). Included in BfR calculator: Selected $LogP_{OW}$ range: <0
[3] Harmonised fraction emitted to floor during surface treatment as depicted in the Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017
[4] HH WGI 2022
[5] considering that the product is applied as spot treatment and dermal exposure is excluded by the included RMMs "Do not use near domestic animals or livestock." and "Do not apply directly on animals." the current dermal exposure to spray is considered too worst case for Seclira Fly Bait. Based on efficacy studies, which shows that 10% treatment of an area results in knockdown of flies. Although the product should not be used near domestic animals or livestock, for the exposure calculations we consider that all of this 10% treatment is available for dermal exposure to spray calculations. Therefore, the calculation is refined by 10%.

Calculations for estimating livestock exposure for Scenario [1] – Screening scenario

Results of the exposure estimates (output table of BfR calculator is included in section 3.2.1) are included in the table below. Estimates above the trigger value are highlighted in red.

Outcome Screening Scenario: Estimated Livestock Exposure (mg a.s./kg bw /d)		
Animal Species		Surface treatment of animal housing (floor&wall of stable without partitions)
Beef cattle		1.2800
Dairy cattle		2.0554
Calf		1.6500
Fattening pig		1.9400
Breeding pig		
Breeding pig	individual housing	2.1212
Breeding pig	group housing	2.7040
Sheep		
Lamb		
Slaughter goat		

Lactating goat		
Broilers		
Broilers	free range, litter floor	3.7647
Broilers	parent broilers, free range (grating floor)	4.0336
Broilers	parent broilers in rearing, free range (grating floor)	3.9216
Laying hen		
Laying hen	battery	2.2055
Laying hen	free range (litter floor)	8.5474
Laying hen	free range (grating floor)	3.8358
Turkey		
Horse		
Rabbit		5.3760

As the trigger value of 0.004 mg/kg bw/d is exceeded, a more realistic worst case exposure assessment was performed (Tier 2).

Calculations for estimating livestock exposure for Scenario [1] – Realistic Worst Case Assessment

The following relevant scenarios where included in the assessment:

- "Oral- Animals licking surfaces"
- "Oral-Uptake of feed (treatment of surfaces surrounding through)"
- "Oral- Chewing on wooden stall edgings"
- "Oral – ingestion of dead insects"
- "Dermal – Rubbing against surfaces"
- "Dermal – Spray treatment"
- "Inhalative – Saturated Vapour Concentration Model (SVC)"

Oral exposure- fly consumption:

Additional information, besides the information included in the BfR calculator:
Concentration of a.s. per fly per day (mg a.s./fly/d) = Quantity of product eaten per fly in 24 hours x Concentration of a.s. in product

The guidance default assumption is that a fly can ingest a maximum of 3.5 mg sucrose per day (i.e. in a 24 hour period), and that it is reasonable to assume that daily biocidal product intake by the fly does not exceed daily sucrose intake.

The concentration of the a.s. in the product is 0.0059 mg a.s. / mg product.

Therefore: Concentration of a.s. per fly per day (mg a.s./fly/d) = 3.5 x 0.0059 = 0.02065

Exposure=AR*No_{fly}/bw*RF

AR: application rate (mg/fly/d)
No_{fly}: fly consumption per animal (default=10, TNsG Table 4)
bw: body weight (kg) (default, TNsG Table 1)
RF: refinement factor (default=1)

Outcome of Livestock Exposure (mg a.s./kg bw/d) refined with empirical transfer factors based on the Octanol–Water Partition Coefficient (log P_O/W) [mg/kg bw/d] and 50% systemic availability for dermal exposure:

				Total livestock exposure = Sum Oral * TF based on logP_{OW} + Sum Dermal * systemic availability + Sum Inhalative					
Animal Species		**Sum Oral Exposure**	**Sum Dermal and Inhalative Exposure**	**Eggs**	**Milk**	**Muscle**	**Fat**	**Liver**	**Kidney**
Beef cattle	-	0.0123	0.0131			0.0133	0.0132	0.0133	0.0133
Dairy cattle	-	0.0393	0.0118		0.0126	0.0126	0.0122	0.0126	0.0126
Calf	-	0.0255	0.0197			0.0202	0.0199	0.0202	0.0202
Fattening pig	-	0.0422	0.0204			0.0212	0.0208	0.0212	0.0212
Breeding pig	-	0.0027	0.0147			0.0147	0.0147	0.0147	0.0147
Breeding pig	individual housing	0.0399	0.0147			0.0155	0.0151	0.0155	0.0155
Breeding pig	group housing	0.0467	0.0147			0.0156	0.0152	0.0156	0.0156
Sheep	-	0.0000	0.0007		0.0007	0.0007	0.0007	0.0007	0.0007
Lamb	-	0.0000	0.0007			0.0007	0.0007	0.0007	0.0007
Slaughter goat	-	0.0000	0.0517			0.0517	0.0517	0.0517	0.0517
Lactating goat	-	0.0000	0.0289		0.0289	0.0289	0.0289	0.0289	0.0289
Broilers	-	0.1215	0.0005			0.0029	0.0017	0.0029	0.0029
Broilers	free range, litter floor	0.1215	0.0037			0.0061	0.0049	0.0061	0.0061
Broilers	parent broilers, free range (grating floor)	0.1215	0.0044			0.0068	0.0056	0.0068	0.0068
Broilers	parent broilers in rearing, free range (grating floor)	0.1215	0.0041			0.0065	0.0053	0.0065	0.0065
Laying hen	-	0.1087	0.0004	0.0037		0.0026	0.0015	0.0026	0.0026
Laying hen	battery	0.1550	0.0024	0.0070		0.0055	0.0039	0.0055	0.0055
Laying hen	free range (litter floor)	0.1087	0.0074	0.0106		0.0096	0.0085	0.0096	0.0096
Laying hen	free range (grating floor)	0.1087	0.0036	0.0069		0.0058	0.0047	0.0058	0.0058

Turkey	-	0.0295	0.0004			0.0009	0.0007	0.0009	0.0009
Horse	-	0.0000	0.0183			0.0183	0.0183	0.0183	0.0183
Rabbit	-	0.0000	0.0015			0.0015	0.0015	0.0015	0.0015

Outcome of Worst Case Consumer Exposure refined with empirical transfer factors based on the Octanol–Water Partition Coefficient (log P_O/W) [mg/kg bw/d]and 50% systemic availability for dermal exposure:

	$WCCE_{muscle}$[1]	**$WCCE_{fat}$[1]**	**$WCCE_{liver}$[1]**	**$WCCE_{kidney}$[1]**	**$WCCE_{milk}$[1]**	**$WCCE_{eggs}$[1]**	**$WCCE_{total}$ [2]**
EMA Food Basket[3] - chronic - adult	2.59E-04	4.31E-05	8.62E-05	4.31E-05	7.23E-04	1.17E-05	0.0012
	Goat	Goat	Goat	Goat	Goat	Laying hen	
EFSA PRIMo[4] - chronic - adult	5.52E-05	4.15E-06	8.47E-07	3.26E-08	1.55E-04	6.20E-06	0.0002
	Bovine	Pig	Pig	Bovine	Bovine	Laying hen	
EFSA PRIMo[4] - chronic - child	4.73E-05	2.78E-06	3.74E-06	2.89E-07	7.50-04	9.44E-06	0.0008
	Pig	Pig	Pig	Bovine	Bovine	Laying hen	
EFSA PRIMo[4] - acute - adult	1.03E-04	4.22E-05	5.02E-05	4.67E-05	5.32E-04	2.98E-05	
	Pig	Pig	Bovine	Pig	Goat	Laying hen	
EFSA PRIMo[4] - acute - child	2.57E-04	3.54^{E}-05	1.01E-04	4.73E-05	1.56E-03	8.71E-05	
	Pig	Pig	Bovine	Bovine	Bovine	Laying hen	

[1] WCCE = ((transfer factor (based on $logP_{OW}$) x oral exposure) + (dermal exposure x 50% systemic availability) + inhalative exposure) x food intake ÷ human body weight.

Transfer factors are based on the Octanol-Water Partition Coefficent (logPOW) for the maximum tranfer of an oral dose to livestock edible tissues (Leeman et al. 2007)

Based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%

[2] $WCCE_{total} = WCCE_{muscle} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$

[3] EMA 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 [4] EFSA PRIMo rev 3.1 (EFSA 2018), also included in BfR calculator (see excelsheet in section 3.2.1, Sheet Defaults 5 Food Cons).

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

The product is produced and formulated outside of the EU. The product must be disposed of or incinerated in accordance with local regulations, therefore there is no risk of exposure via disposal.

Combined exposure

Combined exposure covers the combination of routes of exposure as well as all the scenarios in which a person can come in contact with the biocidal product leading to the estimation of the worst case exposure value. In case of Seclira the worst case exposure value is covered by a combination of Professional Scenario 1, Non-professional Scenario 1 and 2 and Non-professional Scenario 3. Dietary exposure is not taken into account as the concentrations of a.s. taken up via food are negligible.

Scenarios and values to be used in risk assessment - Dinotefuran			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/ PPE**	**Estimated total uptake**
1 (professional) + 1 (non-professional) +2+3	Adults		
	Private House	1/none	4.83×10^{-2} mg/kg bw/d
	Large Building		1.04×10^{-2} mg/kg bw/d
	Small Stable		9.45×10^{-3} mg/kg bw/d
	Large Stable		3.14×10^{-2} mg/kg bw/d

Scenarios and values to be used in risk assessment – Acetone			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/ PPE**	**Estimated total uptake**
1 (professional) + 1 (non-professional) 2+3	Adults		
	Private House	1/none	1080 mg/m^3
	Large Building		100 mg/m^3
	Small Stable		152 mg/m^3
	Large Stable		61.7 mg/m^3

Summary of exposure assessment

Scenarios and values to be used in risk assessment - Dinotefuran			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/ PPE**	**Estimated total uptake**
1.	Professionals, Non-professionals		
	Private House	1/none	4.71×10^{-2} mg/kg bw/d
	Large Building		8.86×10^{-3} mg/kg bw/d
	Small Stable		8.74×10^{-3} mg/kg bw/d
	Large Stable		2.42×10^{-2} mg/kg bw/d
2.	Professionals, Non-professionals		
	Private House	1/none	5.83×10^{-4} mg/kg bw/d
	Large Building		1.41×10^{-3} mg/kg bw/d
	Small Stable		4.98×10^{-4} mg/kg bw/d
	Large Stable		7.05×10^{-3} mg/kg bw/d
1+2+3	Professionals, non-professionals		
	Private House	1/none	4.83×10^{-2} mg/kg bw/d
	Large Building		1.04×10^{-2} mg/kg bw/d
	Small Stable		9.45×10^{-3} mg/kg bw/d
	Large Stable		3.14×10^{-2} mg/kg bw/d
3.	General population: Infants, toddlers, children, adults		
	Private House (infant)	1/none	3.8×10^{-3} mg/kg bw/d
	Private House (toddler)		3.0×10^{-3} mg/kg bw/d
	Private House (child)		3.4×10^{-4} mg/kg bw/d
	Private House (adult)		5.3×10^{-4} mg/kg bw/d
	Large Building (child)	1/none	8.9×10^{-3} mg/kg bw/d
	Large Building (adult)		1.5×10^{-4} mg/kg bw/d
	Small Stable (child)	1/none	1.3×10^{-4} mg/kg bw/d
	Small Stable (adult)		2.1×10^{-4} mg/kg bw/d
	Large Stable (child)	1/none	8.9×10^{-5} mg/kg bw/d
	Large Stable (adult)		1.4×10^{-4} mg/kg bw/d

Scenarios and values to be used in risk assessment – Acetone			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Professionals		
	Private House	1/none	1080 mg/m^3
	Large Building		100 mg/m^3
	Small Stable		152 mg/m^3
	Large Stable		61.7 mg/m^3
1+2+3	Professionals		
	Private House	1/none	1080 mg/m^3
	Large Building		100 mg/m^3
	Small Stable		152 mg/m^3
	Large Stable		61.7 mg/m^3

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) [mg/kg bw/d]	AF[1]	Correction for oral absorption	Value [mg/kg bw/d] or [mg/m³]
$AEL_{short\text{-}term}$	Rabbit (NZW) oral developmental toxicity study	175	100	100% (no correction)	1.75
$AEL_{medium\text{-}term}$	Dog oral (dietary) 1 year study	22	100	100% (no correction)	0.22
$AEL_{long\text{-}term}$	Dog oral (dietary) 1 year study	22	100	100% (no correction)	0.22
ARfD	Rabbit (NZW) oral developmental toxicity study	175	100	100% (no correction)	1.75
ADI	Dog oral (dietary) 1 year study	22	100	100% (no correction)	0.22
IOELV Acetone	-	-	-	-	1210 mg/m³

[1] standard default assessment factors of 10 to account for potential interspecies variability and of 10 to account for intra-species variability

Risk for industrial users

Not applicable

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d; IOELV mg/m³	Estimated uptake mg/kg bw/d; mg/m³	Estimated uptake/exposure AEL, IOELV (%)	Acceptable (yes/no)
Scenario [1]						
Private House	1					
Dinotefuran		22	0.22	4.71×10^{-2}	21	Yes
Acetone			1210	1080	89	Yes
Large Building	1					
Dinotefuran		22	0.22	8.86×10^{-3}	4	Yes
Acetone			1210	100	8	Yes
Rural:						
Small Stable	1					
Dinotefuran		22	10.22	8.74×10^{-3}	4	Yes
Acetone			1210	152	13	Yes
Large Stable	1					
Dinotefuran		22	0.22	2.42×10^{-2}	11	Yes
Acetone			1210	61.7	5	Yes
Scenario [2] Dinotefuran						
Private House						
Large Building	1	22	0.22	5.83×10^{-4}	0.3	Yes
Small stable	1	22	0.22	1.41×10^{-3}	1	Yes
Large stable	1	22	0.22	4.98×10^{-4}	0.2	Yes
	1	22	0.22	7.05×10^{-3}	3	Yes

Combined scenarios

Combined exposure covers the combination of routes of exposure as well as all the scenarios in which a person can come in contact with the biocidal product leading to the estimation of the worst case exposure value. In case of Seclira®FlyBait the worst case exposure value is covered by a combination of application of the product (scenario 1), washing of coveralls (scenario 2) and touching of treated areas (scenario 3, included at non-professional use)). Dietary exposure is not taken into account as the concentrations of a.s. taken up via food are negligible. The combined exposure will be compared to the $AEL_{long\text{-}term}$ for Dinotefuran of 0.22 mg/kg bw a day.

A cumulative risk assessment of dinotefuran (active substance) and acetone (SoC) is considered not relevant as dinotefuran results in systemic effects and acetone only exerts local effects.

Scenarios combined for Dinotefuran	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [1]+[2]+[3]						
Private House	1	22	0.22	4.83×10^{-2}	22	Yes
Large Building	1	22	0.22	1.04×10^{-2}	5	Yes
Small Stable	1	22	0.22	9.45×10^{-3}	4	Yes
Large Stable	1	22	0.22	3.14×10^{-2}	14	Yes

Scenarios combined for Acetone	Tier	IOELV mg/m3	Estimated exposure mg/m³	Estimated exosure/ IOELV (%)	Acceptable (yes/no)
Scenario [1]+[2]+[3]					
Private House	1	1210	1080	89	Yes
Large Building	1	1210	100	8	Yes
Small Stable	1	1210	152	13	Yes
Large Stable	1	1210	61.7	5	Yes

Local effects

Conclusion
Scenarios 1, 2 and 3 have been assessed as described in chapter 2.2.6.2 and are considered to be acceptable. The risk assessment using the $AEL_{long\text{-}term}$ (i.e. 0.22 mg/kg bw/d) results in safe exposure for the professional user for all intended uses including combination of professional application (scenario 1) and exposure by washing coveralls and touching treated areas by an adult (respectively scenario 2 and scenario 3).

Risk for non-professional users

Conclusion
For the non-professional user, the same exposure as for the professional user is envisaged. In addition, for a non-professional user, an $AEL_{medium\text{-}term}$ would be used for the risk assessment. The $AEL_{medium\text{-}term}$ for dinotefuran, is the same as the $AEL_{long\text{-}term}$, which is used for the professional user assessment (i.e. 0.22 mg/kg bw/d). Subsequently, the same %AEL as derived for professional exposure will be derived for non-professional exposure. As safe use is identified in Tier 1 (i.e. without including personal protective equipment) for the professional user, also safe use is concluded for the non-professional exposure.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [3] Dinotefuran						
Private House						
Infant	1	175	1.75	3.8×10^{-3}	0.2	Yes
Toddler		175	1.75	3.0×10^{-3}	0.2	Yes
Child		175	1.75	3.4×10^{-4}	0.02	Yes
Adult		175	1.75	5.3×10^{-4}	0.03	Yes
Large Building						Yes
Child	1	175	1.75	8.9×10^{-3}	0.5	Yes
Adult		175	1.75	1.5×10^{-4}	0.01	Yes
						Yes
Small stable						
Child	1	175	1.75	1.3×10^{-4}	0.01	Yes
Adult		175	1.75	2.1×10^{-4}	0.01	Yes
Large stable						
Child	1	175	1.75	8.9×10^{-5}	0.005	Yes
Adult		175	1.75	1.4×10^{-4}	0.01	Yes

Combined scenarios

Combined risk is possible in case of adults applying the product (scenario 1), via washing of coveralls (scenario 2) and contact with the treated surfaces post-application (scenario 3). This combined exposure is included at professional use, and is the same for non-professional use. As the $AEL_{long\text{-}term}$ (for professional use) and $AEL_{medium\text{-}term}$ (for non-professional use) are identical: 0.22 mg/kg bw/d, the same %AEL is derived for professional and non-professional use. In Tier1, safe use is identified.

Aggregated risk

Risk assessment for aggregated exposure.

