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

PUBLIC

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)

Ameisen Streu- und Gießmittel PROX

Product type 18, Insecticide

Etofenprox as included in the Union list of approved active substances of Regulation (EU) No 582/2012

Case Number in R4BP: BC-BJ074337-40

Competent Authority: Austria

01/12/2023 (Final)

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Changes history table

Austria was the reference member state for this authorisation, for which renewal is applied. Please find in the table below the overview of the changes made to the PAR since the initial authorisation in Austria dated 13 September 2018. The R4BP-asset number in the Ref MS is AT-0013227-0000. The first authorisation expiry date is 13th September 2024. The authorisation was mutually recognised in parallel in Norway, France, Germany and Finland (asset numbers NO-0019664-0000, FR-0012748-0000, DE-0019681-0000, FI-0019727-0000). In Poland and in Spain the biocidal product was authorised via mutual recognition in sequence (asset numbers PL-0027603-0000, ES-0028323-0000).

Application type	**refMS**	**Case number in the refMS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment / renewal)**	**Chapter/ page**
NA-APP	AT	BC-FE018096-56	13/09/2018	Initial assessment	PAR
NA-TRS	N/A	BC-NA045155-57	09/04/2019	Change of authorisation holder	SPC
NA-MIC	AT	BC-XU052485-99	24/08/2020	Addendum under point 4 of PAR: **-** Addition of a dosing aid to the shaker can. - Change in pack sizes (extension from a single sizes to a range of pack sizes from 100 g to 575 g). - Extension of shelf-life to 24 months. - Addition of another product production site. - Change of address of authorisation holder.	3.1 Packaging 3.2 Physical, chemical and technical properties 3.5.5 Conclusion on Efficacy SPC
NA-TRS	AT	BC-PP084017-20	23/03/2023	Change of name and address of authorisation holder and manufacturer of product	SPC

1 Conclusion

Ameisen Streu- und Gießmittel PROX is a WG (water dispersible granules) biocidal product containing etofenprox as active substance. The product is used as a product type 18 insecticide by non-professional users for the control of *Lasius sp.,* Black ants.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the Use # 1 Insecticide – adult ants – outdoor - non-professionals – pouring and Use # 2 Insecticide – adult ants – outdoor - non-professionals - scattering, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No. 1272/2008 are available in the SPC.

The biocidal product does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product contains the active substance etofenprox, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. Etofenprox is currently under the renewal review process (rMS Austria).

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains etofenprox which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: The active substance meets two of the three PBT criteria; it is bioaccumulative (B) and toxic (T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[2]. The assessment is presented under section 3.10 of the PAR. The competent authority concluded that in Austria the chemical diversity of active substances in authorised biocidal products in order to minimise the occurrence of resistance is not given yet. Thus the biocidal product "Ameisen Streu- und Gießmittel PROX" will be authorised for a period not exceeding **5 years** in accordance with Article 23(6) of Regulation (EU) No 528/2012.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[2] The document is available in CIRCABC at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex and the confidential annex restricted to MS only. The manufacturers of the biocidal product are listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substance are available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against ants (adults/forager) for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.
Since no substance of concern has been identified, the human health risk assessment is based on etofenprox.

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable acute or chronic risk to professional users, non-professional users and professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the use(s), food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance(s) is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the use(s), exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on etofenprox.

Based on the risk assessment, it is unlikely that the intended Uses 1 and 2 cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

Post-authorisation conditions

None.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	18
Type(s) of formulation	WG (water dispersible granules)

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the authorised uses, use instructions, and risk mitigation measure(s) refer to the respective sections of the SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (refMS)[8]	Comment (refMS)[9]
1	Insecticide – adult ants – outdoor - non-professionals – pouring	18	Scientific name: *Lasius* sp. Common name: Black ants Development stage: adults/ forager	Pouring of an aqueous solution of the granules on ant nest entrances on hard surfaces (e.g. sheltered terrace); If necessity arises application shall be repeated every 4 weeks during one ant season.	10 g/L/m²	General public (non-professional)	R	HH RMM N-221: Do not use near domestic animals or livestock. N-321, modified: Avoid contact to treated surfaces/areas, in particular by children/toddler. ENV RMM N-119, modified: Apply only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water. To reach nests located under

								terraces, pour the product carefully in crack and crevices or between tiles seals and avoid run off of product to surrounding soil.
2	Insecticide – adult ants – outdoor - non-professionals – scattering			Scattering of the ready to use granules into or directly around ant nest entrances on hard surfaces (e.g. sheltered terrace); If necessity arises application shall be repeated every 4 weeks during one ant season.	8 g/m²		R	HH RMM N-221: Do not use near domestic animals or livestock. N-321, modified: Avoid contact to treated surfaces/areas, in particular by children/toddler. ENV RMM N-119, modified: Apply only on hard surface under a roof, on areas that are not liable

								to submersion or becoming wet, i.e. protected from rain floods and cleaning water. To protect bees and other pollinators, cover granules for example with a flower pot or tile, ensuring that the ants still get access to the bait.

[8] refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☐
not identical ☒

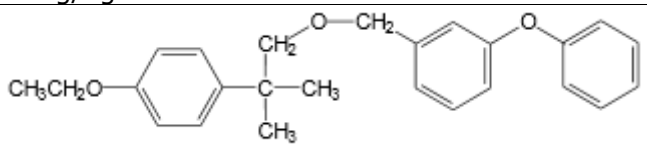
to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

Note: the former product code of Ameisen Streu- und Gießmittel PROX "SPU-00220-I" (the code is given in several studies) was changed together with the authorisation holder to CE 011 C0264. The current product code no longer reflects the abbreviation of the previous authorisation holder of the biocidal product but the current authorisation holder Certis Europe B.V. (renamed in June 2022 to Certis Belchim B.V.). The composition remained the same.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Etofenprox
Chemical name	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether
EC number	407-980-2
CAS number	80844-07-1
Index number in Annex VI of CLP	604-091-00-3
Minimum purity / content	970 g/kg
Structural formula	

2.5 Information on the source(s) of the active substance(s)

Is the source of etofenprox the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 of Regulation No. 528/2012?

☒ Yes
☐ No

2.6 Candidate(s) for substitution

The following candidate for substitution has been identified:

- Etofenprox

The following criteria for substitution are met:

- Bioaccumulative (B)
- Toxic (T)

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

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

Based on the available information, no significant indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More detailed information is available in the confidential annex of the PAR.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product Ameisen Streu- und Gießmittel PROX

	Classification	**Labelling**
Hazard Class and Category code	Aquatic Acute 1 Aquatic Chronic 1 Lactation	*No labelling element*
Hazard Pictograms	*No classification element*	 GHS09
Signal word(s)	Warning	Warning
Hazard statements	H362: May cause harm to breast-fed children. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.	H362: May cause harm to breast-fed children. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements*	*No classification element*	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P201: Obtain special instructions before use. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P263: Avoid contact during pregnancy and while nursing. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment P391: Collect spillage. P501: Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).
Supplemental hazard statements	None.	
Notes	P101, P103, P201 and P260 have been added compared to the previous PAR version. P308 + P313 (IF exposed or concerned: Get medical advice/attention) is already captured in section 5.3. of SPC.	

2.9 Letter of access

A comprehensive letter of access concerning etofenprox (approved by Commission Implementing Regulation (EU) No. 1036/2013 as an existing substance, PT 18) is submitted. The letter of access authorises the competent authorities to use, refer to and rely on the proprietary data to assess the applicant's application for the authorisation of Ameisen Streu- und Gießmittel PROX in accordance with Regulation (EU) No. 528/2012 in the product type 18. At the first product authorisation stage (NA-APP) the applicant (which is also the data owner) submitted new studies for the refinement of the $PNEC_{soil}$ to FR. Based on these studies the $PNEC_{soil}$ was refined and agreed by MS at ENV WGIV 2016.