According to Chapter 4 of the Guidance for Human Health Risk Assessment, Volume III, Part B+C (ECHA, ver 3, 2017) a combined risk assessment shall be performed if the biocidal product contains active substances or substances of concern (SoCs) requiring a quantitative systemic risk assessment.

In case there is a common mechanism of action (similar mode of action) or if there are common target organs (dissimilar mode of action) for individual substances in a product, the hazard index would be determined by the addition of the individual hazard quotients for each substance as estimated in the concerned intended uses.

A cumulative risk assessment of dinotefuran (active substance) and acetone (SoC) is considered not relevant as dinotefuran results in systemic effects and acetone only exerts local effects.

Risk for consumers via residues in food

Exposure to consumers via residues in food, and via residues in food of animal origin, is not expected based upon the label instructions for use i.e., no food items will be exposed and animal exposure to the biocidal product needs to be avoided. The product is directed to areas where flies congregate and settle (which is likely a place not too close to the animals i.e. walls and ceilings). Furthermore, the label instructions for use specify the following:

- Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.
- Do not store near food, drink and feed.
- Do not use near domestic animals or livestock.
- Do not apply directly on animals.

However, since the product is to be applied as a spot treatment in animal housing, in a worst case secondary exposure to animals to spray drift is considered. Animals are exposed via inhalation, dermal and oral: through inhalation of the product itself (considered worse case as the product should not be used directly on animals), oral (through licking/chewing behaviour) and dermal, through rubbing behaviour. As exposure to spray drift is considered, oral (excluding the oral exposure scenario by eating dead flies) and dermal exposure are refined by a value of 11% or 0.11 as refinement factor (derived from the harmonised fraction emitted to floor during surface treatment as depicted in the Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017).

Systemic effects, chronic exposure

	Tier	ADI/ARfD mg/kg bw/d	$WCCE_{total}$[1] mg/kg bw/d	Estimated uptake/ ADI/ARfD (%)	Acceptable (yes/no)
EMA Food Basket[2]	1	0.22	0.0012	0.53	yes
EFSA PRIMo[3] - chronic - adult	1	0.22	0.0002	0.10	yes
EFSA PRIMo[3] - chronic - child	1	0.22	0.0008	0.37	yes

[1] $WCCE_{total} = WCCE_{muscle} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$

WCCE = ((transfer factor (based on $logP_{OW}$) x oral exposure) + (dermal exposure x 50% systemic availability) + inhalative exposure) x food intake ÷ human body weight.

Transfer factors are based on the Octanol-Water Partition Coefficent (logPOW) for the maximum tranfer of an oral dose to livestock edible tissues (Leemans et al. 2007)

Based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%

[2] EMA 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
[3] EFSA PRIMo rev 3.1 (EFSA 2018), also included in BfR calculator, Sheet Defaults 5 Food Cons

Systemic effects, acute exposure

	Tier	ARfD mg/kg bw/d	WCCE[1] mg/kg bw/d	Estimated uptake/ ADI/ARfD (%)	Acceptable (yes/no)
EFSA PRIMo[2] - acute - adult	1	1.75	Muscle: 1.03E-04 Fat: 4.22E-05 Liver: 5.02E-05 Kidney: 4.67E-05 Milk: 5.32E-04 Eggs: 2.98E-05	Muscle: 0.01 Fat: 0.00 Liver: 0.00 Kidney: 0.00 Milk: 0.03 Eggs: 0.00	yes
EFSA PRIMo[2] - acute - child	1	1.75	Muscle: 2.57E-04 Fat: 3.54E-05 Liver: 1.01E-04 Kidney: 4.73E-05 Milk: 1.56E-03 Eggs: 8.71E-05	Muscle: 0.01 Fat: 0.00 Liver: 0.01 Kidney: 0.00 Milk: 0.09 Eggs: 0.00	yes

[1] $WCCE_{total} = WCCE_{muscle} + WCCE_{fat} + WCCE_{liver} + WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$
WCCE = ((transfer factor (based on $logP_{OW}$) x oral exposure) + (dermal exposure x 50% systemic availability) + inhalative exposure) x food intake ÷ human body weight.
Transfer factors are based on the Octanol-Water Partition Coefficent (logPOW) for the maximum tranfer of an oral dose to livestock edible tissues (Leemans et al. 2007)
Based on HH WGI 2022 discussions, it was agreed that animal systemic availability after dermal exposure is 50%
[2] EFSA PRIMo rev 3.1 (EFSA 2018), also included in BfR calculator, Sheet Defaults 5 Food Cons

Considering the WCCE and the comparison to the ADI for chronic exposure or to the ARfD for acute exposure result in %ADI or %ARfD values <1% using EMA Food Basket or EFSA PRIMo v3.1, there is no concern for consumers after exposure to residues after the use of Seclira Fly Bait.

For dinotefuran MRL values are included in Reg. (EU) No 491/2014; 0.1 mg/kg for food of animal origin, excluding poultry and eggs that is set at 0.02 mg/kg. Therefore, livestock exposure values will be compared to the MRLs. As worst case, the livestock exposure in mg/kg bw/d is considered as mg/kg available in the tissues.

Livestock exposure

	Tier	MRL mg/kg	Livestock expsosure[1] mg/kg	Acceptable (yes/no)
Bovine	1	0.1	0.0122-0.0202	yes

Pig	1	0.1	0.0147-0.0212	yes
Sheep	1	0.1	0.0007	yes
Goat	1	0.1	0.0289-0.0517	yes
Poultry[2]	1	0.02	0.0017-0.0106	yes
Horse	1	0.1	0.0183	yes
Rabbit	1	0.1	0.0015	yes

[1] Range of total livestock exposure in muscle, fat, liver, kidney and where applicable milk and/or eggs are included.
Overview table is included in the exposure section: Calculations for estimating livestock exposure for Scenario [1] – Realistic Worst Case Assessment in table on: Outcome of Livestock Exposure (mg a.s./kg bw/d) refined with empirical transfer factors based on the Octanol–Water Partition Coefficient (log P_O/W) [mg/kg bw/d] and 50% systemic availability for dermal exposure:
[2] full range of livestock exposure is indicated. Range for total livestock only referring to eggs is: 0.0037-0.0106 mg/kg.

The calculated livestock exposure values show that they comply to the existing MRLs.

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

For the professional user combined exposure to the active ingredient and substances of concern applies and has been addressed further above in section 2.2.6. No risk has been observed after combined exposure assessment.

2.2.7 Risk assessment for animal health

The product is intended for use inside urban buildings and animal stables, therefore there is the possibility that livestock and pets could be exposed to the product. To eliminate the potential for exposure to animals, the following risk mitigation measures are applied:

- Do not apply directly on animals.
- Do not (use/apply) directly on or near food, feed, drinking water or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinking water or drinks, or livestock/pets.
- Do not store near food, drink and feed.
- For use only in areas that are inaccessible to children, pets and non-target animals.
- Do not use near domestic animals or livestock

Although pet exposure is excluded as much as possible with the RMMs included above for the use of Seclira fly bait when used in buildings, exposure cannot be fully excluded. However, the same is true for exposure of children. For the HH risk assessment child/toddler/infant exposure is considered (scenario 3, exposure via re-entering a treated room and accidentally touching of treated surfaces, and for infant/toddlers hand-to-mouth

exposure). Therefore, we consider that the exposure of pets is covered by the human health risk assessment.

As the biocidal product Seclira fly bait is used as an insecticide in animal housing (PT18), secondary exposure of livestock animals towards residues of the active substance cannot be excluded. The exposure of livestock animals was estimated on the basis of the application rates and in-use concentrations using the BfR calculator.

Animals are exposed via inhalation, dermal and oral, through inhalation of the product itself (considered worse case as the product should not be used directly on animals), oral (through licking/chewing behaviour) and dermal, through rubbing behaviour. The product is to be applied to the 10% to the area (spot treatment). Therefore, it is not likely that animals will be constantly in contact with the product. Moreover, the product is used where flies congregate, which is likely a place not to close to the animals.

As worst case, the WCCE was calculated (see for more specific information the description of scenario 1 included in WCCE in the HH section).

Total exposures per animal are indicated in the table below.
With a view to the animal safety assessment, the exposure estimates of the a.s. was compared to the respective NOAEL. For Dinotefuran the NOAEL of the Dog oral (dietary) 1 year study of 22 mg/kg bw/d was used. The toxicity-exposure-ratio (TER) has been calculated according to according to the Risk Assessment for Birds and Mammals, EFSA 2009 (page 40), which is compared with the trigger value of 5. Therefore, the NOAEL of 22 mg/kg bw/day is taken as a point of departure. Calculations are to be found in the attached excel Seclira fly bait - Dietary exposure revised.xlsx in the tab Animal exposure TOTAL.

Animal Species	**total exposure (mg/kg bw/day)**	**NOAEL (mg/kg bw/day)**	**TER**
Beef cattle	0.03	22	866
Dairy cattle	0.05	22	431
Calf	0.05	22	487
Fattening pig	0.06	22	351
Breeding pig	0.02	22	1264
Breeding pig	0.05	22	403
Breeding pig	0.06	22	358
Sheep	0.00	22	33150
Lamb	0.00	22	30308
Slaughter goat	0.05	22	425
Lactating goat	0.03	22	760
Broilers	0.12	22	180
Broilers	0.13	22	176
Broilers	0.13	22	175
Broilers	0.13	22	175
Laying hen	0.11	22	202
Laying hen	0.16	22	140
Laying hen	0.12	22	190
Laying hen	0.11	22	196
Turkey	0.03	22	737
Horse	0.02	22	1204
Rabbit	0.00	22	14625

Conclusion

Following the TER approach, the use of Seclira fly baits in animal housing is considered of no concern for all animals as all values are (much) higher than 5. Animal exposure is considered of no concern and no further evaluation is needed.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

Dinotefuran:
The effect assessment for water and sediment are the same as those set during the active substance approval process and provided in the Dinotefuran PT 18 Assessment Report (2014).
No sediment PNEC was provided because Dinotefuran has a low K_{OC} of 31.4 $L.kg^{-1}$; therefore, the calculation of the $PNEC_{sediment}$ is not required: "*It should be noted that no consideration of sediment compartment has been included as both the $PNEC_{sediment}$ and $PEC_{sediment}$ would need to be calculated using the Equilibrium Partitioning Method using relevant PEC and PNEC values for surface waters. As a consequence, the PEC/PNEC ratios for surface water and sediment will be identical*" (Dinotefuran PT18 Assessment Report, 2014) i.e.; the assessment for surface water also covers the assessment for sediment.

Following the approval of dinotefuran as a PT18 active substance further data are available which are submitted in support of the application for authorisation of SECLIRA FLY BAIT for its intended use which differs to that for the dinotefuran representative product. Expansion of the database on terrestrial organisms allows for a revised $PNEC_{soil}$ which was agreed at WG V ENV 2019. Full details for the derivation of $PNEC_{soil}$ are presented in the IUCLID dossier.

Metabolites:
Regarding metabolites, DN is a major metabolite in in the aquatic compartment (sediment) whilst MNG is a major metabolite in the terrestrial (soil) compartment. (Dinotefuran PT18 Assessment Report, 2014).

Compound	Compartment (units)	PNEC
Dinotefuran	Freshwater (mg/L)	2.54E-04*
	Soil (mg/kg wwt)	**1.6E-03****
	STP (mg/L)	100
DN	Sediment (mg/kg wwt)	5E-02
MNG	Soil (mg/kg wwt)	1.6E-04***

* Based on measured concentrations in study with *Chironomus*, indicating that the risk can be assessed on pure AS content

** Based on nominal concentrations in study with *Enchytraeus crypticus*, indicating that the risk has to be assessed on technical AS content

*** No effect data are available for MNG in the terrestrial compartment. It is assumed, and in common with the Dinotefuran PT18 Assessment Report, 2014, that MNG is at a worst-case x 10 more toxic than parent.

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

Aquatic classification SECLIRA FLY BAIT

Ecotoxicity data are not available for the product. Therefore, classification is based on toxicity data of individual components in the mixtures according to the tiered approach (Fig. 4.1.2, the Regulations (EU) No. 286/2011 (2011)). Dinotefuran, the active ingredient which makes up 0.5 % of the product, is the only classified component for ecotoxicological hazards.

The guidance on the Application of the CLP Criteria states that fish, crustacea and algae cover a range of trophic levels and are considered as surrogate for all aquatic organisms (p. 496, ECHA 2017).

As stated in the Assessment Report, dinotefuran is classified as H400 (M=10) and H410 (M=10). The summation method was applied for classification of the two mixtures as described in the CLP regulation, Table 4.1.2 (EC 2011). For chronic 1, the following formula (A) needs to be fulfilled:

(A) Chronic 1 x M ≥ 25%
0.5 % x 10 = 5 %

Since 5 % is not ≥ 25 %, formula (B) needs to be applied:

(B) (M x 10 x Chronic 1) + Chronic 2 ≥ 25 %
(10 x 10 x 0.5 %) + 0 % = 50 %

Since 50 % is ≥ 25 %, SECLIRA FLY BAIT is classified as chronic 2 (H411).

Further physico-chemical property studies

No further physico-chemical property studies are available on the product (other than those summarised in section 2.2.2). However, additional data regarding metabolite MNG are available and are utilised in the environmental risk assessment, therefore they are summarised below. These data have not been previously evaluated in the EU, but note that solubility and vapour pressure has only a negligible effect on the outcomes of the environmental risk assessment as the substance shall not evaporate to air. For the ENV calculations however, in the first tier the original CAR values were used, but refinements were added for convenience of relevant member states for their own decision.

Summary table - Further physico-chemical property studies (metabolite MNG)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Solubility in water	OECD 105 EC A.6	99.5% dinotefuran Batch #: EBI-3338	11.48 g/L in Milli-RO water	[redacted] (2001) Report no.: 2018/7005854
Vapour pressure	OECD 104 EC A.4	99.5% dinotefuran Batch #: EBI-3338	7 x 10^{-8} Pa at 25 ºC	[redacted] (2001) Report no.: MTU 136/004549

The Ctgb eCA accepts the values on the solubility and vapour pressure of metabolite MNG for the calculations as an 2nd tier.

Further Ecotoxicological studies

No further ecotoxicological studies are available on the product. However, additional data regarding exposure of dinotefuran to soil organisms is presented in the table below and was agreed at WG V ENV 2019; Ctgb are granted access to the data via a Letter of Access from the active substance data owner.

Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies - Dinotefuran									
Method, Guideline, GLP status, Reliability	Species/ Inoculum	End point	Exposure		Results			Remarks	Refe-rence
			Design	Dura-tion	NOEC	EC_{50}	EC_{100}		
OECD 216/217, GLP, reliability 2	Soil microflora	Carbon and nitrogen transformation	Aerobic conditions in the dark	28 day	NOEC nitrogen transformation 1.39 mg a.s./kg dw soil (equivalent to 1.22 mg a.s./kg ww soil) NOEC carbon transformation 174 mg a.s./kg dw soil (equivalent to 154 mg a.s./kg ww soil)			ECx values were not calculated because dose responses were not observed.	[redacted], 2016 IUCLID 9.2.1
OECD 220, GLP, reliability 2	*Enchytraeus crypticus*	Mortality and reproduction	Aerobic conditions, 16 h light/ 8 h dark	28 day	-	0.28 mg/kg soil dw (reprod uction)	-	0.052 mg/kg dw soil, corrected for standard organic matter content to 0.018 mg/kg dw soil, which is equivalent to 0.016 mg/kg ww soil	[redacted] 2016 IUCLID 9.2.2
OECD 208, GLP, reliability 2	*Brassica napus, Glycine max, Helianthus annuus, Solanum lycopersicum, Avena sativa, Allium cepa*	Seedling emergernce and growth	Aerobic conditions, 16 h light/ 8 h dark	21 day	NOEC 55 mg a.s./kg dw soil, corresponding to 48.9 mg a.s./kg ww soil*			For various species ECx values could not be calculated and therefore the lowest EC50 value could not be determined.	[redacted] 2016 IUCLID 9.2.3

Summary table of further ecotoxicological studies - Dinotefuran									
Method, Guideline, GLP status, Reliability	Species/ Inoculum	End point	Exposure		Results			Remarks	Refe-rence
			Design	Dura-tion	NOEC	EC_{50}	EC_{100}		
OECD 226, GLP, reliability 2	*Hypoaspis aculeifer*	Mortality and reproduction	Aerobic conditions, 16 h light/ 8 h dark	14 day	NOEC 85.0 mg a.s./kg dw soil, which corresponds to 74.8 mg a.s./kg ww soil			ECx values are considered less reliable.	[redacted] 2016 IUCLID 9.5
OECD 232, GLP, reliability 1	*Folsomia candida*	Mortality and reproduction	Aerobic conditions, 12 h light/ 12 h dark	28 day	NOEC 0.12 mg a.s./kg dw soil, which corresponds to 0.11 mg a.s./kg ww soil			ECx values are not considered relevant, because a dose response was not observed.	[redacted] 2016 IUCLID 9.5
OECD 213, 214, GLP, reliability 2 (contact exposure), not reliable (oral exposure)	*Apis mellifera*	Mortality	Laboratory study	48 hour		LD50 (contact) 0.056 µg per bee		Oral acute toxicity test, the non-treated control mortality was 13.3% and the negative control solution (Triton X-100) mortality was 16.7%.	[redacted] 2000 IUCLID 9.5

*In line with the GD on BPR ENV Part B+C (section 3.1), a NOEC may be calculated as LOEC/2 when LOEC > 10% and < 20% effect. Hence, the lowest NOEC is calculated to be 55 mg a.s./kg dw soil, corresponding to 48.9 mg a.s./kg ww soil.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	PNEC soil 0.0016 mg/kg ww soil
Justification for the value/conclusion	The PNEC in the original CAR was set at 0.00017 mg/kg ww based on equilibrium partitioning. The database is expanded to include three tropic levels of primary producers, decomposers and consumers. Acutely it is demonstrated that primary producers are likely not the most sensitive species. Therefore, it is appropriate to apply an assessment factor of 10 to the NOEC corrected for standard organic matter content to the most sensitive species, *Enchytraeus crypticus* NOEC 0.016 mg/kg wet weight to determine the PNECsoil 0.0016 mg/kg ww soil.