2.10 Data submitted in relation to product authorisation

No new data on the active substance or substances of concern have been submitted.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle (for uses 1 and 2)	Nominal volume of bottle: Content of 100 g up to 575 g granules	HD-PE	Child resistant screw cap (PP) and dosing aid (PP)	Non-professional	Yes
Shaker can (for use 2 only)	Nominal volume of shaker can: Content of 100 g up to 575 g granules	Material in order from inside to outside: Brown kraft paper laminated with aluminium foil with PET (PVC-free) lacquer coating. Steelplate bottom	Turnable strewer (PE) and dosing aid (PP)	Non-professional	Yes

Description of the bottle:

HDPE bottles (rectangular, round or squarish)

Volume of bottles: content of 100 g up to 575 g granules (i.e. 100 g, 125 g, 250 g, 300 g, 375 g, 400 g, 500 g, 575 g)

Safety:

HDPE bottles with outer and inner cap, flow restrictor, child resistant screw cap, tamper evidence, clicked on dosing aid for accurate dosing of the granules.

The flow restrictor of the bottle describes the seal of the bottle. The seal is an extra HDPE disk heated-in after filling of the product in order to close the bottle. The seal has a 10 mm hole. This small opening of the bottle restricts the flow of the granules. Further, the bottle neck is narrow, restricting the flow of the product from the packaging.

The following pictures of the packaging are exemplary for the bottles:

Description of the shaker can:

Shaker can, material in order from inside to outside: Brown kraft paper laminated with aluminium foil with PET (PVC-free) lacquer coating.

Volume of shaker can: content of 100 g up to 575 g granules (i.e. 100 g, 125 g, 250 g, 300 g, 375 g, 400 g, 500 g, 575 g)

Safety:

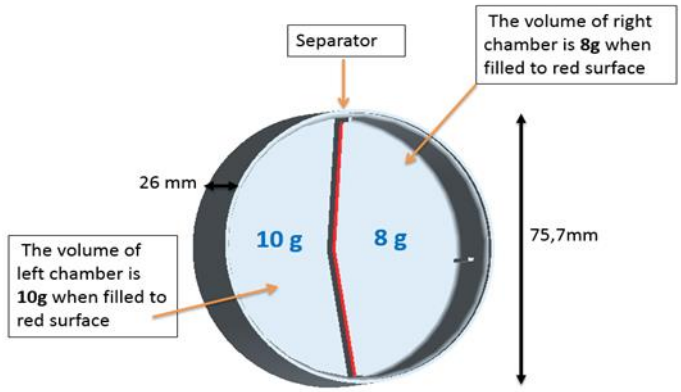
Outer and inner cap, steelplate bottom. The turnable strewer with holes serves as a flow restrictor. Clicked-on dosing aid (PP) for accurate dosing of the granules.

The following pictures of the packagings are exemplary for the shaker cans:

Explanation and examples of the clicked on dosing devices:

The dosing aid is clicked on the packaging. Depending on the size of the packaging, the respective lid and measuring cap is adopted in shape, diameter and size. I.e. lids with larger diameters might be equipped with a separator, while lids of smaller packaging are provided with a specific scale at the edge of the lids for the exact dosing.





Explanation for measurement of the required amount:

Measure the required amount of product by filling a layer of granules from the packaging up to the mark at the side of the lid or – in case of larger packaging - up to the edge of the septum, which is dividing the measuring cup in two partitions (highlighted red in the above schematic drawing). The partition enables the measurement of the required amount of granules also with larger diameters of packaging.
The lids are labelled 8 g for scattering application and 10 g for pouring application.

Measures to handle the risk of losses during the mixing/loading step

Since the edge of the dosing lid is higher than the marks, spilling or overdosing is prevented. If accidentally more granules than the indicated dose is released from the package this has to be collected. The "Instructions for safe disposal of the product and its packaging" have to be followed.

3.2 Physical, chemical, and technical properties

No new data were provided for re-assessment. The new guidance 'Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) version 2.0, May 2018' was taken into account and the new endpoints are addressed accordingly. Generation of new experimental data was not required.

Thus, the conclusions from the former assessment regarding physical, chemical and technical properties remain valid for Ameisen Streu- und Gießmittel PROX (former product code SPU-00220-I).