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

No further data are available on the product.

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

No further data are available on the product.

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

No further data are available on the product.

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

Not relevant.

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, a summary table is additionally provided:

Identification of relevant receiving compartments based on the exposure pathway						
Scenario*	Fresh-water**	STP	Air	Soil	Ground-water	Secondary poisoning
Scenario 1	yes	yes	no	yes	yes	no
Scenario 2	yes	yes	no	yes	yes	no
Scenario 3	yes	yes	no	yes	yes	no

*Scenario 1: Barrier treatment inside domestic buildings by non-professionals (general public)
Scenario 2: Barrier treatment inside domestic and large buildings by professionals and trained professionals
Scenario 3: Barrier treatment inside animal buildings on farms by non-professionals (general public), professionals and trained professionals)
**Freshwater sediment is covered by the freshwater assessment

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

No further e-fate studies are available on the product.

However, following the approval of dinotefuran as a PT18 active substance, further data are available on the active substance and metabolite MNG which are submitted in support of the application for authorisation of SECLIRA FLY BAIT for its intended use which differs to that for the dinotefuran representative product.

Regarding the degradation of dinotefuran in water/sediment, this study was agreed at WG V ENV 2019, the adsorption/desorption in soil study on MNG has not been evaluated previously in the EU. Note that degradation in water is not considered in the environmental risk assessment. An additional study was submitted regarding MNG's mobility in soils.

Summary table on further studies on fate and behaviour in the environment

Dinotefuran

Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentration, C_0[mol/l]	Half-life, DT_{50} [d]	Remarks	Reference [1]
Water/sediment, OECD 308, OPPTS 835.4300, OPPTS 835.4400, GLP, reliability 2	Water and sediment	6.64 and 8.51	11.1 to 15.5	0.199 to 0.204 mg/L	DegT50 (whole system) for the aquatic environment = 145.4 days (study results were normalised to 12°C)	vP in aquatic environment	[redacted], 2011 IUCLID 10.1.3

Metabolite MNG

Method, Guideline, GLP status, Reliability	Soil	Adsorbed AS [%]	Ka	K_{OC}	Kd; Kd_{OC}; Ka/Kd	r^2	1/n	Remarks	Reference
OECD 106 (2000), Commission Directive 95/36/EC, EPA 163-1 (1989), Annex Revision 3 by FAO (draft 1993), GLP, Reliability 1, Key study	Soil I: (Speyer 2.2, Germany)	23.4#	0.164	8	0.267; 12; 0.614	0.9946	0.90	Adsorption, desorption isotherms were determined in an advanced test on five soils at five concentrations. The soil/solution ratio was 1:1 and an equilibrium time of 48 hours was used.	[redacted] (2001), Report no.: 729055 IUCLID 10.1.2
	Soil II: Senozan, France	20.5#	0.164	16	*	0.9893	0.93		
	Soil V: North Dakota, USA	19.9$	0.749	31	0.592; 25; 1.265	0.9984	0.92		
	Soil VI: North Dakota, USA	20.3$	0.122	8	*	0.9888	0.89		
	Soil VII: Minnesota, USA	40.0$	0.696	24	0.804; 28; 0.866	0.9983	0.91		

[1] Please include the reference to IUCLID.

* due to low adsorption, it was not possible to calculate the desorption coefficients for these soils.

Ka = Freundlich adsorption coefficient (from the advanced study)

Ka_{OC} = Freundlich adsorption coefficient based on organic carbon content (from the advanced study)

Kd = Freundlich desorption coefficient

Kd_{OC} = Freundlich desorption coefficient based on organic carbon content

Ka/ Kd = Adsorption / Desorption distribution coefficient

% of applied amount adsorbed after 48 hours in preliminary test

$ % of applied amount adsorbed after 48 hours in screening test

<table>
<tr><th colspan="2">Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment</th></tr>
<tr><td>Value/conclusion</td><td>

DegT₅₀ total system dinotefuran: 94.65 days at 12ºC[1]
0.2137 formation fraction Parent to MNG (see section 3.2.2 for details).
MNG K_{OC} is 15.01 L/kg geometric mean value ([redacted] (2001), report no.: 729055, IUCLID 10.1.2).
MNG 1/n is 0.91, arithmetic mean value ([redacted] (2001), report no.: 729055, IUCLID 10.1.2).

Note that although the eCA has evaluated these studies and accepted the updated Koc and 1/n, because these studies were not discussed at WG, for the first tier the original CAR values were used in the risk assessment
</td></tr>
<tr><td>Justification for the value/conclusion</td><td>
[1]Based upon the geometric mean of the following total system values (n=4) results:
DegT₅₀ 88.3 d at 12 ºC (pond system)*
DegT₅₀ 112 d at 12 ºC (river system)*
DegT₅₀ 55.81 d at 12 ºC (lake system)**
DegT₅₀ 145.4 d at 12 ºC (lake system)**

*Dinotefuran PT18 Assessment Report, 2014
** Outcomes of WG evaluation

The geometric whole system DegT₅₀ can be used for risk assessment, using the values described together with those reported in the Dinotefuran PT18 Assessment Report (2014).

Outcomes of WG evaluation:

Ctgb evaluated the study with the use of the following guidances and tools, The evaluation has been discussed at EU level and concluded at WG November 2019.

<table>
<tr><td>Guidance / manual</td><td>Software</td></tr>
<tr><td>OECD 308
RIVM manual
OPPTS 835 3100
OPPTS 835 3180</td><td>Kinetic software Cake</td></tr>
</table>

<u>Methods:</u>

The following water characteristics can be defined:
<table>
<tr><td></td><td>System I</td><td>System II</td></tr>
<tr><td>Name</td><td>Calwich Abbey Lake</td><td>Swiss Lake</td></tr>
<tr><td>Date of sampling</td><td>04 May 2010</td><td>04 May 2010</td></tr>
<tr><td>Organic carbon [%] water</td><td>5.2</td><td>7.5</td></tr>
<tr><td>pH water</td><td>8.51</td><td>6.64</td></tr>
</table>
</td></tr>
</table>

Appearance	Clear, non-turbid, colourless	Clear, non-turbid, slight brown colour

The following sediment characteristics can be defined:

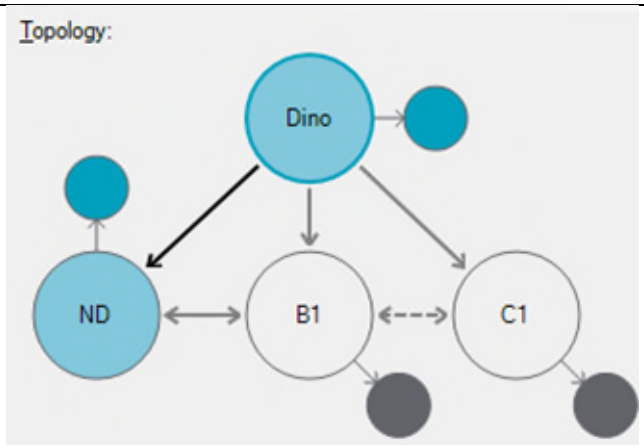
	System I	**System II**
Name	**Calwich Abbey Lake**	**Swiss Lake**
Water body type	Large perennial lake	Shallow lake
Origin	Derbyshire, UK	
Sediment texture	Sandy silt loam Dark coloured loam containing a few twigs, leaves and stones. Slight to moderate smell	Loamy sand Brown sandy sediment with darker patches containing a few twigs, leaves and stones. Slight smell
UK classification % sand (63 µm-2 mm) % silt (2 –63 µm) % clay (< 2 µm)	 29 55 16	 87 7 6
USDA classification % sand (50 µm-2 mm) % silt (2 –50 µm) % clay (< 2 µm)	 32 53 15	 91 4 5
pH value (water method) sediment	7.6	6.3
Cation exchange capacity [meq/ 100 g]	17.0	2.7
Microbial biomass [mg microbial C/sample]	See table 3 in study report. Stable biomass in treated samples.	
Organic carbon [%] aerobic	4.7	4.5
Organic carbon [%] anaerobic	4.3	1.1
Hardness mg equivalent ($CaCO_3$/L)	226	24.9

Observations water and sediment characteristics:
The Calwich abbey lake system has a clayish sediment. The Swiss lake has a sandy sediment (coarse sediment).
The OC% in the anaerobic part of the swiss lake sediment is very low compared to the aerobic sediment, even though this has been sampled at the same depth (5-10 cm).
The report shows no details on the sampling between the aerobic and anaerobic sediment in the Swiss lake system. It is assumed that the anaerobic part is taken from the lower portion of the sediment layer.

The OC% isn't that different between the two systems' aerobic part, although this parameter should ideally be different according to OECD 308 item 23. The OECD 308 study that has been included in the AR (Volkel) included two sediments with an OC of 0.67 and

	3.1%, which ensures a broad range of OC in the dataset. Therefore the limited range of the OC% in this study is acceptable. Taking the above into consideration, the sampling data shows no aberrant results. The study schedule shows that the aerobic experiment acclimatisation was initiated at May 12th. This is 8 days after the sampling took place. The actual test study started at May 25th. The anaerobic experiment acclimatisation was initiated at May 24th, which is 20 days after sampling took place. The actual test study started at August 10th. Therefore, acclimatisation took place for over 2 ½ months. Item 39 of OECD 108 states that this should not exceed four weeks. It is not reported why the acclimatisation had to take more than 2 months. Possibly the pH or redox did not reach stability before that time. The report states that the oxygen saturation levels fell to zero during the acclimatisation phase, even though the redox potential was still above 100 mV. Perhaps the study director decided to wait for the redox to become low before initiating the experiment. This information cannot be obtained from appendix 3 (Measurements of redox, pH and oxygen concentration during acclimatisation period). Measurement and reporting of the nitrate, sulfate, bioavailable iron, and possibly other electron acceptors could have been useful to explain the redox behaviour. The total biomass differed around one power of magnitude between the aerobic and anaerobic sediment, both at the start and the end of the experiment. This suggests a healthy biomass. Therefore, this acclimatisation phase is acceptable, even though the OECD 308 item 31 mentions that storage should not exceed 4 weeks. The study set-up made sure no volatiles could escape the system; three traps were installed (one for organic compounds and two for CO_2). The application rate that was applied in the test was equivalent to 0.6 kg/ha. This equals 0.06 g/m^2. The application rate as reported in the environmental section of the PAR is 0.14 g/m^2. This is comparable (factor 2.3). The number of replicates and blanks is acceptable, although single samples were taken at several timepoints (t=0 and 3d). There were 8 vessels per test (label F and G), and three vessels for each control (abiotics, biotics, 10x rate, OC% and methanogenesis). The extraction method for the sediment was both done with medium extraction (acetonitrile) but also with a harsh extraction (acetonitrile+ hydrochloric acid). The latter method was sufficient for extraction of the bound residues (NER). All recoveries were >94% AR, which is more than the required minimum. NER was around 10% of the sediment bound AR%. **Results**

	The two radiolabels showed similar results. This can be seen when comparing the label results in Distribution and recovery of radioactivity tables 4a-b, 5a-b, 6a-b and 7a-b in the appendix of the study report ([redacted], 2011). A clear transportation of the measured AR% from the water to the sediment can be seen. At the end of the study (100 days), around 60% of the AR% was measured in the sediment. These results are comparable to the Volkel study (Assessment report 2014). This behaviour is not expected for the a.s., based on the K_{oc} of 31.4 L/kg (Assessment report 2014. Full mineralisation to CO_2 was limited (max 10% in aerobic system, max 0.5% in anaerobic system). Component "DN" (1-methyl-3-(tetrahydro-3-furylmethyl)guanidinium) showed an increasing tendency in the aerobic swiss lake water (1.8 and 4.0 % AR at 30 and 100 days respectively). In the sediment compartment of the Calwich system, the metabolite (G-label) had a max.observed % of 63.2%. Metabolite DN is considered a major metabolite according to the BPR guidance Vol IV definitions. DE commented on the observation of other possible major metabolites. These are component 1 (Table 17) and Component 4 (Table 15 and 18) which are observed at concentrations >5% AR on two consecutive sampling timings and at an increasing tendency at the end of study, respectively. Ctgb (NL) agrees on both cases. However, NL does not consider it necessary to further investigate these two metabolites at this moment. It should be noted that during the renewal of dinotefuran (May 2022), the notifier should put effort in identifying the unknown major components. Taking the two observations together (high distribution in sediment, high increase of metabolite DN in the sediment), it is expected that metabolite DN has a strong sorption capacity. However, based on the known dataset for metabolite DN, that is not the case. Most likely the study set-up (high ratio sediment:water) results in a sorption to sediment, regardless of the Kf value of the tested substances. **Kinetic evaluation** Ctgb recalculated the DT_{50} of all compartments and systems to verify the applicant's results. As a deviation to FOCUS kinetics, the values before and after a detectable amount were not set to 0.5 LOD but to 0 instead. Since the value of LOD is 0.08% AR, this deviation is expected to have little effect on the results of the kinetic fit. Only SFO was included since this method resulted in acceptable fits. These details can be found in the separate appendix (see attached file) . The following degradation route was included:



Aerobic experiment

Aquatic sediment	Label	Compartment	DT50 (days) (20 °C)		Average DT50 (days) (20 °C)	
			Dino	DN	Dino	DN
Calwich Abbey Lake	F-14C	water	21.1	>1000	21.0	>1000
	G-14C		20.9	>1000		
Swiss Lake	F-14C	water	38.7	11.83	38.7	>1000
	G-14C		38.7	>1000		
Calwich Abbey Lake	F-14C	sediment	0.369	>1000	0.364	>1000
	G-14C		0.359	>1000		
Swiss Lake	F-14C	sediment	38.6	>1000	45.1	>1000
	G-14C		51.5	>1000		
Calwich Abbey Lake	F-14C	total system	27.7	>1000	27.5	>1000
	G-14C		27.3	>1000		
Swiss Lake	F-14C	total system	53.3	>1000	52.4	>1000
	G-14C		51.5	>1000		

When normalised to 12°C (converted from 20ºC to 12ºC (factor 2.14[2]))

Aquatic sediment	Compartment	Average DT_{50} (days) (**12 °C**)
		Dinotefuran
Calwich Abbey Lake	water	42.98

[2] Conversion to 12ºC: DT50(X ºC) = DT50(t)·e(0.095·(T-X)); where X = 12ºC for freshwater; e= 2.718. Adapted equation 28 from BPR guidance Vol IV, after AHEE-3 meeting (19/09/24-26)

Swiss Lake	water	107.77
Calwich Abbey Lake	sediment	144.98
Swiss Lake	sediment	147.11
Calwich Abbey Lake	total system	55.81
Swiss Lake	total system	145.40

The anaerobic results are not taken into consideration for the further evaluation.

Conclusion/discussion:

Calwich Abbey ($DegT_{50}$ whole system, 12ºC)
55.81 days (Ctgb) versus 45.9 days (applicant)
Swiss lake ($DegT_{50}$ whole system, 12ºC)
145.4 days (Ctgb) versus 121 days (applicant)
Calwich Abbey (DT_{50} water, 12ºC)
42.98 days (Ctgb) versus 35.7 days (applicant)
Swiss lake (DT_{50} water, 12ºC)
107.8 days (Ctgb) versus 89.3 days (applicant)
Calwich Abbey (DT_{50} sediment, 12ºC)
145.0 days (Ctgb) versus 27.7 days (applicant)
Swiss lake (DT_{50} sediment, 12ºC)
147.1 days (Ctgb) versus 242.7 days (applicant)

At WGV 2019 the DegT50 (whole system) for the aquatic environment = 145.4 days was agreed as only value.

Leaching behaviour (ADS)

Not relevant

Testing for distribution and dissipation in soil (ADS)

No further data are available on the product.

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

No further data are available on the product.

Testing for distribution and dissipation in air (ADS)

No further data are available on the product.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Acute aquatic toxicity

Data waiving	
Information requirement	Information on the acute toxicity to aquatic organisms or plants under field conditions.
Justification	The product is not intended for spraying near to surface waters, based upon it's intended indoor use in urban buildings and animal buildings on farms.

Chronic aquatic toxicity

Data waiving	
Information requirement	Information on the chronic toxicity to aquatic organisms or plants under field conditions.
Justification	The product is not intended for spraying near to surface waters, based upon it's intended indoor use in urban buildings and animal buildings on farms.

Measured aquatic bioconcentration

Data waiving	
Information requirement	Information on the measured aquatic bioconcentration
Justification	The product is not intended for spraying near to surface waters, based upon it's intended indoor use in urban buildings and animal buildings on farms.

Estimated aquatic bioconcentration

Data waiving	
Information requirement	Information on the estimated aquatic bioconcentration
Justification	The product is not intended for spraying near to surface waters, based upon it's intended indoor use in urban buildings and animal buildings on farms.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

It is noted that dinotefuran is a new furanicotinyl insecticide (reported to represent the third generation of neonicotinoid compounds) and could therefore potentially demonstrate toxicity to bees. Intended targeted indoor applications are as a barrier treatment against flies in urban buildings and animal housings, such locations are not selectively foraged by bees. "*Product placement would limit any potential increase in the attractiveness of the bait that these other ingredients may have. Consequently, the risk to bee colonies from direct exposure to the product is likely to be minimal*." (BPC Opinion for Dinotefuran, 2014). Since SECLIRA FLY BAIT is only intended for indoor use, direct releases to local soil are not expected.

It is recognised that indoor applications in rural areas may be to animal housing which could be partially open and an exposure of bees might be possible. Additionally contaminated manure or activated sludge on land may lead to exposure of flowering plants transporting the substances via the roots to the flowers and thus nectar/pollen feeding bees. Dinotefuran acute data on bees has been submitted in support of this product authorisation.

There is currently no agreed EU guidance available for the assessment of exposure to pollinators. To indicate to product users the hazard to bees, the following sentence is included on the product label:

"This biocidal product contains dinotefuran which is dangerous to bees."

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Barrier treatment (indoors) against flies, applied via aerosol spraying to surfaces in domestic buildings by non-professionals Scenario 2: Barrier treatment (indoors) against flies, applied via aerosol spraying to surfaces in domestic and large buildings by professionals and trained professionals Scenario 3: Barrier treatment (indoors) against flies, applied via aerosol spraying to surfaces in stables by non-professionals, professionals and trained professionals
ESD(s) used	- Emission Scenario Document OECD 'ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses' (ENV/JM/MONO (2008)14, 17 July 2008). - Emission Scenario Document OECD 'ESD for insecticides for stables and manure storage systems' (ENV/JM/MONO (2006)4, 25 January 2006). - Addendum (2015) to Emission Scenario Document OECD 'ESD for insecticides for stables and manure storage systems' (ENV/JM/MONO(2006)4, 25 January 2006). - Addendum (2016) to Emission Scenario Document OECD 'ESD for insecticides for stables and manure storage systems' (ENV/JM/MONO(2006(4, 25 January 2006). - Technical Agreements for Biocides November 2021. - AHEE-2: Exposure assessment of metabolites in the terrestrial compartment, 02 August 2019.
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment

	and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.
Groundwater simulation	Scenario 3: Higher tier FOCUS PEARL 4.4.4 modelling for groundwater refinements from the application of manure to land
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation: No Use: Yes Service life: (via wet cleaning) Scenario 2: Production: No Formulation: No Use: Yes Service life: (via wet cleaning) Scenario 3: Production: No Formulation: No Use: Yes Service life: (via manure application to land and via STP)
Remarks	None

Emission estimation

Scenario [1]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Barrier treatment (indoors) against flies by spraying in domestic buildings by non-professionals (general public) at a rate of 16 g product/m² (=80 mg a.i./m²).			
Application rate of biocidal product	16	g/m²	Set
Fraction of active ingredient in product	0.593 (tech) 0.588 (pure)	%	Set
Treatment rate (ai) for area	0.08	g/m²	Set
Area of house for application	20 / 5.9*	m²	Prescribed (Barrier)
Number of potential houses treated per catchment	4000	-	Default
Quantity of product per house	9.44E+01	g	Set
Number of preparations per day house	0	-	Set (product RTU)
Number of applications per day per house	1	-	Default
Fraction emitted to the air from application	2.00E-02	-	Prescribed (aerosol)
Fraction emitted to the applicator from application	4.00E-03	-	Prescribed (aerosol)
Fraction emitted to the floor from application	1.26E-01	-	Prescribed (aerosol)
Fraction emitted to the treated surfaces from application	8.50E-01	-	Prescribed (aerosol)
Cleaning efficiency	0.2	-	Prescribed (aerosol - surface)
Simultaneity factor	8.15E-03	-	Prescribed (3-11 applications per year)

*For the emission route air and applicator this area treated equals 20 m² for a house for a barrier treatment. The area treated for the emission routes floor and applicator refer to the wet cleaned areas of 5.9 m² of a house.

Calculations for Scenario [1]

Please refer to Section 3.2.2 for calculations.

Scenario [2]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Barrier treatment (indoors) against flies by spraying in domestic and large buildings by professionals and trained professionals at a rate of 16 g product/m² (=80 mg a.i./m²).			
Application rate of biocidal product	16	g/m²	Set
Fraction of active ingredient in product	0.593 (tech) 0.588 (pure)	%	Set
Treatment rate (ai) for area	0.08	g/m²	Set
Area of house for application	20 / 5.9*	m²	Prescribed (Barrier)
Area of larger building for application	93 / 27*	m²	Prescribed (Barrier)
Number of potential houses treated per catchment	4000	-	Default
Number of potential large buildings treated per catchment	300	-	Default
Quantity of product per house	9.44E+01	g	Set
Quantity of product per larger building	4.32E+02	g	Set
Number of preparations per day house	0	-	Set (product RTU)
Number of preparations per day larger building	0	-	Set (product RTU)
Number of applications per day per house	1	-	Default
Number of applications per day per larger building	1	-	Set
Fraction emitted to the air from application	2.00E-02	-	Prescribed (aerosol)
Fraction emitted to the applicator from application	4.00E-03	-	Prescribed (aerosol)
Fraction emitted to the floor from application	1.26E-01	-	Prescribed (aerosol)
Fraction emitted to the treated surfaces from application	8.50E-01	-	Prescribed (aerosol)
Cleaning efficiency	0.2	-	Prescribed (aerosol - surface)
Simultaneity factor	8.15E-03	-	Prescribed (3-11 applications per year)

*For the emission route air and applicator this area treated equals 20 m² for a house and 93 m² for a large building for a barrier treatment. The area treated for the emission routes floor and applicator refer to the wet cleaned areas of 5.9 m² of a house and 27 m² of a larger building.

Calculations for Scenario [2]
Please refer to Section 3.2.2 for calculations.

Scenario [3]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Barrier treatment (indoors) against flies by spraying in animal buildings on farms by professionals, trained professionals and non-professionals (general public) at a rate of 16 g product/m² (=80 mg a.i./m²).			
Application rate of biocidal product	16	g/m²	Set
Fraction of active ingredient in product	0.593 (tech) 0.588 (pure)	%	Set
Area to be treated with prescribed amount	1	m²	Set
Treatment rate (ai) for area	0.08	g/m²	Set
Type of application	Spraying	-	Set
Area to be treated	Wall and roof	-	Only 10% of the surface is treated (barrier treatment)
Manure distribution on grassland	Spreading	-	Set

Calculations for Scenario [3]
Please refer to Section 3.2.2 for calculations.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP	3.81E-03	Scenario 1
STP	5.12E-03 (Tech) 5.08E-03 (pure	Scenario 2
STP	8.82E-03	Scenario 3*

*Worst-case value reported for completeness (Animal category 16: Turkeys in free range), however, label restriction: Do not use in stables connected to the STP

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway						
Scenario	Fresh-water*	STP	Air	Soil	Ground-water	Secondary poisoning
Scenario 1	yes	yes	no	yes	yes	no
Scenario 2	yes	yes	no	yes	yes	no
Scenario 3	yes	no**	no	yes	yes	no

*Freshwater sediment is covered by the freshwater assessment

**The applicant added a risk mitigation measure that prevents emission to the municipal sewer when applied in stables.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks*
Dinotefuran			
Molecular weight	202.2	g/mol	
Melting point	107.5	°C	
Vapour pressure (at 25 ºC)	5.0E-05	Pa	
Water solubility (at 20 °C)	5.45E+04	mg/L	
Log Octanol/water partition coefficient (Log K_{OW})	-0.644	Log 10	
Organic carbon/water partition coefficient (K_{OC})	31.4	L/kg	
Freundlich adsorption coefficient (1/n)	0.868	-	Arithmetic mean, derived from study [redacted] (2001)**
Biodegradability	Not biodegradable	-	
DT_{50} for biodegradation in surface water	94.65	d (at 12ºC)	
DT_{50} for degradation in soil	19.2	d (at 12ºC)	
DT_{50} for degradation in air	2.4	hr	
MNG – major metabolite in soil			
Chemical name	1-methyl-2-nitroguanidine	-	
Molecular mass	118.1	g/mol	
MNG maximum occurrence in soil	16	% (of applied radioactivity)	
Vapour pressure	16.9 (at 25 ºC)	Pa	Original CAR value

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks*
Water solubility (at 20 °C)	1000	mg/L	Original CAR value
DT_{50} for degradation in soil	137	d (at 12ºC)	[redacted] 2003b
Rate constant	5.06E-03	d^{-1}	Calculated
Formation fraction	0.2137	-	CAKE kinetic evaluation of study [redacted] (2003)***
Organic carbon/water partition coefficient (K_{OC})	2.70	L/kg	Worst case value derived from the CAR.
Freundlich adsorption coefficient (1/n)	1	-	Worst case value, although at the time the CAR was agreed the default was 0.9
Tier 2 values (evaluated and accepted by the eCA, but not yet EU harmonised			
Organic carbon/water partition coefficient (K_{OC})	15.01	L/kg	Geometric mean, derived from study [redacted] (2001)**
Freundlich adsorption coefficient (1/n)	0.91	-	Arithmetic mean, derived from study [redacted] (2001)**
DN – major metabolite in sediment			
Chemical name	1-methyl-3-(tetrahydro-3-furylmethyl) guanidine	-	
Molecular mass	157.2	g/mol	
DN maximum occurrence in total pond system	32.6	% (of applied radioactivity)	

* Parameters are taken from the Dinotefuran PT18 Assessment Report, 2014 unless otherwise stated.

** Völkel (2001) was previously not evaluated for a.s. approval of dinotefuran, submitted at a late stage preventing EU harmonisation.

*** Völkl (2003) was previously evaluated for a.s. approval of dinotefuran, however the formation fraction to metabolite MNG derived for risk assessment of SECLIRA FLY BAIT was not previously derived for a.s. approval.

Calculated fate and distribution in the STP**		
Compartment	Percentage [%]	Remarks*
Air	2.60E-07	Relevant for Scenarios 1 and 2
Water	99.6	
Sludge	0.40	
Degraded in STP	0	

* EUSES output unless otherwise stated

**SimpleTreat v4.0

Calculated PEC values

All PEC values were based on technical concentration in the first tier. Refinement to pure concentration is applied for scenario 2 for the emission to water, and considered appropriate because the $PNEC_{water}$ is based on measured concentrations.

Summary table on calculated PEC values					
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L^3]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Dinotefuran					
Scenario 1	1.90E-03	1.90E-04	*	2.80E-05	6.05E-03
Scenario 2	2.55E-03	2.55E-04	*	3.75E-05	8.12E-03
Scenario *2* refinement		2.53E-04			
Scenario 3	n.a.**	1.05E-04 ***	*	1.28E-03#	**2.38E-01**
MNG					
Scenario 1	nr	nr	nr	3.26E-06	6.02E-03
Scenario 2	nr	nr	nr	4.38E-06	8.11E-03
Scenario 3	nr**	nr	nr	1.88E-04##	**1.16E-01** [1]
DN					
Scenario 1	nr	nr	5.93E-05	nr	nr
Scenario 2	nr	nr	7.98E-05	nr	nr
Scenario 3	nr**	nr	7.58E-05	nr	nr

1 PEC_{GW} reported is based upon the concentration in porewater. PECGW was further calculated using a simulation tool (FOCUS PEARL), the results for the different simulated scenarios are provided in a separate tables below.

nr: not a relevant route of exposure

* PECsed is covered by the PECwater assessment.

** The applicant added the following risk mitigation measure to the SPC: Do not use in stables connected to the STP.

*** Exposure is via manure application to land.

#: worst-case value reported (Veal calf, grassland, after 10 years of successive manure application based on nitrogen emission standards.)

##: the value for sows in groups is reported (grassland, after 10 years of successive manure application based on nitrogen emission standards.). The overall maximum results from veal calves equals 1.76E-04 mg/kg, see section 3.2.2 for details.

Summary table on calculated PEC values – dinotefuran						
Scenario	**PECGW [µg/L]**	**LOCATION**	**APPLICATION SCHEME**	**CROP CALENDAR**	**SOIL TYPE**	**METEO STATION**
Scenario 3	<0.001*	JOKIOINEN	Grass	JOKI-GRASS	JOKI-S_Soil	JOKI-M

*FOCUS PEARL output, concentration for all PEARL scenarios was <0.001 µg/L, see section 3.2.2

Summary table on calculated PEC values – MNG – Tier 1						
Scenario	**PECGW [µg/L]**	**LOCATION**	**APPLIC. SCHEME**	**CROP CALENDAR**	**SOIL TYPE**	**METEO STATION**
Scenario 3	0.04560	CHATEAUDUN	Grass	CHAT-GRASS	CHAT-S_Soil	CHAT-M
	0.08854	HAMBURG	Grass	HAMB-GRASS	HAMB S_Soil	HAMB-M
	0.12322	JOKIOINEN	Grass	JOKI-GRASS	JOKI-S_Soil	JOKI-M
	0.05073	KREMSMUENSTER	Grass	KREM-GRASS	KREM-S_Soil	KREM-M
	0.04204	OKEHAMPTON	Grass	OKEH-GRASS	OKEH-S_Soil	OKEH-M
	0.03013	PIACENZA	Grass	PIAC-GRASS	PIAC-S_Soil	PIAC-M
	0.02394	PORTO	Grass	PORT-GRASS	PORT-S_Soil	PORT-M
	0.00000	SEVILLA	Grass	SEVI-GRASS	SEVI-S_Soil	SEVI-M
	0.00713	THIVA	Grass	THIV-GRASS	THIV-S_Soil	THIV-M
	0.01185	CHATEAUDUN	Arable	CHAT-WCEREALS	CHAT-S_Soil	CHAT-M
	0.01470	HAMBURG	Arable	HAMB-WCEREALS	HAMB- S_Soil	HAMB-M
	0.023170	JOKIOINEN	Arable	JOKI-WCEREALS	JOKI-S_Soil	JOKI-M
	0.01062	KREMSMUENSTER	Arable	KREM-WCEREALS	KREM-S_Soil	KREM-M
	0.01103	OKEHAMPTON	Arable	OKEH-WCEREALS	OKEH-S_Soil	OKEH-M
	0.00768	PIACENZA	Arable	PIAC-WCEREALS	PIAC-S_Soil	PIAC-M
	0.00698	PORTO	Arable	PORT-WCEREALS	PORT-S_Soil	PORT-M
	0.00029	SEVILLA	Arable	SEVI-WCEREALS	SEVI-S_Soil	SEVI-M
	0.00722	THIVA	Arable	THIV-WCEREALS	THIV-S_Soil	THIV-M

*FOCUS PEARL output, concentration for worst-case PEARL scenario shown and worst-case dose, for further details see section 3.2

Tier 2 calculations

Summary table on calculated PEC values – MNG – Tier 2						
Scenario	**PEC_{GW}** [µg/L]	**LOCATION**	**APPLICATION SCHEME**	**CROP CALENDAR**	**SOIL TYPE**	**METEO STATION**
Scenario 3	0.056958	JOKIOINEN	Grass	JOKI-GRASS	JOKI-S_Soil	JOKI-M

Primary and secondary poisoning

In relation to primary poisoning, no assessment has been considered necessary. Primary poisoning could occur when "*insecticides are applied together with food attractant*". Whilst SECLIRA FLY BAIT contains a palatability agent; it is intended for indoor applications only as barrier treatment (i.e., a limited surface area is treated).

Additionally, the product is not in a form that could be sufficiently appetent to birds or mammals. Dinotefuran is unlikely to bioaccumulate in the aquatic or terrestrial environment according to the TGD. It has a low log K_{OW} (-0.64), it is not highly adsorptive (K_{OC}), it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features do not indicate accumulation. The low accumulation potential is supported by low BCF for fish and earthworms reported in the Dinotefuran PT18 Assessment Report (2014). The bioconcentration factor for fish is 0.068 L/kg wwt and a default BMF of 1. The bioconcentration factor for earthworms is 0.843 L/kg wwt and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Major metabolites MNG (soil) and DN (aquatic compartment) have predicted log Kow values of -1.17 and -0.18 respectively so are also not expected to bioaccumulate. Consequently, further consideration of the risk of secondary poisoning was unnecessary.

2.2.8.3 Risk characterisation

Atmosphere

It is not necessary to consider exposure to the air compartment because the active substance is not volatile; vapour pressure 5.0 x 10^{-5} Pa at 25°C.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	<0.001
Scenario 2	<0.001
Scenario 3	n.a.*

*Not applicable. The applicant stated that the product should not be applied in stables connected to the municipal sewer. The applicant added the following measure to the SPC: Do not use in stables connected to the STP.

Conclusion: The PEC/PNEC ratio for urban uses (scenarios 1 and 2) and rural use (scenario 3) is <1.

Aquatic compartment

Summary table on calculated PEC/PNEC values - AS	
	PEC/PNEC$_{water*}$
Scenario 1	7.43E-01
Scenario 2	1.000 (Technical) 9.95E-01 (pure)
Scenario 3	4.15E-01**

* the assessment for sediment is covered by the assessment for water
** worst case PEC/PNEC, use in Veal calves housing, where exposure is via application of manure to land.

Summary table on calculated PEC/PNEC values – metabolite DN	
	PEC/PNEC$_{sed}$
Scenario 1	1.11E-03
Scenario 2	1.53E-03
Scenario 3	1.52E-03*

* worst-case use (Veal calves (3)).

Conclusion: The PEC/PNEC ratio in water for urban uses (scenarios 1 and 2) and rural uses (scenario 3) is <1 for dinotefuran. Please note that a refinement is accepted considering that the PNECwater is based on measured concentrations making possible a risk assessment based on the pure amount of AS in the product.

The PEC/PNEC ratio in sediment for urban uses (scenarios 1 and 2) and rural uses (scenario 3) is <1 for metabolite DN.

Hence, risks to water and sediment are considered to be acceptable from the intended uses of the product.

Terrestrial compartment

Summary table on calculated PEC/PNEC values - AS	
	PEC/PNEC$_{soil}$
Scenario 1	2.10E-02
Scenario 2	2.90E-02
Scenario 3	9.88E-01*

** worst case PEC/PNEC, use in Veal calves housing, exposure via manure application to land

Summary table on calculated PEC/PNEC values – metabolite MNG	
	PEC/PNEC$_{soil}$
Scenario 1	2.03E-02
Scenario 2	2.74E-02
Scenario 3	1.17E-01*

* worst case PEC/PNEC, use in Veal calves housing, exposure via manure application to land.