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20°C and 101.3 kPa	Visual inspection	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Solid granules	Anonymous 2007a
3.1.1.	Physical state at 20°C and 101.3 kPa	Visual inspection	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Free-flowing solid granules, like crystals of sugar	
3.1.2.	Colour at 20°C and 101.3 kPa	Visual inspection	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Yellowish	
3.1.3.	Odour at 20°C and 101.3 kPa	Olfactory inspection	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Characteristic	
3.2.	Acidity, alkalinity and pH value	GLP: Yes Guideline: CIPAC MT 75.3	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Result: pH = 5.84 (mean of 2 measurements)	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
			1 % in water, 20°C (±1°C)			
3.3.	Relative density / bulk density	GLP: Yes Guideline CIPAC 186	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Result: Pour density = 0.9 g/mL Tap density = 0.95 g/mL		Anonymous 2007b
3.4.1.1.	Storage stability test – **accelerated storage**	GLP: Yes Guideline CIPAC MT46 The parameters which were determined in this study are: appearance, colour, odour, weight change of the test item container, content of active ingredient (HPLC with UV detection), pH value (CIPAC MT 75.3), wettability (CIPAC MT 53.3), persistent foaming (CIPAC MT 47.2), dispersibility of water dispensible granules (CIPAC MT 174), suspensibility (CIPAC MT 184), wet sieving (CIPAC MT 185), dry sieve analysis of water	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Results before storage	Results after storage at 54°C for 2 weeks	Anonymous 2007a
				a.s. content: 0.90 % w/w	a.s. content: 0.90 % w/w	
				Appearance/odour: Yellowish granules which looked like crystals of sugar. The test item had a clearly noticeable, characteristic odour	Appearance/odour: Yellowish granules which looked like crystals of sugar. The test item had a clearly noticeable, characteristic odour	
				Container weight: 1804.3 g	Container weight: 1802.3 g	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
		dispersible granules (CIPAC MT 170), dustiness of granular products (CIPAC MT 171) and friability/attrition characteristics (CIPAC MT 178.2).		pH-value (1 % aqueous suspension): 5.84	pH-value (1 % aqueous suspension): 5.82	
				Dustiness: 2.1 mg (0.007 % w/w) of the weighted sample	Dustiness: 1.5 mg (0.005 % w/w) of the weighted sample	
				Dispersibility: 97.5 %	Dispersibility: 97.6 %	
				Suspensibility: 96.3 %, strong sedimentation was found after 30 minutes of standing	Suspensibility: 96.4 %, strong sedimentation was found after 30 minutes of standing	
				Mean wet sieving residue on a 75 µm sieve: 1.37 %	Mean wet sieving residue on a 75 µm sieve: 1.66 %	
				Conclusion: no significant alteration of phys-chem properties. No significant changes of weight of the test item container after storage (-0.1 %). The a.s. content was 0.90 % w/w before and after the storage.		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				The appearance, pH, wettability, persistent foaming form aqueous dilution, dispersibility, suspensibility, dustiness of granular formulations, as well as wet and dry sieving were measured before and after storage at 54°C for 14 days. Results for these tests were considered acceptable before and after storage.		
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	GLP: No Guideline: Technical – Monograph No. 17 – shelf life for 3 years	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Results before storage	Results after 37 month of storage at ambient temperature	Anonymous 2010a
				a.s. content: 0.99 % w/w	a.s. content: 1.03 % w/w	
				Appearance/odour: the test item is a yellowish, free-flowing solid formulation. The odour is hardly perceptible.	Appearance/odour: the test item is a yellowish, free-flowing solid formulation. The odour is hardly perceptible.	
				pH-value (1 % aqueous suspension): 5.8	pH-value (1 % aqueous suspension): 5.9	
				Dustiness: 4.2 mg (0.015 %) of the weighted sample	Dustiness: 1.4 mg (0.005 %) of the weighted sample	
				Persistent foaming, foam volume: 7 mL	Persistent foaming, foam volume: 9 mL	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Suspensibility: 97 %,	Suspensibility: 97 %,	
				Wet sieve residue on a 71 µm sieve: 0.33 %	Wet sieve residue on a 71 µm sieve: 1.01 %	
				Conclusion: No significant deviations of the physical properties of SPU-00220-I after the storage test over 12, 27 and 37 months at ambient temperature were observed. The a.s. content was 0.99 % w/w before and 1.03 % w/w after the storage for 37 months. The appearance, pH, particle size distribution, dust content, wettability, persistent foaming form aqueous dilution, suspensibility as well as wet sieving were measured before and after storage at ambient temperature for 12, 27 and 37 months. Results for these tests were considered acceptable before and after storage. Within the first product evaluation, the 37 month storage stability study was already submitted and assessed. However, because a supporting study on the efficacy/palatability of 2 y aged product was submitted (see below), the shelf life of Ameisen Streu- und Gießmittel was set to **2 years.**		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**			Test not required, since the biocidal product is a solid and no liquid formulation.	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**			The effect of light is not relevant for Ameisen Streu-und Gießmittel PROX. The biocidal product is not intended to be stored in the exposure of intense light.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	For the ambient storage studies, the biocidal product must be stored in the worst case commercial packaging and the stability of the packaging must be assessed. This should include observations on the appearance of the packaging and an assessment of the weight change on storage.	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 % w/w)	The product package is typically stored indoors in a shelf at room temperature and not exposed to intensive humidity. Submission of data on effects of humidity is not required as the packaging precludes moisture. The results of the storage test are considered conclusive. Effects on temperature: see below.	Anonymous 2010a
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	10 l bucket showed no evidence of peeling, cracking or discoloration (37 months) The HDPE plastic material is acceptable for extrapolation to the commercial packaging (HDPE bottles of smaller volume, 500 mL nominal). The container material is comparable to the commercial packages with respect to flexibility and is equivalent in all relevant characteristics. No adverse effects on the physical and chemical properties of the biocidal product are foreseeable with HDPE bottles or the shaker cans. The cardboard of the shaker can packaging is likewise considered not reactive with the originally packaged dry biocidal	Anonymous 2010a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				product, which is consisting mainly of sugar; and no further substances potentially corrosive or reactive towards the packaging materials are included.	
3.5.1.	Wettability	GLP: Yes Guideline: CIPAC MT 53.3 (100 mL Standard water D + 5 g test item)	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Result: <1 sec with/without swirling (thus acceptable, <1 min without swirling)	Anonymous 2007a, Anonymous 2010a
3.5.2.	Suspensibility, spontaneity, and dispersion stability	GLP: Yes Guideline: CIPAC MT 174 (900 mL Standard water D + 9 g test item)	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Guideline: CIPAC MT 174 Result: 97.5 % dispersibility (mean of 2) Guideline: CIPAC MT 184 Result: 96.3 % suspensibility (mean of 2)	Anonymous 2007a, Anonymous 2010a
3.5.3.	Wet sieve analysis and dry sieve test	GLP: Yes Guideline: CIPAC MT 185 (wet sieve) Guideline: CIPAC MT 170 (dry sieve) (100 mL tap water + 10 g test item) Justification for selection of CIPAC MT 170 instead of CIPAC MT 58: The test results according to CIPAC MT 170 (Walter, 2007) which we provided allow the determination of finer fractions than those of MT 58. The sieve sizes used in	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Guideline: CIPAC MT 185 (wet sieve) Result: Residue on 75 µm sieve ≤1.83 % (thus acceptable <2 %) Guideline: CIPAC MT 170 (dry sieve) Result: x1 =250 µm where Rx ≥90 % x2 =1000 µm where Rx ≤10 %	Anonymous 2007a, Anonymous 2010a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		this test separated ASG into more gradations (sieve sizes 40, 50, 75, 125, 250, 500, 1000, 2000 and 3350 µm). Therefore, the data are appropriate and sufficient for the assessments.			
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability			Not applicable (the biocidal product is a solid, no stable emulsion is to be maintained for optimal efficacy)	
3.5.5.	Disintegration time			Not applicable (the biocidal product is not a tablet and does not depend on disintegration of the tablet in a solvent for optimal efficacy.)	
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	GLP: Yes Guideline: CIPAC MT 171 (Dustiness) Guideline: CIPAC MT 178 (Friability and attrition characteristics)	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Guideline: CIPAC MT 171 (Dustiness) Result: nearly dust free (mean gravimetric collected dust on filter: 2.1 mg (0.007 % w/w) of sample) Guideline: CIPAC MT 178 (Friability and attrition characteristics) Result: attrition resistance =100 %	Anonymous 2007a, Anonymous 2010a
3.5.7.	Persistent foaming	GLP: Yes Guideline: CIPAC MT 47.2	An aqueous solution of the b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %) at 2 g/200 mL created no foam (according to	Guideline: CIPAC MT 47.2 Result: no foam (10 g/L)	Anonymous 2007a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			CIPAC MT 47.2)		
3.5.8.	Flowability/pourability/dustability	Applicability depends on the formulation type (nature) of the biocidal product. Guideline: CIPAC MT 170 (dry sieve)	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	From the information given above (dry sieve analysis, suspensibility, storage stability) it can be concluded that the granular product does not change appearance during storage and is nearly dust free. No further test considered mandatory for further description of product characteristics flowability/pourability/dustability. Analysis of particle size distribution within the 3-Years-storage stability test showed no evidence of clumping. Therefore it may be accepted that the flowability is not influenced by storage time. Pourability: Not applicable: The biocidal product is not a suspension concentrate, capsule suspension or suspoemulsion.	Anonymous 2007a, Anonymous 2010a
3.5.9.	Burning rate — smoke generators			Not applicable (no application as a smoke)	
3.5.10.	Burning completeness — smoke generators			Not applicable (no application as a smoke)	
3.5.11.	Composition of smoke — smoke generators			Not applicable (no application as a smoke)	
3.5.12.	Spraying pattern — aerosols / spray			Not applicable (no application as an aeorsol)	
3.6.1.	Physical compatibility			Since concomitant use with any other products is not intended, this type of data is not considered to be required. The physical compatibility does not need to be addressed. ASG is not intended to be used with	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				any other product.	
3.6.2.	Chemical compatibility			Not applicable (no chemical incompatibility known). Since concomitant use with any other products is not intended, this type of data is not considered to be required. The chemical compatibility does not need to be addressed. ASG is not intended to be used with any other product.	
3.7.	Degree of dissolution and dilution stability			Testing of dissolution is not applicable for Ameisen Streu- und Gießmittel PROX (required only for products used in a water soluble bag and for all tablets). The biocidal product is a water dispersible granule formulation (WG). Further, testing of dilution stability is only required for water-soluble preparations and therefore not applicable. Ameisen Streu- und Gießmittel PROX is a WG and has only suspensible quality. In case of pouring application the required amount of Ameisen Streu- und Gießmittel PROX is mixed, followed by direct and complete application. No keeping/storage, no standing time after the addition of water is foreseen but rather direct and complete application of the amount of prepared liquid. Therefore stability of the dilution, demonstrated by further testing is not required.	
3.8.	Surface tension	Even though the biocidal product is solid, the surface	b.p. as supplied (100 % w/w): freshly	Result: 1 g test item/L in water resulted in the mean surface tension of 68.0 mN/m at 20°C; thus, the product	Anonymous 2014a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		tension of an aqueous solution of the biocidal product was determined GLP: No Guideline OECD 115	prepared aqueous test solution of 1 g/L	is considered not to be surface active (>60 mN/m)	
3.9.	Viscosity			Viscosity is a property of fluids. Since the biocidal product is a solid, this type of data is not considered to be required.	

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Ameisen Streu- und Gießmittel PROX is a WG (water dispersible granules). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. No new data were provided for re-assessment. The new guidance 'Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) (2018)' was taken into account and the new endpoints are addressed accordingly. Generation of new experimental data was not required. However, the following minor changes were performed: The function of one co-formulant was changed from "attractant" to "bait base" in accordance with CG-45-2021-03 Definitions and functions of co-formulants. Moreover, the justifications for physical- and chemical compatibility and dilution stability were updated. Ameisen Streu- und Gießmittel is a ready-for-use insecticidal product supplied in form of solid dust-free granules *[WG water dispersible granules]*. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Implications for labelling: concerning physical, chemical or technical properties is not required for Ameisen Streu- und Gießmittel PROX. Within the first product evaluation, the 37 month storage stability study was already submitted and assessed. However, because a supporting study on the efficacy/palatability of 2 years aged product was submitted (see below), the shelf life of Ameisen Streu- und Gießmittel was set to 2 years.

3.3 Physical hazards and respective characteristics

No new experimental data was provided for re-assessment. The new guidance Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C, 2018) was taken into account, and the new endpoints are addressed accordingly.

The conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	The product SPU-00220-I is a sugar based granular formulation and consists of etofenprox as active ingredient and is formulated with emulsifiers, attractor, repellent, dye, anti-clumping agent and water. None of the ingredients contains any N-halogen compounds or other groups in relevant concentration which can readily distribute oxygen required for an explosive reaction. The classification procedures for self-reactive substances and mixtures and explosive properties can be waived as there are no chemical groups present in the biocidal product, associated with explosive or self-reactive properties (cf. CLP regulation, section 2.1.4.3. a) and 2.8.4.2. a)). A detailed discussion of this endpoint is included in the confidential annex of the PAR (cf. section 4).		Anonymous 2014b
4.2.	Flammable gases	Not applicable (the biocidal product is not a gas)		
4.3.	Flammable aerosols	Not applicable (the biocidal product is not an aerosol)		
4.4.	Oxidising gases	Not applicable (the biocidal product is not a gas)		
4.5.	Gases under pressure	Not applicable (the biocidal product is not a gas)		
4.6.	Flammable liquids	Not applicable (the biocidal product is not a liquid)		
4.7.	Flammable solids	GLP: Yes Guideline: A.10	b.p. as supplied (100 % w/w) batch number 0261127 (AS % 1 %)	Result: not highly flammable solid (method/study complies with requirements of guideline UN-test N.1)
4.8.	Self-reactive substances	No self-reactive substance (No strong exothermic decomposition of		P. Gregory,

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
	and mixtures	the substance can be initiated by temperatures well above the normal storage and transport temperatures (e.g. 75°C, CLP criterium) Criteria for self-reactive substances and mixtures are described in the section 2.8 of Annex I to the CLP Regulation. The biocidal product is a sugar based granular formulation and consists of etofenprox as active ingredient and is formulated with emulsifiers, attractor, deterrent, dye, anticlumping agent and water. Except Sudan orange, 1-phenylazo-2-naphthol, none of the ingredients contains reactive groups or combination of groups which are associated with explosive or self-reactive properties. The biocidal product contains very low concentrations of Sudan orange (0.001 % w/w). However, Sudan orange (CAS no. 842-07-9) contains an azo-group attached to aromatic groups (table A 6.1 of the UN MTC Appendix 6 indicates only aliphatic azo groups as alerting functional groups). In general, aromatic azo compounds are less reactive than aliphatic azo compounds. Moreover, Sudan Orange (CAS no. 842-07-9) predominantly, if not exclusively exists in the hydrazine tautomeric form (P. Gregory, 2003). A detailed discussion of this endpoint is included in the confidential annex of the PAR (cf. section 4). Since it is considered that the biocidal product does not present any risk for self-reactiveness and tests do not need to be performed. Concluding, for Ameisen Streu- und Gießmittel PROX no classification procedures for self-reactive substances and mixtures need to be applied (compliant with 2.8.4.2 of Annex I to the CLP-Regulation). No classification as self-reactive mixture is required, a justification of the given reasons is considered sufficient to waive a further experimental study.		comprehensive coordination chemistry II, 2003, vol 9, pp. 549-579
4.9.	Pyrophoric liquids	Not applicable (the biocidal product is not a liquid)		
4.10.	Pyrophoric solids	The classification procedure for pyrophoric solids needs not to be applied since experience in manufacture and handling shows that the product Ameisen Streu- und Gießmittel PROX does not ignite spontaneously on coming into contact with air at normal temperatures. The product is known to be stable at room temperature for prolonged periods of time (please refer to the storage stability tests submitted). Ameisen Streu- und Gießmittel PROX is not pyrophoric, which can safely be concluded further from the composition of the biocidal product. The granular biocidal product itself and none of the ingredients is liable to ignite in contact with air, even in small quantities. The conduction of a test according to UN Test N.3 as given in Section		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		33.3.1.5 of the UN-MTC is not required for Ameisen Streu- und Gießmittel PROX, as there are no indications based on experience in handling and use, pyrophoric properties of Ameisen Streu- und Gießmittel PROX can safely be excluded. No classification as pyrophoric substance or mixture according to the CLP criteria as described in the criteria given in section 2.9 of Annex I to the CLP Regulation is required, a justification of the given reasons is considered sufficient to waive a further experimental study.		
4.11.	Self-heating substances and mixtures	The relative self-ignition temperature is 390°C, according to the testing guideline for auto-flammability (solids - determination of relative self-ignition temperature). In Method A.16., however no sharp temperature increase was observed. The biocidal product does not contain any organometallic compounds or substances/mixtures containing transition metals (cf. section 2.77.7 of the ECHA guiudance on the Application of CLP criteria, July 2017). None of the ingredients of the biocidal product, which is based mainly on sugar, is known to exhibit self-heating properties. Moreover, the biocidal product is placed on the market in rather small package sizes (up to 575g granules per package). Even in large amounts and after long periods of time it will not develop self-heat, which would require classification according to the CLP criteria (Section 2.8 and 2.10). Also refer to storage stability confirmation, see IUCLID Section 3.4). No further testing is justified.		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Not applicable: None of the ingredients of the biocidal product, which is based mainly on sugar, is known to emit any gases when in contact with water. Thus classification according to the CLP criteria is not required. No further testing is justified.		
4.13.	Oxidising liquids	Not applicable (the biocidal product is not a liquid)		
4.14.	Oxidising solids	Justification of non-submission: Based on the formulation and the physical chemical properties it is evident that Ameisen Streu- und Gießmittel PROX does not possess any oxidising properties The product Ameisen Streu- und Gießmittel PROX is a sugar based granular formulation and consists of etofenprox as active ingredient and is formulated with emulsifiers, attractor, repellent, dye, anticlumping agent and water. None of the ingredients contains any chlorate, perchlorate, peroxide or hypochlorite groups or other groups in relevant concentration in the formulation Ameisen Streu- und Gießmittel PROX which can readily distribute oxygen required for an oxidising reaction. Moreover, with exception to the anti-clumping agent, ingredients of the biocidal product contain oxygen, however only chemically bonded only to carbon or hydrogen atoms. The anti-clumping agent is considered to be not oxidising according to the Ellingham diagram. According to the material safety data sheets (MSDS) of the active ingredient		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		etofenprox and all co-formulats none of them are classified to be oxidisable. No R-phrases directed to an oxidising property. Ameisen Streu- und Gießmittel PROX is not highly flammable solid in the sense of the consolidated version of Council Directive 67/548/EEC Annex V (Council Directive 92/69/EEC), Method A.10 (results in full compliance with UN-test N.1) The relative self-ignition temperature is 390°C, according to the testing guideline for auto-flammability (solids - determination of relative self-ignition temperature) in the sense of the consolidated version of Council Directive 67/548/EEC Annex V (Council Directive 92/69/EEC), Method A.16. But no sharp temperature increase was observed (Reference: please refer to: cross reference to other study (IUCLID Section 4.2 Flammability.001, which is Anonymous (2007d) see above). Overall, the components of Ameisen Streu- und Gießmittel PROX do not provide the structural prerequisites for a highly exothermic reaction. Accordingly, it can be demonstrated conclusively from the structure data on the ingredients, from the material safety data sheets, from information of auto-ignition temperature and flammability that the formulation Ameisen Streu- und Gießmittel PROX does not possess any oxidising properties. Classification of Ameisen Streu- und Gießmittel PROX is not required for oxidising properties.		
4.15.	Organic peroxides	Not applicable (none of the ingredients contain a bivalent –O-O-structure)		
4.16.	Corrosive to metals	None of the ingredients has the intrinsic property to materially damage metals. Based on the composition, the biocidal product (main component sugar) is considered not to damage/destroy metals by chemical action. In Chapter 1.7.16 Point 4.16 of the Guidance on biocides legislation Volume I the Criteria for corrosive to metals are described. According to the classification criteria the test C.1 (as described in part III, Section 37.4.1.1 of the UN-MTC) is relevant for the determination of corrosive properties of liquids and solids that may become liquid during transport (as a substance corrosive to metal, packing group III/category 1 during transport). The biocidal product is a solid granular product based on crystalline sugar, which may not become liquid during transport, therefore this test does not apply to the product as only liquid or fluid media may induce a corrosion process. An experimental study according to UN Test C.1 (designed for liquids only) does not provide relevant information on the solid product and on the conclusion about classification of corrosive properties of the biocidal product towards metals. It is packed and transported without contact to metals in closed bottles/cans, without contact to humidity and the conditions for storage and shelf life of the product specify that the container should be kept tightly closed and dry in a cool, well-ventilated place (avoidance of moisture). It is explicitly given in the Guidance on the Application of the		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		CLP Criteria Version 5.0 – July 2017, chapter 2.16.4.1.: Application of the classification criteria in the UN-MTC, Section 37.4 excludes solids, while 'liquids and solids that may become liquids (during transport)', have to be considered for such a classification.		
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Not applicable (the biocidal product is not liquid or gas)		
4.17.2.	Relative self-ignition temperature for solids	GLP: Yes Guideline A.16 (The test principle fully complies with the data requirements according to Reg. (EU) 528/2012 (test according to UN-test N.4)	b.p. as supplied (100 % w/w) batch number 0261127 (AS 1 %)	Result: self-ignition temperature =390°C without sharp temperature increase. An endothermic effect in the temperature range of 160-220°C was observed. After this effect a small exothermic reaction occurred at approx. 220°C. From this temperature on the test item temperature remained permanently slightly (temperature difference: 10 K) above the oven temperature and led to a maximum temperature of 411°C.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.17.3.	Dust explosion hazard	Dust explosive hazard is relevant for products which present or produce a relevant dust content, leading to the possibility of dust explosions or which are indicated to be incompatible with other substances. The biocidal product is a granular formulation with a dust content of 0.007 % (CIPAC 171, Anonymous (2007a) and a high attrition resistance of 100 %; Anonymous (2010a), PAR 2.2.2). The results of the dry sieve analysis (CIPAC 170, Anonymous 2007b, Anonymous 2010a) show that the particle size of the biocidal product ranges between 250 µm (sum of residues on all sieves was ≥90 %) and 1000 µm (sum of residues on all sieves was ≤10 %.). The residues on all sieves on 500 µm were ≤50.2 %. It contains etofenprox as the active substance, emulsifiers, attractor, repellent, dye, anticlumping agent and water, all not prone to enhance the chance of explosion (Anonymous (2014b)). It consists mainly of sugar, which is not predestined to ignite or propagate flame in the amount at application. Especially, in view of an insignificant dispersion in air at application in its use, no mechanical stressing, and no foreseeable ignition source near application areas, the risk of the formation of a hazardous explosive atmosphere during application of Ameisen Streu- und Gießmittel PROX is negligible. Therefore, Ameisen Streu- und Gießmittel PROX does not need to be examined further concerning a hazard of dust explosivity in use.		