Conclusion: The PEC/PNEC ratio in soil for urban uses (scenarios 1 and 2) and rural uses (scenario 3) is <1 for dinotefuran and metabolite MNG.

Hence, risks to the soil compartment are considered to be acceptable from the intended uses of the product.

Groundwater

Groundwater concentrations of dinotefuran are <0.1 µg/L following urban uses and rural uses, therefore acceptable risk has been demonstrated.

Determination of groundwater concentrations following urban uses (scenarios 1 and 2) was based upon the predicted porewater concentration of dinotefuran in agricultural soil and resulted in a concentration of <0.00512 and 0.00689 µg/L, respectively.

Determination of groundwater concentrations following rural uses (scenario 3) required refinement using PEARL, since the calculated porewater concentrations exceeded the groundwater drinking limit during this screening phase (0.238 µg/L based on worst-case value from veal calf), and in all cases resulted in concentrations <0.0001 µg/L.

Groundwater concentrations of metabolite MNG are <0.1 µg/L following urban uses (scenarios 1 and 2) and resulted in concentrations of 0.00773 and 0.000559 µg/L, respectively and rural uses (scenario 3) resulting in a concentration of 0.116 µg/L based upon worst-case value from veal calf), refinement with Pearl calculations on basis of the MNG parameters in the original CAR the 0.1 µg/L standard for the production of drinking water from groundwater is exceeded in Jokioinen soil (0.12 µg/L) when treated manure is spread over grassland. Groundwater concentrations is <0.1 µg/L in all other ground types.

For convenience for member states where this use and Jokioinen soil type is relevant a refinement can be considered taking into consideration updated endpoints for the Koc and

freundlich adsorption coefficient (1/n) from studies evaluated by the eCA, but due to the late submission not discussed for EU harmonisation. Pearl calculations using these parameters show Groundwater concentrations <0.1 ug/L in all ground types.

Primary and secondary poisoning

Conclusion: A primary and secondary poisoning assessment is not necessary since the product is applied indoors to a limited surface area, and the product is not in a form that could be sufficiently appetent to birds. Furthermore, dinotefuran and its major metabolites MNG and DN, are not expected to bioaccumulate.

Mixture toxicity

A stepwise approach was employed to determine if 1) the SECLIRA FLY BAIT contained substances of concern (SoC) as defined in Regulation (EU) No. 525/2012 (BPR) Article 3(f); and 2) if the formulation contained any potential SoC.

In a first step, each component was investigated for the following properties to determine if they are a SoC via a review of available EU harmonised classifications and/or classifications reported in REACH registration dossiers and/or CLP notifications:

- substances meeting the criteria for classification as hazardous according to CLP regulation, and present in the biocidal product at a concentration leading to the product to be regarded as hazardous
- substances which meet the PBT criteria
- substances which meet the criteria for being a POP

It was concluded that following this exercise, none of the components are a SoC requiring evaluation of mixture toxicity.

In a second step, each component was investigated for properties that may render them as a potential SoC defined according to ECHA Guidance on BPR: Volume III Parts B+C, Version 4.0, Dec. 2017 and Volume IV Parts B+C, Version 2.0, Oct. 2017 as:

- Active substances PTs contained in the product for which a draft final Competent Authority Report is available. This criterion identifies other active substances in the biocidal product that act as co-formulants. Those substances should be regarded as SoCs because they potentially affect environmental organisms due to their intrinsic biological activity. They should be considered as SoCs if they are present in the biocidal product at a concentration ≥ 0.1%. Exemptions are possible under the following condition: the substance is contained in Annex I of the BPR
- Substances that enhance the effect of the active substance in the product, e.g. synergists. Substances that have been included in the candidate list established in accordance with the REACH Regulation, Article 57 (f) and 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR.

Additionally specific to the environmental assessment:

- Substances which meet two of the criteria for being PBT according to the REACH Regulation.
- Substances for which an Environmental Quality Standard (EQS) has been derived.

It was concluded that following this exercise, none of the components are a potential SoC requiring evaluation of mixture toxicity for the environment.

Aggregated exposure (combined for relevant emission sources)

Output of the decision tree on the need for estimation of aggregated exposure:

- Other regulatory areas: No
- Overlap in time and space: No (different pest species and field of use)

According to TAB ENV July 2021 (entry ENV 151), it is not necessary to sum the emissions from the use of the same product which is used by both non-professionals (general public) and professionals (and trained professionals):

> "*If a product is intended for household use against a certain organism and it can be used by both professionals and non-professionals, the emissions from professional/non-professional use should not be aggregated for the exposure estimation.*
>
> *The value for Fsim should in this case be understood as reflecting frequency of use regardless of user category. I.e., it is assumed that the treatment is applied by either a non-professional user or a professional user, during the same treatment period.*"

A label restriction prevents the use of the product in stables connected to the STP (due to exceedance in water compartment). Therefore, it is not appropriate to conduct an aggregated exposure for SECLIRA FLY BAIT where exposure to environmental compartments is via the STP.

Overall conclusion on the risk assessment for the environment of the product

The risk assessment for SECLIRA FLY BAIT has been conducted for 3 use scenarios: 1) non-professional (general public) use inside domestic buildings against flies via barrier treatments; 2) professional and trained professional use inside domestic and large buildings against flies via barrier treatments; and 3) non-professional, professional and trained professional use inside animal buildings on farms against flies via barrier treatment.

The PEC/PNEC ratios in all environmental compartments of relevance for dinotefuran, MNG and DN are <1. On basis of the original CAR parameters for MNG all groundwater concentrations are below 0.1 µg/L, except for emission of treated manure to grassland on Jokioinen soil. Member states where this use and Jokioinen soil type is relevant a refinement can be considered taking into consideration updated endpoints for the Koc and freundlich adsorption coefficient (1/n) from studies evaluated by the eCA, but due to the late submission not discussed for EU harmonisation. Pearl calculations using these parameters show Groundwater concentrations <0.1 ug/L also in this soil type.

Therefore acceptable risk has been demonstrated following the intended uses of SECLIRA FLY BAIT in accordance with the SPC and all groundwater concentrations are below 0.1 µg/L, therefore acceptable risk has been demonstrated following the intended uses of SECLIRA FLY BAIT.

Dinotefuran

An assessment for air is not required, as dinotefuran is not volatile (vapour pressure 5.0×10^{-5} Pa at 25°C).

For scenarios 1 and 2, the PEC/PNEC ratio in the STP is <0.001, therefore the risk is acceptable. There will be no exposure to the STP from scenario 3 use.

For scenarios 1, 2, and 3, the PEC/PNEC ratio in water, which also covers the sediment risk assessment, are 5.91E-01, 8.07E-07 and 8.04E-01, respectively. The PEC used for scenario 3 is based on the worst-case exposure which is from beef cattle housing.

For scenarios 1, 2, and 3, the PEC/PNEC ratio in soil is 8.81E-03, 1.19E-02 and 1.37E-03, respectively. The PEC used for scenario 3 is based on the worst-case exposure which is from beef cattle housing.

For scenarios 1 and 2, the groundwater concentration was estimated based on the predicted porewater concentrations of dinotefuran in agricultural soil and resulted in concentrations < 0.00001 µg/L. For scenario 3, the groundwater concentration was calculated using PEARL based upon the worst-case application to agricultural land from beef cattle housing and resulted in concentrations <0.001 µg/L.

MNG

MNG is a major metabolite in soil, therefore exposure in soil and subsequently in groundwater has been assessed.

For scenarios 1, 2, and 3, the PEC/PNEC ratio in soil is 2.03E-02, 2.74E-02and 7.85E-01, respectively. The PEC used for scenario 3 is based on the next worst-case exposure which is from sows in groups housing (the RCR for worst-case housing, veal calves, equals 1.1, however veal calves can still be considered safe due to the very conservative PNEC setting).

For scenarios 1 and 2, the groundwater concentration was estimated based on the predicted porewater concentrations of dinotefuran in agricultural soil and resulted in concentrations of 7.73E-03µg/L (scenario 1) and 5.59E-04 µg/L (scenario 2). For scenario 3, the groundwater concentration was calculated using PEARL based upon the worst-case application to agricultural land from beef cattle housing and resulted in a maximum concentration of 0.075 µg/L (JOKIOINEN).

DN

DN is a major metabolite in sediment, therefore exposure to sediment has been assessed for the relevant scenarios 1, 2 and 3.

For scenarios 1 and 2, the PEC/PNEC ratio in sediment is 1.19E-03 and 1.60E-03, respectively. For sicario 3, the PEC/PNEC ratio in sediment is 1.52E-03, based upon the worst case (Veal calves).

2.2.9 Measures to protect man, animals and the environment

Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Avoid breathing spray.
Do not apply directly on animals.
Use only in a well-ventilated area.
Provide adequate ventilation (industrial ventilation or keeping windows and doors open).
The stay in the treated area should be minimised.
Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets
Do not store near food, drink and animal feedingstuff.
Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.
For use only in areas that are inaccessible to infants, children, pets and non-target animals.
Wet cleaning of surfaces is recommended after the desired efficacy is achieved.
Do not use in animal housings where exposure to a STP or direct emission to surface water cannot be prevented.
Do not use in veal calf animal housing.
Cover feeding area with plastic sheets.
Do not use near domestic animals or livestock
Avoid any leakage/splash or spray drift deposition that may infect the animals and their feeding area.
This biocidal product contains dinotefuran which is dangerous to bees

2.2.10 Assessment of a combination of biocidal products

SECLIRA FLY BAIT is not intended to be authorised for use with other biocidal products.

2.2.11 Comparative assessment

In the Guidance document on comparative assessment of biocidal products, it is stated that:

- a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection;
- as a general rule, at least three different and independent "active substance/mode of action" combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

The applicant considers therefore, in line with the Guidance document, that the chemical diversity, concerning active substances against House flies and Stable flies is not adequate in order to minimise the occurrence of resistance in the target organisms. Indeed, less than three different active substances - mode of action combinations are available through authorised insecticides in NL for the uses claimed for SECLIRA FLY BAIT.

The applicant is not aware of any eligible non-chemical alternative which is likely to meet the required criteria of Article 23.3 of the BPR. ECHA will collect information about non-chemical alternatives during the public consultation in the context of the renewal of dinotefuran and a new comparative assessment will be conducted at the time of renewal of SECLIRA FLY BAIT.

Background

SECLIRA FLY BAIT contains the active substance Dinotefuran. During the European evaluation, Dinotefuran was considered to meet two of the criteria for being PBT (Persistent bioaccumulation and toxic) in accordance with Annex XIII to regulation (EC) No 1907/2006, namely to be very persistent (vP) and toxic (T). Dinotefuran fulfils thereby the criterion in Article 10.1.d), Regulation (EU) No 528/2012 for the purpose of authorizing products in accordance with Article 23 of that Regulation, and should consequently be regarded as candidate for substitution.

NL, the Reference Member State (RefMS) has asked the applicant to perform a comparative assessment for SECLIRA FLY BAIT and to include it to the product dossier submission. Therefore, BASF carried out this comparative assessment, in accordance with article 23 of the BPR.

According to the guidance document "Technical Guidance Note on comparative assessment of biocidal products", CA-May15-Doc.4.3.a – Final, RefMS shall discuss the suitability of identified BPs authorised under BPD or BPR, as well as non-chemical alternative, under its own market as well as under other member states markets. However, detailed information regarding products authorised in other Member States cannot yet be obtained as the ECHA dissemination platform for biocidal product is not yet in place. Therefore, until the R4BP is populated with searchable SPCs and ECHA can further develop the search tool, Member States are only requested to compare the relevant BP to the alternative BPs authorised in their territory. Thus, this comparative assessment performed by the applicant is restricted to biocidal products authorised in the Netherland.

There is no available information concerning non-chemical alternatives. Such information shall be available, according to Article 10.3 in Regulation (EU) No 528/2012, through the public consultation carried out by ECHA in connection of the approval or renewal of an active substance that is a candidate for substitution.

According to the guidance document "Technical Guidance Note on comparative assessment of biocidal products", CA-May15-Doc.4.3.a – Final, (hereinafter – the Guidance document) a tiered approach preceded by a screening phase, should be followed when carrying out a comparative assessment.

Mapping of existing alternatives to the relevant BP

- From information collected on ECHA and Ctgb websites, the applicant identified 35 PT 18 products authorised under the BPR or BPD in NL.

Considering that alternative BPs shall be authorised for at least one of the intended uses of the relevant BP, 7 BPs out of the 35 BPs identified shall be considered relevant alternatives authorised against **the same target organisms** for **indoor uses** ("eligible alternatives").

Table 1: aBPs to SECLIRA FLY BAIT

PT18 BP 20180315 supporting Doc.xlsx

According to Article 10.3 in Regulation (EU) No 528/2012, such information shall be available, through the public consultation carried out by ECHA at the time of approval of the active substance. No contribution was submitted during the public consultation performed for dinotefuran in 2014.

The only non-chemical alternative identified by the applicant is the glue board but its use is far from providing the same level of efficacy as chemical alternatives, and can therefore not be considered eligible alternative.

1.- Screening phase

The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a detailed comparative assessment. Article 23.3(b), Regulation (EU) No 528/2012, refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two *sine qua non* conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase it shall be checked whether the diversity of the active substance, product type and mode of action combination in biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012, is adequate to minimise the occurrence of resistance in the target organisms. According to the Guidance document, adequate chemical diversity means that at least three different active substances / mode of action combinations should remain available through authorised biocidal products. If not, a conclusion could be reached that there is not an adequate chemical diversity and that it is therefore not pertinent to conduct further investigations. The comparative assessment could therefore be finalised at this stage.

- **Description of the assessment of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.**

In order to facilitate the mapping of existing alternatives to the relevant BP, the applicant used the following segmentation: area of use, category of users (General Public (non-professional) / trained professional & professional*), target organisms leading to 4 combinations:

Combination 1: UPC (Urban Pest Control) / Professional / Flies

Combination 2: UPC (Urban Pest Control) / General Public / Flies

Combination 3: RH (Rural Hygiene) / General Public / Flies

Combination 4: RH (Rural Hygiene) / Professional / Flies

**: It is worth noting that the information presented in the Dutch SPC does not always distinguish between Professionals and Trained Professionals. Therefore, for this CA "professional" includes trained professional and professional.*

Combination 1: UPC / Professional / Flies

Table 2: aBPs to SECLIRA FLY BAIT list on Combination 1

	MoA	AS	BP	CfS (Y or N)
MoA1	4A	Dinotefuran	1BP: SECLIRA FLY BAIT	Y, vP and T
		Imidacloprid	1BP : Lurectron Flybait	Y, vP and T
MoA2	3A	Deltamethrine	2BP K-Othrine WG250, K-Othrine SC 7.5	N N

For the combination 1, three out of seven products correspond to the specific use of SECLIRA FLY BAIT with only two different modes of action. It can, therefore, be concluded that there is not adequate chemical diversity through authorized biocidal products. For Combination 1, the comparative assessment concerning SECLIRA FLY BAIT can be finalized at the screening stage.

Combination 2: UPC / General Public / Flies

Table 3: aBPs to SECLIRA FLY BAIT list on Combination 2

	MoA	AS	BP	CfS (Y or N)
MoA1	4A	Dinotefuran	1BP SECLIRA FLY BAIT	Y, vP and T
		Imidacloprid	1BP FliegenKöder	Y,vP and T

For the combination 2, one out of seven products corresponds to the specific use of SECLIRA FLY BAIT with similar mode of action. It can, therefore, be concluded that there is not adequate chemical diversity through authorized biocidal products. For Combination 2, the comparative assessment concerning SECLIRA FLY BAIT can be finalized at screening stage.

Combination 3: RH / General Public / Flies

Table 4: aBPs to SECLIRA FLY BAIT list on Combination 3 segment

	MoA	AS	BP	CfS
MoA1	4A	Dinotefuran	1 BP SECLIRA FLY BAIT	Y, vP and T
MoA2	5	Spinosad	1BP Elector	Y, P and T

For the combination 3, one out of seven products corresponds to the specific use of SECLIRA FLY BAIT with only two different modes of action. It can, therefore, be concluded that there is not adequate chemical diversity through authorized biocidal products. For Combination 3, the comparative assessment concerning SECLIRA FLY BAIT can be finalized at screening stage.

Combination 4: RH / Professional / Flies

Table 5: aBPs to SECLIRA FLY BAIT list on Combination 4 segment

	MoA	AS	BP	CfS (Y or N)
MoA1	4A	Dinotefuran	1 BP SECLIRA FLY BAIT	Y, vP and T
		Imidacloprid	1BP Quick bait	Y, vP and T
MoA2	3A	Deltamethrine	1BP K-Othrine Sc 7.5	N
MoA3	5	Spinosad	1BP Elector	Y, P and T

For the combination 4, three out of seven products correspond to the specific use of SECLIRA FLY BAIT with three different modes of action. Although it could, be concluded that there is adequate chemical diversity through authorized biocidal products, considering the widely spread resistance to pyrethroids and the emerging problem of resistance to Imidacloprid in

housefly populations (Khan et al. 2017, Ma et al. 2017, Scott, 2017, Akiner and Cağlar, 2012, Memmi, 2010, Kaufman et al. 2009, Cao et al. 2006), it is technically reasonable to consider that the chemical diversity is not enough. Resistance to two out of the three products authorized has been reported.