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
No new data was provided for re-assessment. The new guidance 'Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) (2018)' was taken into account and the new endpoints are addressed accordingly. Justification for waiving data have been updated in accordance with CLP Regulation. The ready to use product is not explosive, not oxidising, is not highly flammable and does not self-ignite. Based on the data provided, no classification or labelling is required based on physical and chemical properties of the product.

3.4 Methods for detection and identification

The conclusion from the former assessment regarding analytical detection and identification remains valid.
A method of analysis for the determination of the active substance etofenprox in the product and/or product preparations of Ameisen Streu- und Gießmittel PROX (former product code SPU-0022-I) was developed and validated. The method validated is the same as used in the storage stability studies and consists of a HPLC-method with a reversed phase column (RP select B) and UV detection. The method has been sufficiently validated addressing specificity, linearity and accuracy. System precision has also been addressed. In the study Anonymous (2007c) five samples were prepared from product Batch No. 0261127 resulting in an RSD of ±0.19 %. The maximum value according to modified Horwitz equation amounts to 2.68 % for an active substance concentration of 1 %. This means that the RSD is acceptable. In the further study submitted with this application (Anonymous 2020), an additional method was developed for the determination of the suspensibility of the formulation. Etofenprox was determined with a HPLC/UV method and a detection wavelength of 210 nm based on the guideline SANCO/3029/99 rev. 4.. The analyte was identified by the retention time and the UV-spectra. The method has been successfully validated addressing specificity, linearity and accuracy.
Analytical methods for the determination of etofenprox residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. A respective letter of access (LOA) is submitted and can be found Section 13 of the IUCLID dossier.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues										
Principle of the method Reversed phase HPLC*: Preparation of standard and sample solutions with a mixture of methanol and water (external standard calibration with etofenprox). Analysis is done by HPLC-UV at 210 nm with a reversed phase column (RP select B) and mobile phase using gradient with a flow rate of 0.9 mL/min."]*										
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level and Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Etofenprox in Ameisen Streu- und Gießmittel PROX (SPU-00220-I)	Range: 29.89 µg/mL to 298.92 µg/mL, y=26,228 x-1.8505, r^2 >0.999 (1.000)	No interferences have been observed (<3 % of total peak area for target analyte)	Fortification at nominal concentration of the product, which amounts to 1 % w/w 5 replicates	100.2 – 102.4	101.1	± 0.83 (variation coeff: ± 0.82)	Reference substance etofenprox 104.18 µg/mL	5 Result: (precision confirmed according to the Horwith equation)	Not applicable	Anonymous 2007c
Etofenprox in aqueous dilutions of Ameisen Streu- und Gießmittel PROX (SPU-00220-I)	Low recovery samples: 9.97-199 mg/L. y=0.4597 x+0.2874, r^2 >0.999 (1.0000) High recovery samples:	No interferences have been observed (<3 % of total peak area for target analyte)	Fortification at nominal concentration of the product, which amounts to 1 % w/w 5 replicates 4 replicates	88.05 - 98.44 106.9 – 110.0	92.3 108	4.8 1.2	38.2 mg/L (Low) 135.2 mg/L (High)	5	34 mg/L	Anonymous 2020

	10.5 - 210 mg/L, y=0.5209 x+0.1945 , r^2 >0.999 (1.0000)									

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method (Anonymous 2007c) for the determination of etofenprox in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. A further analytical method (Anonymous 2020) was recently reported for the determination of etofenprox in aqueous dilutions of the biocidal product (SANCO/3029/99 rev.4.). Methods for the detection of etofenprox in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required.

3.5 Assessment of efficacy against target organisms

For this renewal of the product, no new data were provided since the requirements didn't change for re-assessment, although there is a newer version of the Guidance in force (Guidance on the BPR, Vol. II Efficacy, Parts B+C, ECHA 2018). Accordingly, the conclusion from the former assessment regarding efficacy remains valid. The requirements for PT 18 products do also not change in recent Guidance versions.

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Main Group 03: Pest Control
Product Type 18 (Insecticides, acaricides and products to control other arthropods)
The target organisms are adult worker ants (forager) of black Garden ants (*Lasius niger*).

The intended effect of Ameisen Streu- und Gießmittel PROX is the reduction of forager ants around buildings in private areas on sheltered surfaces (e.g. sheltered terraces).
The label claim for Ameisen Streu- und Gießmittel PROX is the reduction of the number of forager ants outside the nest, which weakens the colony and could lead to migration from the area.
Ants are the reason for inconvenience of humans, as increased incidences of ant populations around buildings may cause constructional damage e.g. formation of hollow spaces under terrace tiles leading to risk of accidents. Further, with ants around buildings the likelihood of ants coming indoors, leading to a reduction of hygienic standard, is increased.

The product is intended for non-professional use.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

The target insects are knocked down and killed upon ingestion or contact with the active substance etofenprox. The toxic properties of etofenprox are based on its effect on sodium channels of the insect's nervous system. Etofenprox promotes continuous influx of sodium ions leads to hyper stimuli of motor neurons, tremor of the muscles and finally to paralysis and death.
Etofenprox is acting as an insecticide by direct contact or ingestion. It acts on the insect nervous system by disturbing the normal neuro-transmittance. No relevant time delay until first symptoms occur is to be expected. However, despite the insecticide`s immediate effect a certain residence time needs to be allowed for, in order to ensure sufficient reduction of target insects. A reduction of ant activity was reported 24h after treatment in the efficacy studies.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT18 *Use 1 and 2:* scattering of dry granules, pouring of solution	Ameisen Streu- und Gießmittel PROX (SPU-00220-I); 1 % etofenprox	Black ants (*Lasius niger*)	Simulated use test; rates of 2, 4 and 8 g/m² (scattering), and diluted in water at rates of 2.5, 5, and 10 g/L/m² (pouring) 6.72 m² test chambers; min. 100 worker ants and brood/colony Temperature: 18.0-27.3°C Relative humidity: 20–65 % Mortality was assessed by counting the dead ants in the test arena. Up to 5 d post-treatment observation (evaluation 2, 4, 6, 24 h, daily up to 5 days) 4 replicates were performed.	Mortality (whole colony) of 38.6 % with 8 g/m², 43.3 % with 10 g/L/m² at the end of the test period (120 h) Reliability 3 The Test was not considered for evaluation but supporting information.	Anonymous (2008).	*Efficacy data to support these claims.001/* Simulated use test to determine the efficacy of ant granules (SPU-00220-I) against black ants, *Lasius niger*
PT18 *Use 1 and 2:* scattering of dry granules, pouring of solution	Ameisen Streu- und Gießmittel PROX (SPU-00220-I); 1 % etofenprox	Black ants (*Lasius niger*)	Simulated use test; rates of 2, 4 and 8 g/m², and diluted in water at rates of 2.5, 5, and 10 g/L/m² Product was applied within the test chamber (roughly 50 % of area and nest of ants (colonies incl. queen ,brood of all stages and about 1000-2000 workers)). Temperature: 24-25°C. Relative humidity: 54–69 % Mortality was derived from the number of dead ants under treated conditions compared to the untreated conditions. The reduction of forager ants is derived from the correlation of the number of forager ants under treated conditions with the number of forager ants in the control.	100 % Mortality within 24 h at 8 g/m² and 10 g/L/m², resp. was achieved for both application types. Scattering lead to reduction of forager ants above 90 % after 3 and 4 weeks. Pouring lead to 100 % after 2 weeks, 86.8 % after 3 weeks and 81.3 after 4 weeks. Reliability 2	Anonymous (2009a)	*Efficacy data to support these claims.002/* Efficacy of SPU-00220-I against black ants.

			Observation after 1, 3, 7 and 10 days, 2, 3, 4, 5, 6, 7 and 8 weeks, as well as 3, 4, 5 and 6 month after treatment. 3 replicates were performed.			
PT18 *Use 2:* scattering of dry granules,	Ameisen Streu- und Gießmittel PROX (SPU-00220-I); 1 % etofenprox	Black ants (*Lasius niger*)	Simulated use test; 8 g/m² fresh and 2 years aged product. The treatment was done by scattering 50 % of the product on the nest (located in the test arena) and about 50 % of the product on the half of the arena in which the nest was located. 1, 3, 7 and 10 days, 2, 3, 4, 5, 6 and 7 weeks after treatment evaluations were done. The number of dead and living ants found in the test arena (outside the nest) was determined. After 7 weeks evaluation was done for living queens and workers as well as for brood.	Colonies treated with aged product: No living queen in 2 of 3 replicates and no brood in 1 of 3 replicates. Colonies treated with fresh product: No living queen and no brood in 1 of 3 replicates. During evaluation almost no activity (on average 0-1 ants) visible outside the nest. 220 dead and 646 living workers (fresh product) and 167 dead and 733 living workers (aged product) were found after 7 weeks. 3 untreated controls: A living queen and a lot brood each. During evaluation a lot of activity (on average 18-108 ants) visible outside the nest. On average 140 dead and 1467 living workers were found in the controls after 7 weeks. Reliability 2	Anonymous (2018)	*Efficacy data to support these claims.005/* Efficacy of SPU 00220-I with 1.0 % etofenprox tested fresh (<1 year old) and aged (2 years old) against Black ants, *Lasius niger*.
PT18 *Use 1:* pouring of solution	Ameisen Streu- und Gießmittel PROX (SPU-	Black ants (*Lasius niger*), Yellow meadow ant (*Lasius flavus*)	Field test nests of *Lasius niger* of *Lasius flavus,* the exact number of ants in the nests is not reported but with medium to high levels of activity after agitation. Product applied diluted in water at rates of	10 g/L: all treated nests showed zero ant activity at least up to 14 days after treatment. Reliability 3	Anonymous (2009b)	*Efficacy data to support these claims.003/* Field efficacy of drench

	00220-I); 1 % etofenprox		2.5, 5, and 10 g/L/m². For optimal concentration. T =17–25°C; dry weather conditions; 2 weeks post-treatment observation; Effect investigated: activity of ants	<u>The Test was not considered for evaluation but supporting information.</u>		applications of etofenprox GR 1 against Lasius spp.
PT18 *Use 1 and 2:* scattering of dry granules, pouring of solution	Ameisen Streu- und Gießmittel PROX (SPU-00220-I); 1 % etofenprox	Black ants (*Lasius niger*)	Field test, nests of *Lasius niger*, scattering (8 g/m²) or pouring (10 g/L/m²) directly onto the nest and around entrance. Rainfall: June: 167.8 mm (82h41); July: 31.4 mm (28h16); August: no data Temperature: June: min: 14.4°C, max: 20.9°C; July: min: 17.5°C, max: 24.3°C; August: min: 16.1°C, max: 24.8°C Until 3 weeks post-treatment observation; Effect investigated: Reduction of forager ants on ant trails. Reduction of forager ants was calculated by comparing the number of ants passing the measure point in the treated condition to the pre-treatment condition. The product was poured/scattered onto the nest and around the entrance. Nest was examined at end of test period. The final count of alive ants after 3 weeks was zero for the pouring or scattering application compared to 1500 ants in the control. 4 replicates were performed.	Reduction of forager ants of *Lasius niger* by scattering application (8 g/m²) increased to 100 % within the test duration (3 weeks). Whereas, the reduction of forager ants by pouring (10 g/L/m²) was 96 % after two days and increased to 100 % within one week and remained 100 % until the end of the trial (week 3).The untreated control proved an increasing outside activity of the ants during the test. Reliability 1	Anonymous (2010b)	*Efficacy data to support these claims.004/*Field test of the efficacy of an insecticide product against garden ants

3.5.4 Efficacy assessment

Ameisen Streu- und Gießmittel PROX is an insecticidal product used by non-professional users for the control of black ants (*Lasius* spp., black garden ants) in areas around buildings where they interfere with the interests of homeowners. The claimed effect of Ameisen Streu- und Gießmittel PROX is the reduction of forager (worker) ants outside the nest.

The efficacy displayed as the reduction of forager ants, which is the claim of Ameisen Streu- und Gießmittel PROX, was demonstrated in two simulated use and in a field test (Anonymous 2009a; Anonymous 2018; Anonymous 2010b). The requirement of a laboratory test has been waived due to the submission of a reliable field test (Anonymous 2010b). Two more studies have been submitted (Anonymous 2009b; Anonymous 2008) which have not been taken into consideration.

The biocidal product is supplied as granules, and is intended to be either applied dispersed at a rate of 10 g/L/m² (pouring), or as a ready to use product by scattering directly from the package at a rate of 8 g/m².

The product is to be applied in a single application per infestation on hard surfaces only (e.g. terrace, sidewalk, application to soil is not advised) or on nest entrances around buildings to ensure contact to the target ants. If necessity arises application shall be repeated every 4 weeks during one ant season.

Supplement to Simulated use test Anonymous 2009a (considered for evaluation of the efficacy and claim):
In pursuance of the guidance in force (Guidance on the BPR, Vol. II Efficacy, Parts B+C, ECHA 2018) sufficient efficacy (Mortality) for a product intended for use by non-professional users as general surface treatment application has to be proven. The guidance sets the requirements at showing mortality (in percentage) of the target organism after 24 h.

Effect on whole colony:
During product development besides the claimed effect on forager ants outside the nest (forager) the effect of the product on whole colonies was evaluated. In this perspective the exact number of different individual ants per nest was not counted but rather a rough estimation on the total number of individuals (1000-2000) per nest was given. The product showed reduction of ant population but no nest kill.