In addition to the arguments provided above, it is relevant to add that Dinotefuran, despite being classified as MoA 4A according to IRAC, has a slightly different mode of action compared to other first and second generation neonicotinoids (2018/1096183 document from MTAG, Simon-Delso et al. 2015), which contributes to its effectiveness against Imidacloprid-resistant flies (2018/1062030)

- **Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.**

Not applicable

-Conclusion of the screening phase: Stop comparative assessment

In the Guidance document on comparative assessment of biocidal products, it is stated that:

- a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection;
- as a general rule, at least three different and independent "active substance/mode of action" combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

The applicant considers therefore, in line with the Guidance document, that the chemical diversity, concerning active substances against House flies and Stable flies is not adequate in order to minimize the occurrence of resistance in the target organisms. Indeed less than three different active substances - mode of action combinations are available through authorized insecticides in NL for the uses claimed for SECLIRA FLY BAIT.

The applicant is not aware of any eligible non-chemical alternative which is likely to meet the required criteria of Article 23.3 of the BPR. ECHA will collect information about non-chemical alternatives during the public consultation in the context of the renewal of dinotefuran and a new comparative assessment will be conducted at the time of renewal of SECLIRA FLY BAIT.

The comparative assessment concerning SECLIRA FLY BAIT could be finalised at the screening stage and could not demonstrate that any of the criteria in Article 23.3 are met. Therefore, SECLIRA FLY BAIT should not be prohibited or restricted on the market based on the comparative assessment.

Overall conclusion:

The comparative assessment concerning SECLIRA FLY BAIT could be finalised at the screening stage and could not demonstrate that any of the criteria in Article 23.3 are met. Therefore, SECLIRA FLY BAIT should not be prohibited or restricted on the market based on the comparative assessment.

The full comparative assessment can be found in the confidential annex.

References:

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- Ma Z, Li J, Zhang Y, Shan C. and Gao X. 2017. Inheritance mode and mechanisms of resistance to imidacloprid in the house fly *Musca domestica* (Diptera:Muscidae) from China. PLoS ONE 12(12): e0189343.
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3 ANNEXES[3]List of studies for the biocidal product

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
3.1 3.1 3.1 3.2 3.4.1 3.4.2.1 4.16	[redacted]	2018	BAS 395 18 I: accelerated storage stability and corrosion characteristics Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45464 DocID 2018/7005854 Unpublished	No	Yes	BASF
3.2 3.5 3.8	[redacted]	2021	BAS 395 18 I: Determination of Physical Properties Eurofins EAG Agroscience, LLC, 7200 East ABC Lane, Columbia, Missouri 65202, U.S.A. Report no. 90858 DocID 2021/2047539 Unpublished	No	Yes	BASF
3.3 3.9 4.2	[redacted]	2018	BAS 395 18 I: Physical and Chemical Characteristics: Viscosity, Density/Relative Density, and Ignition Distance Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 46175 DocID 2018/7001799 Unpublished	No	Yes	BASF

[3] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
3.4.1	[redacted]	2017	BAS 395 18 I: stability of a liquid formulation at 0 ºC Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 46174 DocID 2017/7016032 Unpublished	No	Yes	BASF
3.4.1	[redacted]	2021	BAS 395 18 I: Storage Stability and Corrosion Characteristics Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 817985 DocID 2021/2032895 Unpublished	No	Yes	BASF
3.4.1	[redacted]	2021	BAS 395 18 I: Storage Stability of Physical and Chemical Characteristics: Internal Pressure, Discharge Rate, pH, Spray Pattern, and Clogging of Dispenser Valve – 24-Month Report Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 878522 DocID 2021/2037703 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
3.4.1	[redacted]	2021	BAS 395 18 I: Determination of Accelerated Storage Stability of Aerosol Physical Properties Eurofins EAG Agroscience, LLC, 7200 East ABC Lane, Columbia, Missouri 65202, U.S.A. Report no. 90857 DocID 2021/2039170 Unpublished	No	Yes	BASF
3.5 3.8	[redacted]	2018	BAS 395 18 I: Surface Tension and Aerosol Spray Pattern Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 46176 DocID 2018/7005408 Unpublished	No	Yes	BASF
3.9	[redacted]	2021	Physical properties of BAS 395 18 I Lot#19317PZ5 for Viscosity BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709, U.S.A. Report no. 878522_4 DocID 2021/2032687 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
4.1 4.4 4.17.1	[redacted]	2017	BAS 395 KL I: explosive properties, oxidising properties and auto-ignition temperature (liquids and gases) Envigo CRS Ltd, Eye, Suffolk, IP23 7PX, UK Report no. XB76YV DocID 2017/7012284 Unpublished	No	Yes	BASF
4.1	[redacted]	2022	Evaluation of physical and chemical properties according to the Regulation (EC) No 440/2008 (Directive 94/37EC)			
5	[redacted]	2017	BAS 395 18 I: Enforcement analytical method for the determination of dinotefuran by high performance liquid chromatography Product Safety Labels, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45463 EAM DocID 2017/7012220 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
6.7	[redacted]	2018	Laboratory bioassay to determine the residual efficacy of a pressurized fly bait product (BAS 395 18 I) against stable flies, *Stomoxys calcitrans*. i2L Research Ltd, Capital Business Park, Wentloog, Cardiff, CF3 2PX, UK Report no. 16/286 DocID 2018/1062029 Unpublished	No	Yes	BASF
6.7	[redacted]	2018	Laboratory bioassay to determine the residual efficacy of an aerosol product against Stable flies, *Stomoxys calcitrans* i2L Research Ltd, Capital Business Park, Wentloog, Cardiff, CF3 2PX, UK Report no. 18/031 DocID 2018/1093863 Unpublished	No	Yes	BASF
6.7	[redacted]	2021	Insecticidal efficacy of BAS 395 KL I (BAS 395 18 I) pressurized fly bait, three years after manufacture, against stable flies as 1-day aged applications in laboratory assays APR/IA Non-Crop Advanced Testing Laboratory, RTP, NC, BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, U.S.A. Report no. WPRN888945 DocID 2021/2039678 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
6.7	[redacted]	2017	Laboratory bioassay to determine the residual efficacy of a pressurized fly bait product (BAS 395 KL I) against Houseflies, *Musca domestica* i2L Research Ltd, Capital Business Park, Wentloog, Cardiff, CF3 2PX, UK Report no. 16/287 DocID 2017/1136552 Unpublished	No	Yes	BASF
6.7	[redacted]	2018	Laboratory bioassay to determine the residual efficacy of an aerosol product against Houseflies, *Musca domestica* i2L Research Ltd, Capital Business Park, Wentloog, Cardiff, CF3 2PX, UK Report no. 18/030 DocID 2018/1093862 Unpublished	No	Yes	BASF
6.7	[redacted]	2021	Insecticidal efficacy of BAS 395 KL I (BAS 395 18 I) pressurized fly bait, three years after manufacture, against house flies as 1-day aged applications in laboratory assays APR/IA Non-Crop Advanced Testing Laboratory, RTP, NC, BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, U.S.A. Report no. NGWPRN888936 DocID 2021/2039673 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
6.7	[redacted]	2021	Simulated-use test to determine the biological efficacy of the aerosol product "BAS 395 18 I", applied on cardboards wrapped with aluminium foil (to simulate non-porous surfaces) applied to a surface corresponding to 2.5 % of the wall plus ceilings area of the test chamber, at different test days against House flies, *Musca domestica* tested in a 20 m³ chamber BioGenius GmbH, Biology TechnologiePark, Campus 1, Friedrich-Ebert-Strasse 75, 51429 Bergisch Gladbach, Germany Report no. BIO084a-21 DocID 2021/2036486 Unpublished	No	Yes	BASF
6.7	[redacted]	2021	Efficacy evaluation of the insecticide "BAS 395 18 I" against *Musca domestica* and *Stomoxys calcitrans* in livestock premises (application rate: 10 % of all walls and ceiling surface) Entostudio S.r.l., Viale del lavoro, 66, 35020, Ponte San Nicolò (PD), Italy Report no. Q059A-21 DocID 2021/2047841	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
6.7	[redacted]	2018	Insecticidal efficacy of BAS 395 KL I pressurized fly bait, one year after manufacture, against house flies as aged (1 and 55 day) applications in laboratory assays APR/IA Non-Crop Advanced Testing Laboratory, RTP, NC, BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, USA Report no. NGWPRN 850375 DocID 2018/1186617 Unpublished	No	Yes	BASF
6.7	[redacted]	2018	Insecticidal efficacy of BAS 395 KL I pressurized fly bait, one year after manufacture, against stable flies as aged (1 and 84 day) applications in laboratory assays APR/IA Non-Crop Advanced Testing Laboratory, RTP, NC, BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, USA Report no. NGWPRN 850375 DocID 2018/1121174 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
8.1.1	[redacted]	2017	Primary Skin Irritation in Rabbits Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45947 DocID 2017/1175881 Unpublished	Yes	Yes	BASF
8.1.2	[redacted]	2017	Primary Eye Irritation in Rabbits Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45946 DocID 2017/1210724 Unpublished	Yes	Yes	BASF
8.3.1	[redacted]	2017	Dermal Sensitization Test in Guinea Pigs - Buehler Method Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45948 DocID 2017/1189885 Unpublished	Yes	Yes	BASF
8.5.1	[redacted]	2017	Acute Oral Toxicity: Acute Toxic Class Method in Rats Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45943 DocID 2017/1177624 Unpublished	Yes	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
8.5.2	[redacted]	2017	Acute Inhalation Toxicity in Rats Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45945 DocID 2017/1177601 Unpublished	Yes	Yes	BASF
8.5.3	[redacted]	2017	Acute Dermal Toxicity in Rats Product Safety Labs, 2394 US Highway 130, Dayton, New Jersey 08810, USA Report no. 45944 DocID 2017/1186406 Unpublished	Yes	Yes	BASF
8.6	[redacted]	2021	^{14}C-BAS 395 I in BAS 395 KV I: Study of Penetration through Human Skin *in vitro* BASF SE, Experimental Toxicology and Ecology, 67056 Ludwigshafen, Germany Report no. 10B0521/15B029 DocID 2018/1082979 Unpublished	No	Yes	BASF
13	[redacted]	2018	Risk Assessment for the Environmental Exposure to BAS 395 18 I containing 0.5% w/w dinotefuran LKC Switzerland Ltd, Hauptstrasse 10, 4414 Füllinsdorf, Switzerland Report no. 21-LKC-13 DocID 2021/2049161 Unpublished	No	Yes	BASF

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
13		2018	Human dietary risk assessment and livestock exposure assessment for the application of BAS 395 18 I LKC Switzerland Ltd, Hauptstrasse 10, 4414 Füllinsdorf, Switzerland Report no. 21-LKC-12 DocID 2021-2049144 Unpublished	No	Yes	BASF

3.2 Output tables from exposure assessment tools

3.2.1 Human health exposure assessment

HHRA:

HHRA Seclira Fly Bait .xlsx

Output per scenario:

Scenario 1
Calculations of application time and application rate for scenario 1:

Private household:
Net application time: 38.5m^2 x 13.67 s/m^2 = 526.3 seconds (8.8 minutes)
Product application rate: 526.3 s x 1.17 g/s = 616 g product
Large public buildings:
Net application time: 93m^2 x 13.67 s/m^2 = 1272 seconds (21.2 minutes)
Product application rate: 1272 s x 1.17 g/s = 1487 g product
Small stable:
Net application time: 33m^2 x 13.67 s/m^2 = 451 seconds (7.5 minutes)
Product application rate: 451 s x 1.17 g/s = 528 g product
Large stable:
Net application time: 465m^2 x 13.67 s/m^2 = 6357 seconds (106 minutes)
Product application rate: 6357 s x 1.17 g/s = 7437 g product

Scenario 1:

Results for scenario *Dinotefuran 0.59% revised - Private House*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.1	mg/m³
Peak concentration (TWA 15 min)	2.7	mg/m³
Mean concentration on day of exposure	9.1×10^{-2}	mg/m³
Year average concentration	2.3×10^{-3}	mg/m³
External event dose	4.6×10^{-2}	mg/kg bw
External dose on day of exposure	4.6×10^{-2}	mg/kg bw
Internal event dose	4.6×10^{-2}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-2}	mg/kg bw/day
Internal year average dose	1.1×10^{-3}	mg/kg bw/day

Dermal

Dermal load	1.6×10^{-3}	mg/cm²
External event dose	8.7×10^{-2}	mg/kg bw
External dose on day of exposure	8.7×10^{-2}	mg/kg bw
Internal event dose	1.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.6×10^{-3}	mg/kg bw/day
Internal year average dose	3.8×10^{-5}	mg/kg bw/day

Oral

External event dose	2.6×10^{-7}	mg/kg bw
External dose on day of exposure	2.6×10^{-7}	mg/kg bw
Internal event dose	2.6×10^{-7}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-7}	mg/kg bw/day
Internal year average dose	6.4×10^{-9}	mg/kg bw/day

Integrated

Internal event dose	4.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	4.7×10^{-2}	mg/kg bw/day
Internal year average dose	1.2×10^{-3}	mg/kg bw/day

Results for scenario *Acetone 29.7% revised - Private House*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.1×10^3	mg/m³
Peak concentration (TWA 15 min)	1.7×10^3	mg/m³
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	4.5×10^1	mg/kg bw
External dose on day of exposure	-	
Internal event dose	4.5×10^1	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Integrated

Internal event dose	4.5×10^1	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Results for scenario *Dinotefuran 0.59% revised - Large Building*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.2×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	2.4×10^{-1}	mg/m³
Mean concentration on day of exposure	1.0×10^{-2}	mg/m³
Year average concentration	2.5×10^{-4}	mg/m³
External event dose	5.1×10^{-3}	mg/kg bw
External dose on day of exposure	5.1×10^{-3}	mg/kg bw
Internal event dose	5.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.1×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-4}	mg/kg bw/day

Dermal

Dermal load	3.8×10^{-3}	mg/cm²
External event dose	2.1×10^{-1}	mg/kg bw
External dose on day of exposure	2.1×10^{-1}	mg/kg bw
Internal event dose	3.8×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.8×10^{-3}	mg/kg bw/day
Internal year average dose	9.3×10^{-5}	mg/kg bw/day

Oral

External event dose	3.9×10^{-8}	mg/kg bw
External dose on day of exposure	3.9×10^{-8}	mg/kg bw
Internal event dose	3.9×10^{-8}	mg/kg bw
Internal dose on day of exposure	3.9×10^{-8}	mg/kg bw/day
Internal year average dose	9.6×10^{-10}	mg/kg bw/day

Integrated

Internal event dose	8.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	8.9×10^{-3}	mg/kg bw/day
Internal year average dose	2.2×10^{-4}	mg/kg bw/day

Results for scenario *Acetone 29.7% revised -Large Building*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.0×10^2	mg/m³
Peak concentration (TWA 15 min)	1.5×10^2	mg/m³
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	4.2	mg/kg bw
External dose on day of exposure	-	
Internal event dose	4.2	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Integrated

Internal event dose	4.2	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Results for scenario *Dinotefuran 0.59% revised - Small Stable*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.8×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	3.9×10^{-1}	mg/m³
Mean concentration on day of exposure	1.5×10^{-2}	mg/m³
Year average concentration	3.7×10^{-4}	mg/m³
External event dose	7.4×10^{-3}	mg/kg bw
External dose on day of exposure	7.4×10^{-3}	mg/kg bw
Internal event dose	7.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	7.4×10^{-3}	mg/kg bw/day
Internal year average dose	1.8×10^{-4}	mg/kg bw/day

Dermal

Dermal load	1.3×10^{-3}	mg/cm²
External event dose	7.4×10^{-2}	mg/kg bw
External dose on day of exposure	7.4×10^{-2}	mg/kg bw
Internal event dose	1.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-3}	mg/kg bw/day
Internal year average dose	3.3×10^{-5}	mg/kg bw/day

Oral

External event dose	5.3×10^{-8}	mg/kg bw
External dose on day of exposure	5.3×10^{-8}	mg/kg bw
Internal event dose	5.3×10^{-8}	mg/kg bw
Internal dose on day of exposure	5.3×10^{-8}	mg/kg bw/day
Internal year average dose	1.3×10^{-9}	mg/kg bw/day

Integrated

Internal event dose	8.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	8.7×10^{-3}	mg/kg bw/day
Internal year average dose	2.2×10^{-4}	mg/kg bw/day

Results for scenario *Acetone 29.7% revised - Small Stable*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.5×10^2	mg/m³
Peak concentration (TWA 15 min)	2.4×10^2	mg/m³
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	6.3	mg/kg bw
External dose on day of exposure	-	
Internal event dose	6.3	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Integrated

Internal event dose	6.3	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Results for scenario *Dinotefuran 0.59% revised - Large Stable*

☐ Show dose descriptions

Inhalation

Mean event concentration	6.5×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-1}	mg/m³
Mean concentration on day of exposure	1.1×10^{-2}	mg/m³
Year average concentration	2.7×10^{-4}	mg/m³
External event dose	5.4×10^{-3}	mg/kg bw
External dose on day of exposure	5.4×10^{-3}	mg/kg bw
Internal event dose	5.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.4×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-4}	mg/kg bw/day

Dermal

Dermal load	1.9×10^{-2}	mg/cm²
External event dose	1.0	mg/kg bw
External dose on day of exposure	1.0	mg/kg bw
Internal event dose	1.9×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-2}	mg/kg bw/day
Internal year average dose	4.6×10^{-4}	mg/kg bw/day

Oral

External event dose	3.6×10^{-8}	mg/kg bw
External dose on day of exposure	3.6×10^{-8}	mg/kg bw
Internal event dose	3.6×10^{-8}	mg/kg bw
Internal dose on day of exposure	3.6×10^{-8}	mg/kg bw/day
Internal year average dose	8.8×10^{-10}	mg/kg bw/day

Integrated

Internal event dose	2.4×10^{-2}	mg/kg bw
Internal dose on day of exposure	2.4×10^{-2}	mg/kg bw/day
Internal year average dose	6.0×10^{-4}	mg/kg bw/day

Results for scenario *Acetone 29.7% revised - Large Stable*

☐ Show dose descriptions

Inhalation

Mean event concentration	6.2×10^{1}	mg/m³
Peak concentration (TWA 15 min)	1.1×10^{2}	mg/m³
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	5.1	mg/kg bw
External dose on day of exposure	-	
Internal event dose	5.1	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Integrated

Internal event dose	5.1	mg/kg bw
Internal dose on day of exposure	-	
Internal year average dose	-	

Scenario 2:

Seclira Fly Bait

Scenario 2: Dermal systemic dose

	Private House	Large Building	Small Stable	Large Stable
Dermal load Dinotefuran (mg/cm^2) Calculated by ConsExpo Web in scenario 1	1,58E-03	3,81E-03	1,35E-03	1,91E-02
Frequency in days/week	5	5	5	5
Surface both hands	820	820	820	820
Transfer from hands (%) Dried fluid from cotton, knitwear to wet hands	30	30	30	30
Dermal absorption (%)	1,8	1,8	1,8	1,8
Body weight (kg)	60	60	60	60
Dermal exposure (mg/kg bw/day)	5,83E-04	1,41E-03	4,98E-04	7,05E-03

Calculation of ingestion rate for scenario 3:

It is assumed that 50% of the hand is contaminated at 100% surface concentration. The hands form about 20% of the total uncovered skin, this means that via, hand-to-mouth

contact 10% of the calculated external dermal exposure is ingested. (HEEG opinion no. n7)

Infant:

2.3 x 10^{-3} mg/cm^2 x 196.8 cm^2 x 50% = 2.26 x 10^{-1} mg

2.26 x 10^{-1} x 10% oral intake x 100% oral absorption / 8 kg bw infant= 2.83 x 10^{-3} mg/kg bw

toddler:

1.9 x 10^{-3} mg/cm^2 x 230.4 cm^2 x 50% = 2.19 x 10^{-1} mg

2.19 x 10^{-1} x 10% oral intake x 100% oral absorption / 10 kg bw toddler= 2.19 x 10^{-3} mg/kg bw

Infant:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Private House*

Results ? | Graphs ? | Sensitivity analysis ? | Exposure fractions ?

☐ Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

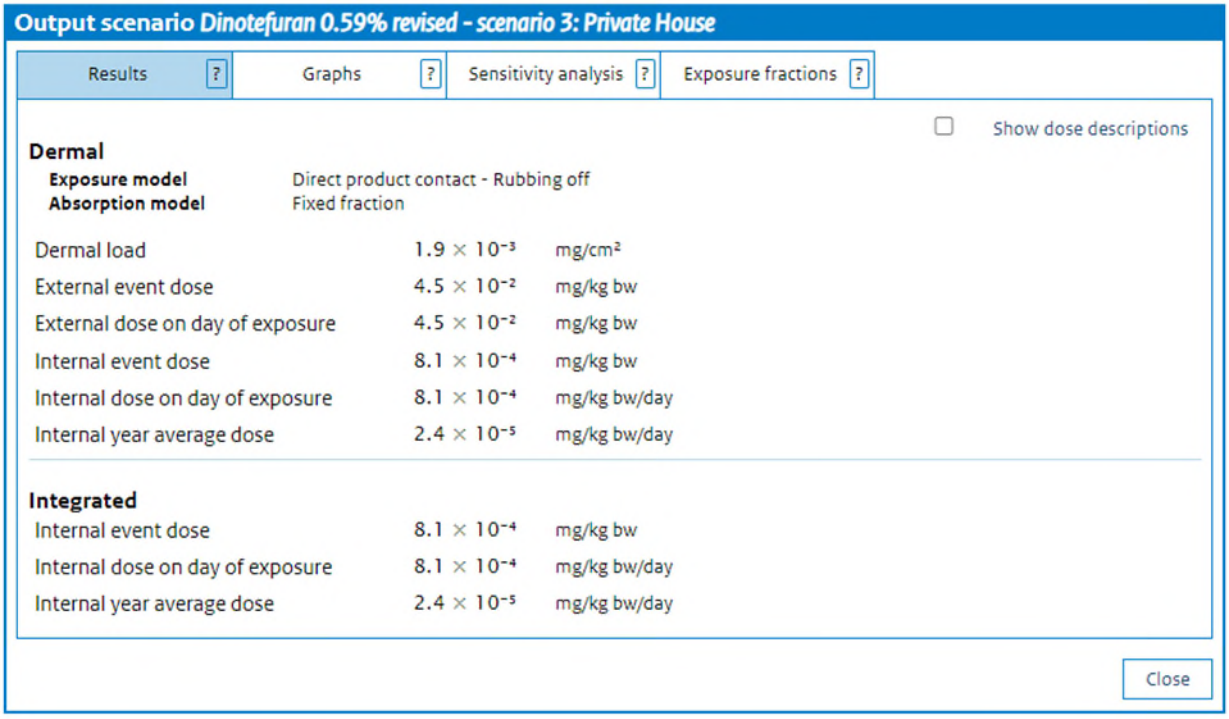
Dermal load	2.3×10^{-3}	mg/cm²
External event dose	5.6×10^{-2}	mg/kg bw
External dose on day of exposure	5.6×10^{-2}	mg/kg bw
Internal event dose	1.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.0×10^{-3}	mg/kg bw/day
Internal year average dose	3.0×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	1.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.0×10^{-3}	mg/kg bw/day
Internal year average dose	3.0×10^{-5}	mg/kg bw/day

Close

Toddler



Output scenario *Dinotefuran 0.59% revised - scenario 3: Private House*

Results | Graphs | Sensitivity analysis | Exposure fractions

Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

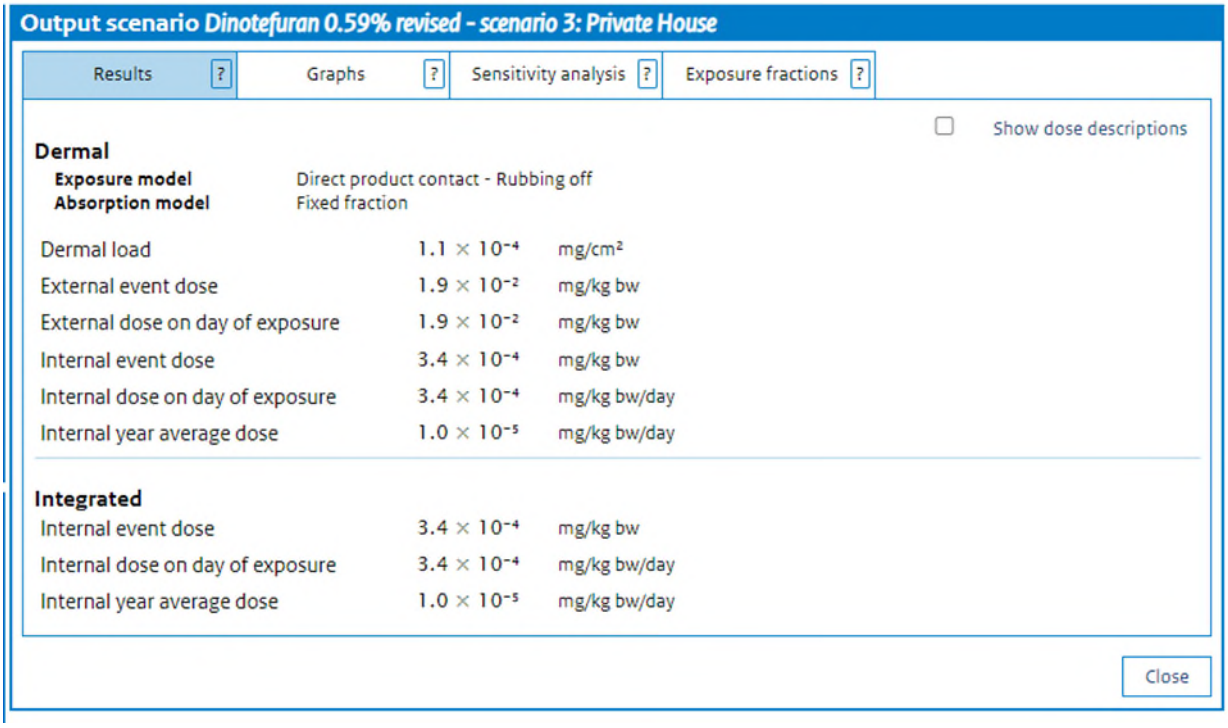
Dermal load	1.9×10^{-3}	mg/cm²
External event dose	4.5×10^{-2}	mg/kg bw
External dose on day of exposure	4.5×10^{-2}	mg/kg bw
Internal event dose	8.1×10^{-4}	mg/kg bw
Internal dose on day of exposure	8.1×10^{-4}	mg/kg bw/day
Internal year average dose	2.4×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	8.1×10^{-4}	mg/kg bw
Internal dose on day of exposure	8.1×10^{-4}	mg/kg bw/day
Internal year average dose	2.4×10^{-5}	mg/kg bw/day

Close

Child:



Output scenario *Dinotefuran 0.59% revised - scenario 3: Private House*

Results | Graphs | Sensitivity analysis | Exposure fractions

Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	1.1×10^{-4}	mg/cm²
External event dose	1.9×10^{-2}	mg/kg bw
External dose on day of exposure	1.9×10^{-2}	mg/kg bw
Internal event dose	3.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.4×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	3.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.4×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-5}	mg/kg bw/day

Close

Adult:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Private House*

Results | Graphs | Sensitivity analysis | Exposure fractions

☐ Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	4.3×10^{-3}	mg/cm²
External event dose	2.9×10^{-2}	mg/kg bw
External dose on day of exposure	2.9×10^{-2}	mg/kg bw
Internal event dose	5.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.2×10^{-4}	mg/kg bw/day
Internal year average dose	1.6×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	5.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.2×10^{-4}	mg/kg bw/day
Internal year average dose	1.6×10^{-5}	mg/kg bw/day

Close

Child:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Large Building*

Results | Graphs | Sensitivity analysis | Exposure fractions

☐ Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	3.0×10^{-5}	mg/cm²
External event dose	5.4×10^{-3}	mg/kg bw
External dose on day of exposure	5.4×10^{-3}	mg/kg bw
Internal event dose	9.8×10^{-5}	mg/kg bw
Internal dose on day of exposure	9.8×10^{-5}	mg/kg bw/day
Internal year average dose	2.9×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	9.8×10^{-5}	mg/kg bw
Internal dose on day of exposure	9.8×10^{-5}	mg/kg bw/day
Internal year average dose	2.9×10^{-6}	mg/kg bw/day

Close

Adult:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Large Building*

Results | Graphs | Sensitivity analysis | Exposure fractions

☐ Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	1.2×10^{-3}	mg/cm²
External event dose	8.4×10^{-3}	mg/kg bw
External dose on day of exposure	8.4×10^{-3}	mg/kg bw
Internal event dose	1.5×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.5×10^{-4}	mg/kg bw/day
Internal year average dose	4.6×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.5×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.5×10^{-4}	mg/kg bw/day
Internal year average dose	4.6×10^{-6}	mg/kg bw/day

Close

Child:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Small Stable*

Results | Graphs | Sensitivity analysis | Exposure fractions

☐ Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	4.1×10^{-5}	mg/cm²
External event dose	7.4×10^{-3}	mg/kg bw
External dose on day of exposure	7.4×10^{-3}	mg/kg bw
Internal event dose	1.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-4}	mg/kg bw/day
Internal year average dose	4.0×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-4}	mg/kg bw/day
Internal year average dose	4.0×10^{-6}	mg/kg bw/day

Close

Adult:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Small Stable*

Results | Graphs | Sensitivity analysis | Exposure fractions

Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	1.7×10^{-3}	mg/cm²
External event dose	1.2×10^{-2}	mg/kg bw
External dose on day of exposure	1.2×10^{-2}	mg/kg bw
Internal event dose	1.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.8×10^{-4}	mg/kg bw/day
Internal year average dose	5.5×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.8×10^{-4}	mg/kg bw/day
Internal year average dose	5.5×10^{-6}	mg/kg bw/day

Close

Child:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Large Stable*

Results | Graphs | Sensitivity analysis | Exposure fractions

Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	2.8×10^{-5}	mg/cm²
External event dose	4.9×10^{-3}	mg/kg bw
External dose on day of exposure	4.9×10^{-3}	mg/kg bw
Internal event dose	8.9×10^{-5}	mg/kg bw
Internal dose on day of exposure	8.9×10^{-5}	mg/kg bw/day
Internal year average dose	2.7×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	8.9×10^{-5}	mg/kg bw
Internal dose on day of exposure	8.9×10^{-5}	mg/kg bw/day
Internal year average dose	2.7×10^{-6}	mg/kg bw/day

Close

Adult:

Output scenario *Dinotefuran 0.59% revised - scenario 3: Large Stable*

Results | Graphs | Sensitivity analysis | Exposure fractions

Show dose descriptions

Dermal

Exposure model	Direct product contact - Rubbing off
Absorption model	Fixed fraction

Dermal load	1.1×10^{-3}	mg/cm²
External event dose	7.7×10^{-3}	mg/kg bw
External dose on day of exposure	7.7×10^{-3}	mg/kg bw
Internal event dose	1.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-4}	mg/kg bw/day
Internal year average dose	4.2×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-4}	mg/kg bw/day
Internal year average dose	4.2×10^{-6}	mg/kg bw/day

Close

Dietary risk assessment and animal risk assessment

Seclira fly bait - Dietary and animal e

3.2.2 Environmental exposure assessment

Scenario 1 and 2


pt18 scenarios echa including stp


pt18 scenarios echa Seclirincluding stp

MNG

Scenario 3


ECHA and NL PT18 Insecticides in anim


ECHA and NL PT18 Insecticides in anim

FOCUS PEARL input - Scenario 3- MNG: consideration of the maximum dose rate (beef cattle) as a risk envelope – application parent and subsequent formation of the metabolite

symbol	**value**	**unit**	**remarks**
molar mass	118.1	g/mol	Assessment Report 2014
DT_{50} soil	137	d at 12ºC	Assessment Report 2014
K_{OC}	2.70	L/kg	Assessment Report 2014
Kom	1.566		Kom=Koc/1.724
Freundlich	1	-	
vapour pressure	16.9	Pa at 25ºC	Assessment Report 2014
water solubility	1000	mg/L at 25ºC	Assessment Report 2014
formation fraction parent to MNG	0.2137	-	CAKE kinetic analysis of study Völkl (2003).

FOCUS PEARL output – Scenario 3-: consideration of the maximum dose rate (beef cattle) as a risk envelope

Concentration closest to the 80th percentile (ug/L)

RUN_ID	SUBSTANCE	DINO	MGNO	LOCATION	APPLICATION SCHEME	CROP CALENDAR	SOIL_TYPE	METEO STATION	IRRIGATIONSCHEME	DEPOSITION SCHEME	REPORT_TYPE
50	DINO	0.000000	0.045607	CHATEAUDUN	DINOgr	CHAT-GRASS	CHAT-S_Soil	CHAT-M	No	No	Leaching
51	DINO	0.000000	0.088547	HAMBURG	DINOgr	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	No	Leaching
52	DINO	0.000000	0.123224	JOKIOINEN	DINOgr	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	No	Leaching
53	DINO	0.000000	0.050733	KREMSMUENSTER	DINOgr	KREM-GRASS	KREM-S_Soil	KREM-M	No	No	Leaching
54	DINO	0.000000	0.042042	OKEHAMPTON	DINOgr	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	No	Leaching
55	DINO	0.000000	0.030139	PIACENZA	DINOgr	PIAC-GRASS	PIAC-S_Soil	PIAC-M	No	No	Leaching
56	DINO	0.000000	0.023942	PORTO	DINOgr	PORT-GRASS	PORT-S_Soil	PORT-M	No	No	Leaching
57	DINO	0.000000	0.000000	SEVILLA	DINOgr	SEVI-GRASS	SEVI-S_Soil	SEVI-M	No	No	Leaching
58	DINO	0.000000	0.007138	THIVA	DINOgr	THIV-GRASS	THIV-S_Soil	THIV-M	No	No	Leaching
59	DINO	0.000000	0.011853	CHATEAUDUN	DINOar	CHAT-WCEREALS	CHAT-S_Soil	CHAT-M	No	No	Leaching
60	DINO	0.000015	0.014707	HAMBURG	DINOar	HAMB-WCEREALS	HAMB-S_Soil	HAMB-M	No	No	Leaching
61	DINO	0.000004	0.023170	JOKIOINEN	DINOar	JOKI-WCEREALS	JOKI-S_Soil	JOKI-M	No	No	Leaching
62	DINO	0.000009	0.010624	KREMSMUENSTER	DINOar	KREM-WCEREALS	KREM-S_Soil	KREM-M	No	No	Leaching
63	DINO	0.000047	0.011030	OKEHAMPTON	DINOar	OKEH-WCEREALS	OKEH-S_Soil	OKEH-M	No	No	Leaching
64	DINO	0.000003	0.007684	PIACENZA	DINOar	PIAC-WCEREALS	PIAC-S_Soil	PIAC-M	No	No	Leaching
65	DINO	0.000001	0.006981	PORTO	DINOar	PORT-WCEREALS	PORT-S_Soil	PORT-M	No	No	Leaching
66	DINO	0.000000	0.000298	SEVILLA	DINOar	SEVI-WCEREALS	SEVI-S_Soil	SEVI-M	No	No	Leaching
67	DINO	0.000000	0.007222	THIVA	DINOar	THIV-WCEREALS	THIV-S_Soil	THIV-M	No	No	Leaching

FOCUS PEARL input - Scenario 3- MNG: consideration of the maximum dose rate (beef cattle) as a risk envelope – application parent and subsequent formation of the metabolite -

2nd Tier Evaluated MNG endpoints for Koc and vapour pressure were used

symbol	**value**	**unit**	**remarks**
molar mass	118.1	g/mol	Assessment Report 2014
DT_{50} soil	137	d at 12ºC	Assessment Report 2014
K_{OC}	15.01	L/kg	Derived from study [redacted] (2001), geometric mean value
Kom	8.71		Kom=Koc/1.724
Freundlich	0.91	-	Derived from study [redacted] (2001), arithmetic mean value
vapour pressure	3.39E-08	Pa at 20ºC	Derived from study [redacted] (2001), mean value
water solubility	1.15E+04	mg/L at 20ºC	Derived from study [redacted] (2001)
formation fraction parent to MNG	0.2137	-	CAKE kinetic analysis of study [redacted] (2003).