Effect on the forager ants:
The product is claimed to reduce the number of forager outside the nest.
Percentage of reduction of forager ants (efficacy) of the product has been calculated based on the number of living ants found outside the nest and in the arena after 24h under treated and control conditions. 24h after treatment the reduction of forager ants for pouring at 10 g/L/m² and scattering 8 g/m² applications was 100 %.

Reduction over the test period is shown in the following table:

Duration in days	Number of living ants in test arena			Reduction of forager ants [%]	
	Untreated control	Scattering 8 g/L/m²	Pouring 10 g/m²	Scattering 8 g/m²	Pouring 10 g/m²
1 (24 h)	2	0	0	100	100
3	14	0	0	100	100
7	20	4	0	80	100
10	93	0	1	100	98.9
14	53	1	0	98.1	100
21	53	0	7	100	86.8
28	80	0	15	100	81.3
35	150	1	27	99.3	82
42	30	1	5	96.7	83,3
49	67	7	11	89.6	83.6
60	50	5	4	90	92
90	83	3	7	96.4	91.6
120	27	8	0	70.4	100
150	11	3	0	72.7	100
180	13	1	0	92.3	100

Starting at day 7 and again at day 28 post application, an interim increase of the number of forager ants outside the nest is observed which leads to an intermediate decrease of reduction of forager ants (80 % in case of scattering) but is >90 % again after 14 and 21 days. In the control the trend may be observed without the influence of the product. This increase of ants is likely to be accountable to the population dynamic of the ant colony, as a new generation of brood that has hatched in the colonies has reached maturity and is leaving the nest to perform the roles of worker ants outside the nest (forager). To further facilitate the display of the population shift during the trial period the following figures (2.2.5.5-1, 2.2.5.5-2) show the reduction of the number of living ants outside the nest (forager) after application of dry (scattering) and dispersed (pouring) Ameisen Streu- und Gießmittel PROX in the tested doses.

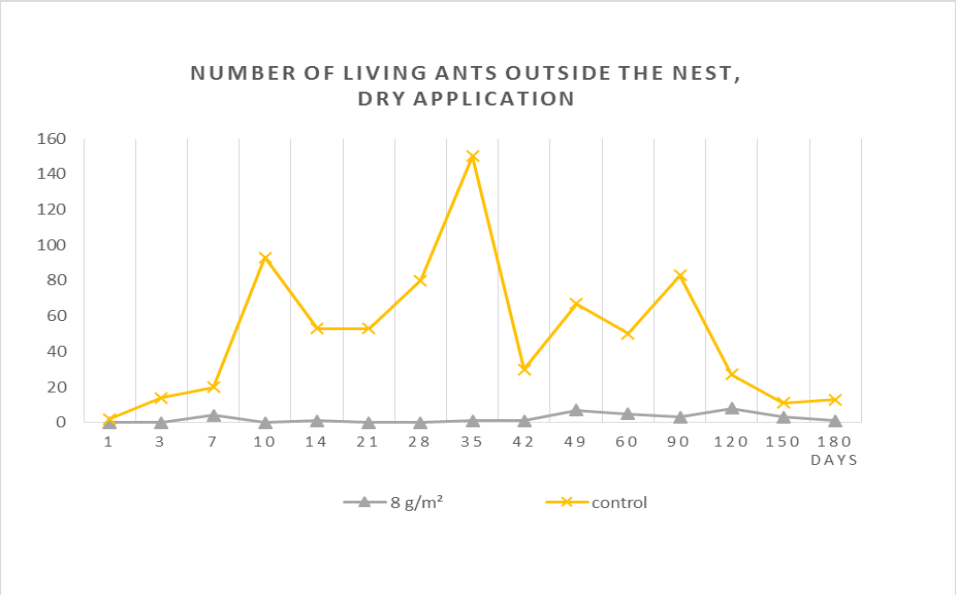


Figure 2.2.5.5-1: Number of living (forager) ants found outside the nest, dry application (scattering) of Ameisen Streu- und Gießmittel PROX at 8 g/m² compared to the untreated control over the test period. Population shifts are clearly visible at different time points of counting.

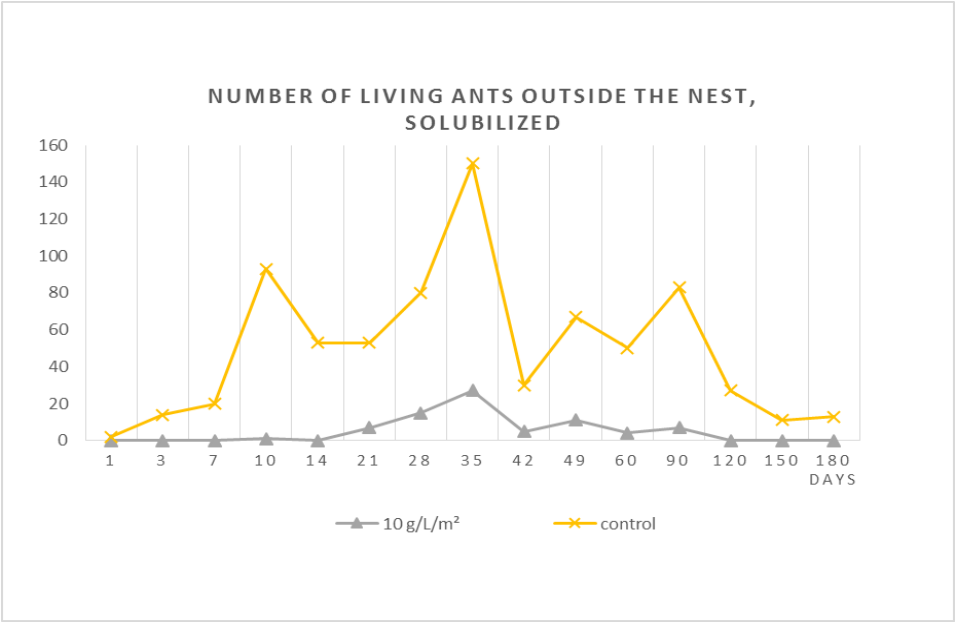


Figure 2.2.5.5-2: Number of living (forager) ants found outside the nest (treated and control), application of dispersed (pouring) Ameisen Streu- und Gießmittel PROX at 10 g/m² compared to the untreated control over the test period. Population shifts are clearly visible at different time points of counting.

Over a period of 4 weeks the reduction of forager ants ranged from 100 % to 81.3 % (after 4 weeks) for the pouring application and 100 % to 80 % (once after 7 days due to population shift) for the scattering application. Thus, to ensure that for both application types (scattering and dispersed) reduction (around 90 %) is achieved until the end of the claimed time, 4 weeks are claimed for reapplication.

Simulated use test Anonymous (2018): (considered for evaluation of the efficacy and claim):
According to the label claim the forager ants outside the nest are the target organisms.
In pursuance of the guidance in force (ECHA 2018) sufficient efficacy (Mortality) for a product intended for use by non-professional users as general surface treatment application has to be proven. The guidance sets the requirements at showing mortality (in percentage) of the target organism after 24h.

Effect on whole colony:
During product development besides the claimed effect on forager ants outside the nest (forager) the effect of the product on whole colonies was evaluated. In this perspective the exact number of different individual ants per nest was not counted but rather a rough estimation on the total number of individuals (1000-2000) per nest was given. The product showed reduction of ant population but no nest kill.

Effect on the forager ants:
The product is claimed to reduce the number of forager outside the nest. Percentage of reduction of forager ants (efficacy) of the product has been calculated based on the number of living ants found outside the nest, and in the arena after 24h under treated and control conditions. 24h after treatment the reduction of forager ants for aged and fresh product at scattering 8 g/m² applications was 100 %.

Reduction over the test period is shown in the following table:

Duration in days	Number of living ants in test arena			Reduction of forager ants [%]	
	Untreated control	Scattering 8 g fresh product /m²	Scattering 8 g aged product /m²	Scattering 8 g fresh product /m²	Scattering 8 g aged product /m²
1 (24 h)	60	0	0	100	100
3	18	0	0	100	100
7	40	0	0	100	100
10	52	1	0	98.1	100
14	44	0	0	100	100
21	42	0	0	100	100
28	58	0	0	100	100
35	68	1	0	98.5	100
42	78	0	5	100	93.6
49	108	0	0	100	100

Starting from the first evaluation on day 1 a decrease of forager ants outside the nest is observed (100 % after scattering of fresh or aged product) compared to the controls.