RUN_ID	SUBSTANCE	DINO	MGN	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DEPOSITION_SCHEME	REPORT_TYPE
50	DINO	0.000000	0.022402	CHATEAUDUN	DINOgr	CHAT-GRASS	CHAT-S_Soil	CHAT-M	No	No	Leaching
51	DINO	0.000000	0.049946	HAMBURG	DINOgr	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	No	Leaching
52	DINO	0.000000	0.056958	JOKIOINEN	DINOgr	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	No	Leaching
53	DINO	0.000000	0.027563	KREMSMUENSTER	DINOgr	KREM-GRASS	KREM-S_Soil	KREM-M	No	No	Leaching
54	DINO	0.000000	0.029150	OKEHAMPTON	DINOgr	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	No	Leaching
55	DINO	0.000000	0.024656	PIACENZA	DINOgr	PIAC-GRASS	PIAC-S_Soil	PIAC-M	No	No	Leaching
56	DINO	0.000000	0.023933	PORTO	DINOgr	PORT-GRASS	PORT-S_Soil	PORT-M	No	No	Leaching
57	DINO	0.000000	0.000000	SEVILLA	DINOgr	SEVI-GRASS	SEVI-S_Soil	SEVI-M	No	No	Leaching
58	DINO	0.000000	0.012843	THIVA	DINOgr	THIV-GRASS	THIV-S_Soil	THIV-M	No	No	Leaching
59	DINO	0.000000	0.004721	CHATEAUDUN	DINOar	CHAT-WCEREALS	CHAT-S_Soil	CHAT-M	No	No	Leaching
60	DINO	0.000015	0.007346	HAMBURG	DINOar	HAMB-WCEREALS	HAMB-S_Soil	HAMB-M	No	No	Leaching
61	DINO	0.000004	0.008131	JOKIOINEN	DINOar	JOKI-WCEREALS	JOKI-S_Soil	JOKI-M	No	No	Leaching
62	DINO	0.000009	0.005043	KREMSMUENSTER	DINOar	KREM-WCEREALS	KREM-S_Soil	KREM-M	No	No	Leaching
63	DINO	0.000047	0.006268	OKEHAMPTON	DINOar	OKEH-WCEREALS	OKEH-S_Soil	OKEH-M	No	No	Leaching
64	DINO	0.000003	0.003517	PIACENZA	DINOar	PIAC-WCEREALS	PIAC-S_Soil	PIAC-M	No	No	Leaching
65	DINO	0.000001	0.003530	PORTO	DINOar	PORT-WCEREALS	PORT-S_Soil	PORT-M	No	No	Leaching
66	DINO	0.000000	0.000388	SEVILLA	DINOar	SEVI-WCEREALS	SEVI-S_Soil	SEVI-M	No	No	Leaching
67	DINO	0.000000	0.003194	THIVA	DINOar	THIV-WCEREALS	THIV-S_Soil	THIV-M	No	No	Leaching

CAKE kinetic evaluation report, derivation of formation fraction from Dinotefuran to metabolite MNG

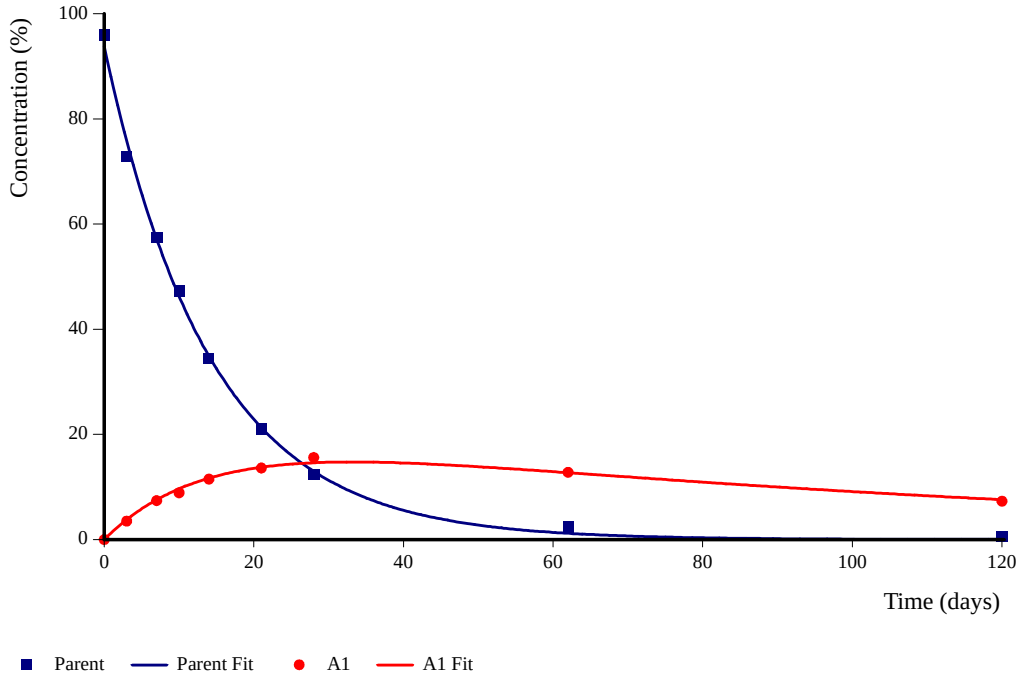
Study: New Study
Data set: Experiment 1 (SFO)
Study date: Donnerstag, 4. Februar 2021
Report generated: Freitag, 25. Juni 2021
Model Setup:
Topology: Parent, A1 with link Parent–A1
Optimiser: IRLS (IRLS Its. 10, IRLS Tol. 1E-05, Max. Its. 100, Tol. 1E-05)
Extra Solver Option: Use If Required
Initial Values of Sequence Parameters:

Parameter	Initial Value	Bounds	Fixed
Parent_0	100	0 to (unbounded)	No
k_Parent	0.1	0 to (unbounded)	No
f_Parent_to_A1	0.5	0 to 1	No
A1_0	0	0 to (unbounded)	Yes
k_A1	0.1	0 to (unbounded)	No

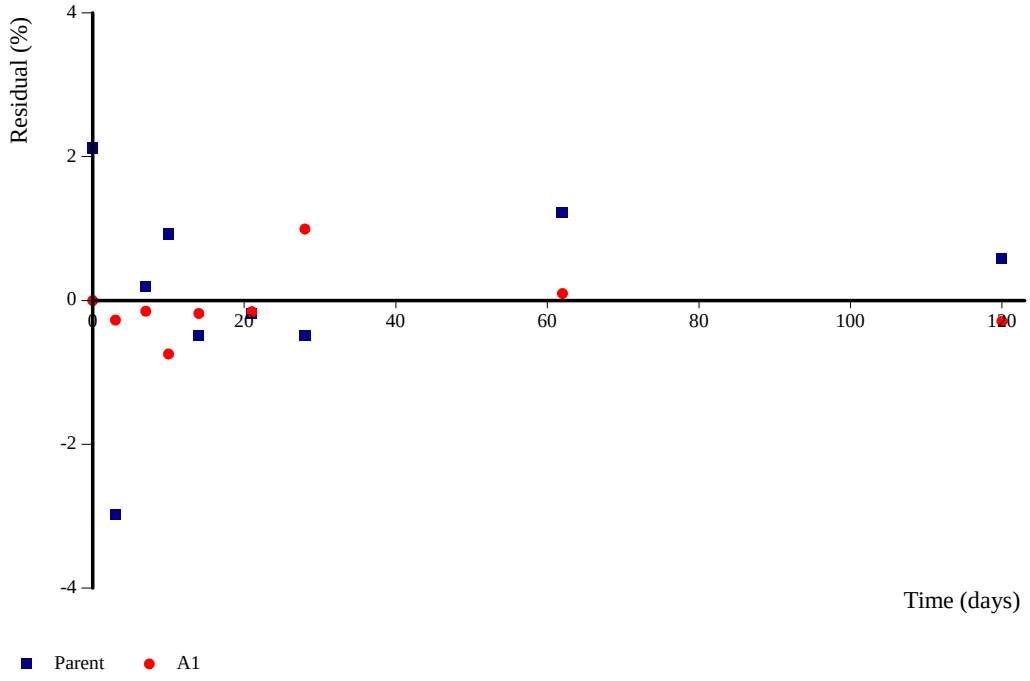
Fit step: Final
Used Extra Solver for SFO model fit: No
Reference Table:

Compartment	Name
Parent	Parent
A1	A1

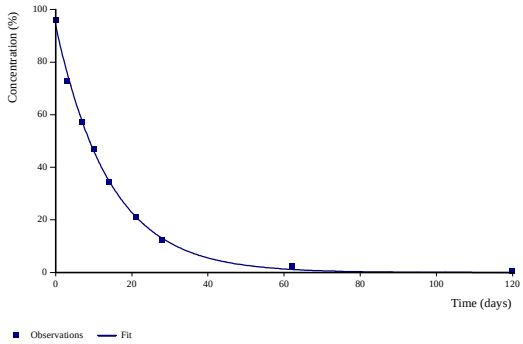
Graphical Summary:
Observations and Fitted Model:

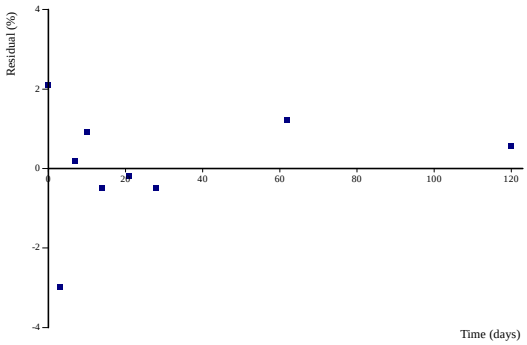

Concentration (%)
100
80
60
40
20
0
0
20
40
60
80
100
120
Time (days)
Parent
Parent Fit
A1
A1 Fit

Residuals:

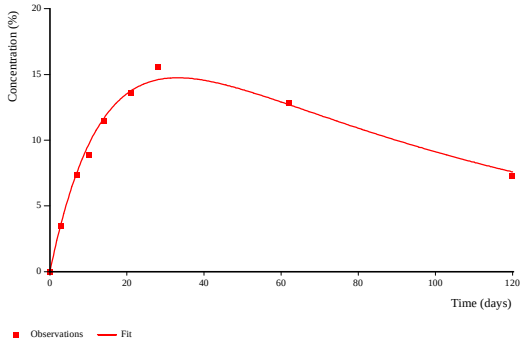

Residual (%)
4
2
0
-2
-4
0
20
40
60
80
100
120
Time (days)
Parent
A1

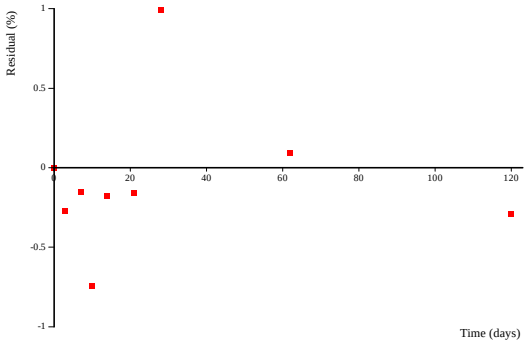
Compartment Parent:





Compartment A1:





Initial Values for this Step:

Parameter	Initial Value	Bounds	Fixed
Parent_0	94.18	0 to (unbounded)	No
k_Parent	0.0716	0 to (unbounded)	No
f_Parent_to_A1	0.2111	0 to 1	No
A1_0	0	0 to (unbounded)	Yes
k_A1	0.009128	0 to (unbounded)	No

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	93.79	1.288	N/A	91.5	96.07	91	96.57
k_Parent	0.07062	0.001989	1.24E-014	0.0671	0.07415	0.06633	0.075
f_Parent_to_A1	0.2137	0.007638	N/A	0.2002	0.2272	0.1972	0.23
k_A1	0.009258	7.38E-004	6.10E-009	0.007951	0.01056	0.007664	0.011

Re-Weighted Sum of Squared Residuals: 18

c^2

Parameter	Error %	Degrees of Freedom
All data	3.62	13
Parent	2.84	7

A1	3.74	6

Decay Times:

Compartment	DT50 (days)	DT90 (days)
Parent	9.82	32.6
A1	74.9	249

Additional Statistics:

Parameter	r² (Obs v Pred)	Efficiency
All data	0.9986	0.9986
Parent	0.9981	0.9981
A1	0.9925	0.9912

Parameter Correlation:

	Parent_0	k_Parent	f_Parent_to_A1	k_A1
Parent_0	1	0.6171	-0.6619	-0.2244
k_Parent	0.6171	1	-0.6869	-0.3636
f_Parent_to_A1	-0.6619	-0.6869	1	0.6698
k_A1	-0.2244	-0.3636	0.6698	1

Observed v. Predicted:

Compartment Parent

Time (days)	Value (%)	Predicted Value	Residual
0	95.9	93.79	2.114
3	72.9	75.88	-2.979
7	57.4	57.2	0.1951
10	47.2	46.28	0.9175
14	34.4	34.89	-0.4924
21	21.1	21.28	-0.1828
28	12.5	12.98	-0.4815
62	2.4	1.176	1.224
120	0.6	0.01957	0.5804

Compartment A1

Time (days)	Value (%)	Predicted Value	Residual
0	0	0	0
3	3.5	3.772	-0.2721
7	7.4	7.549	-0.1491
10	8.9	9.643	-0.7432
14	11.5	11.68	-0.18
21	13.6	13.76	-0.1557
28	15.6	14.61	0.9943
62	12.8	12.7	0.09731
120	7.3	7.589	-0.2893

Sequence Creation Information:

Fit generated by CAKE version 3.4 (Release)
running on R version 3.0.0 (2013-04-03)

Report Information:

Report generated by CAKE version 3.4 (Release)
CAKE developed by Tessella Ltd, Abingdon, Oxfordshire, UK, sponsored by Syngenta
Runtime: .NET Framework 4.8.4261.0

3.3 New information on the active substance

An IUCLID file containing summaries of the new active substance studies is available.

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
3.7.1	[redacted]	2001	MNG vapour pressure Huntingdon Life Sciences, Huntingdon Research Centre, Woolley Road, Alconbury, Huntingdon, Cambridgeshire, PE28 4HS, UK Report no. MTU 136/004549 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
3.9	[redacted]	2001	Physico-chemical testing with MNG: water solubility Inveresk Research, Tranent, EH33 2NE, United Kingdom Report no. 19349 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
5	[redacted]	2017	Method Development and Validation of an Analytical Method for the Determination of Dinotefuran in Two Soils, Surface Water and Groundwater SGS INSTITUT FRESENIUS GmbH, 65232 Taunusstein, Germany Report no. IF-16/03746964 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
6.1	[redacted]	2021	Literature review report: Review of publicly available peer-reviewed literature on the development of resistance against the active substance dinotefuran in insects LKC Switzerland Ltd, Hauptstrasse 10, Postfach 167, 4414 Füllinsdorf, Switzerland Report no. 21-LKC-02 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.1.2	[redacted]	2001	MTI-446 technical: A 96-hour flow-through acute toxicity test with the saltwater mysid (*Mysidopsis bahia*) Wildlife International, Ltd, 8598 Commerce Drive, Easton, Maryland 21601, USA Report no. 236A-104A Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.1.6.2	[redacted]	2011	Dinotefuran: A flow-through life-cycle toxicity test with the saltwater mysid (*Americamysis bahia*) Wildlife International Ltd, 8598 Commerce Drive, Easton, Maryland 61601, USA Report no. 236A-141B Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
9.2.1	[redacted]	2016	Dinotefuran: Effects on the Activity of Soil Microflora under Laboratory Conditions (Nitrogen and Carbon Transformation) Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, 75223 Niefern-Öschelbronn, Germany Report no. S16-00025 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.2.2	[redacted]	2016	Dinotefuran: Reproduction toxicity to the enchytraeid species *Enchytraeus crypticus* in artificial soil ECT Oekotoxikologie GmbH, Böttgerstrasse 2-14, D-65439 Flörsheim, Germany Report no. 15DG2EN Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.2.3	[redacted]	2016	Dinotefuran: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Ibacon GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report no. 107981084 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
9.5	[redacted]	2016	Effects of dinotefuran on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany Report no. 16 10 48 045 S Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.5	[redacted]	2016	Effects of dinotefuran on the reproduction of the collembolan *Folsomia candida* BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany Report no. 16 10 48 044 S Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
9.5	[redacted]	2000	Acute contact and oral toxicity of MTI-446, active to honey bees Landis International, Inc., 3185 Madison Highway, Valdosta, GA 31603-5126, USA Report no. 41421F001 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan

IUCLID section no.	Author	Year	Title Testing laboratory Report number DocID (Un)published	Vertebrate study?	Data protected?	Owner
10.1.2	[redacted]	2001	Adsorption/desorption of 14C-MNG on soils RCC Ltd, 4452 Itingen, Switzerland Report no. 729055 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan
10.1.3	[redacted]	2011	Dinotefuran: aerobic and anaerobic aquatic metabolism Huntingdon Life Sciences, Huntingdon Research Centre, Woolley Road, Alconbury, Huntingdon, Cambridgeshire, PE28 4HS, UK Report no. MCW0008 Unpublished	No	Yes	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chou-ku, Tokyo 103-0027, Japan

3.4 Residue behaviour

Not relevant

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

An IUCLID file containing summaries of the efficacy studies is available.

[4] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6for confidential annex see separate document