In 1 of 3 replicates no living queen was found after 7 weeks for the fresh product and for the aged product in 2 of 3 replicates no living queen was found.

No brood was seen for both, fresh and aged product, in 1 of 3 replicates. Almost no activity (on average 0-1 ants) visible outside the nest was found during the whole evaluation time for both ages tested. After 7 weeks the number of workers was lower (44 % [646 workers] for the fresh product and 50 % [733 workers] for the aged product) compared to untreated control (1467 workers). Means a reduction of workers of 56 % for the fresh product and 50 % for the aged product compared to the untreated control. With all control colonies the relevant queen was found alive. Also brood and on average approx. 1500 workers were found. In summary there was no significant difference in the efficacy (acceptance/palatability/efficacy) between the fresh and aged product.

3.5.5 Conclusion on efficacy

Summarising, the biocidal product is suitable for reduction of garden ants (forager) around buildings. The decrease of the number of forager ants can be achieved by application of Ameisen Streu- und Gießmittel PROX with 10 g/L/m² by using dispersed product (pouring) or with up to 8 g/m² by scattering the granules. A sufficient reduction of the number of forager ants was achieved in all considered efficacy tests. Both types of application aim to achieve the best possible contact of the product with the target organisms (adult forager ants) at the infested site. The active substance is toxic to ants after either direct contact or ingestion. Although it acts also by ingestion, the product cannot be definitely assigned to bait products, since it is not used in bait boxes and especially applied by drenching it acts mainly as contact insecticide.

The requirement for consumer products intended as general surface treatment are sufficiently fulfilled by the provided tests. The need of a laboratory test (see ECHA Guidance on the BPR, Vol. II, Parts B+C, section 5.6.4.4 Ants) was waived due to the submission of an adequate field test (Anonymous 2010b). The submitted simulated use study (Anonymous, 2009a) has been performed using a choice system in order to address the other mode of action (ingestion toxin) in addition. Half of the arena was treated with the product and the alternative food source was presented on the untreated part of the arena. Following the required criteria for bait applications in the laboratory choice test 95 % of test insects (in this case forager ants) have been killed at a given time point. The reduction of forager ants was 100 % for the scattering application after 24 h. The description of the simulated use test in the guidance includes the monitoring of the attractiveness of the bait

formulation to be assessed at regular time intervals (hours). This was not possible due to the low number of living forager ants found during the claimed application time (below 1 living forager per test point). Thus, the low number of living forager ants was regarded as demonstration for the attractiveness of the bait and simulated use study to be a proxy for the required laboratory choice test to demonstrate palatability of the formulation.

In the considered simulated use test the reduction of forager ant activity derived from the correlation of the number of living forager ants under treated conditions with the number of living forager ants in the control was assessed.
In case of the scattering application the reduction of forager ants was above 90 % after 24h, after 7 days at 80 % which is due to the population shift but again above 90 % until 4 weeks (time envisioned for reapplication).
In case of the dispersed application (pouring) the reduction of forager ants was above 90 % after 24h, until 2 weeks after application. 3 weeks post application the reduction of forager ants dropped to 86.3 % and to 81.3 % after 4 weeks.
The field study relevant for the application has been performed employing the proposed technique, i.e. the product is deployed at a rate of 8 g/m² (scattering) or 10 g/L/m² (pouring). In the field test reduction of forager ants was calculated by comparing the number of ants passing the measure point in the treated condition to the pre-treatment condition.
The pouring application resulted in decrease of ant forager ant activity (100 %) outside the nest after 7 days and the high reduction remained for three weeks. In the case of scattering application 100 % reduction was achieved after 21 days.

Reapplication rate of the product:
Using the results of reduction of forager ants from the simulated use test for the pouring application the reduction of forager ants drops to 86.8 % after 3 weeks and to 81.3 % after 4 weeks. However in the field test after 3 weeks (the end of the trial) post application for both application types the reduction of forager ants was 100 %. A 100 % reduction of forager ants in the field trial and additionally the results from the nest opening (no living ants found) indicate that the ant population was strongly influenced by the product. Thus, in case of ongoing infestation or re-infestation to ensure continuous reduction (>90 %) of forager ants for both application rates, 3 weeks are supported by the efficacy tests. However, due to the assumption that in case of continuous infestation (despite reduction of 90-100 %) or re-infestation it would take time until the nest is fully functional and a large number of forager ants may be observed, 4 weeks shall be taken for reapplication.

The intended label claims for the product are:
1. For control of adult garden ants (*Lasius niger*),
2. Reduction of forager ants around buildings at 10 g/L/m² pouring and 8 g/m² scattering application of the product
3. Reapplication after 4 weeks in case of remaining infestation or re-infestation
4. Use on nest entrances on hard surface (e.g. terrace, sidewalk) around buildings outdoors in private areas

The efficacy tests considered for evaluation of this Renewal still support all intended label claims.

Storage stability and claimed shelf life:

The reduction of active substance was below 10 % for the claimed 37 months of storage, thus according to the Guidance no efficacy test for the aged product would be necessary considering the product as general surface treatment. However, it has to keep in mind that due to the mode of action, in case of bait products the guidance states that: "When a bait product is claimed to be effective after a long period of storage, it is necessary to demonstrate that the product will still be effective and attractive after the stated storage period". To address this concern, an additional efficacy test was conducted with aged

product. Only the required amount of 2 years aged product, stored at ambient temperatures, was available for testing in a simulated use test (Anonymous 2018). The simulated use test against Black ants (scattering application; 8.0 g product/m²) was conducted to show the attractiveness, palatability and efficacy of 2 years aged product in comparison to fresh product and controls. The test results (efficacy data given above) demonstrate that the fresh and aged product is equally effective and attractive.
Concluding, a storage stability of Ameisen Streu- und Gießmittel of at least 2 years is demonstrated and is sufficiently supported.

3.5.6 Occurrence of resistance and resistance management

In view of the population dynamics and the mode of action, development of specific resistance of ants to etofenprox may be considered as rather unlikely. A comprehensive summary of reported cases of resistance to etofenprox is provided by the Insecticide Resistance Action Committee's (IRAC) resistance database (available online at http://www.pesticideresistance.org). Etofenprox is classified as an IRAC Mode of Action group 3A insecticide. Several groups of insects, namely mosquitos, cockroaches and cotton bollworm and sweet-potato whitefly are known to exhibit specific resistance. There is no information to date that ants have developed any resistance to the active substance etofenprox. However, for Ameisen Streu- und Gießmittel PROX used against ant infestation, this promotion of resistance is not expected, mainly because the affected forager ants are sterile and do not contribute to the genetic pool.

Resistance management to delay development of resistance and cross resistance in other insects:

1. Always read the label or leaflet before use and follow all the instructions provided
2. Avoid permanent and exclusive usage of the product
3. Alternate the use of insecticides
4. Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.)
5. The users should report to the authorisation holder if the treatment is ineffective
6. Check the treated areas once a week
7. If the infestation persists contact a professional

3.5.7 Known limitations

Possible restrictions or recommendations concerning the use of the product in specific environmental or other conditions are not prescribed. The product is intended to be applied only at infestation to control visible active ants outside the nest (forager) which is only relevant in good weather conditions and at summer time. However, the product shall be protected from rain and water spilling.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

According to the applicant, the product is not intended to be authorised for use with other biocidal product(s).

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

No new information/data for hazards described under 3.6.1.1 – 3.6.1.8 were provided. Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

3.6.1.1 Skin corrosion and irritation

No *in vitro* or human data on the biocidal product concerning skin corrosion and irritation are available. In the following table data on an *in vivo* study on skin corrosion/irritation are given.

Table 3.9 Summary table of animal studies on skin corrosion/irritation

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**
OECD TG 404 (Acute Dermal Irritation/ Corrosion), EC B.4 GLP RL 1	Rabbit (Himalayan), 3 males	500 mg SPU-00220-I/patch and animal (1 or 2 g of the test item were mixed with 0.5 or 1 mL aqua *ad iniectabilia*, 750 mg of this paste was applied per animal (^ 500 mg test item/animal), semi-occlusive conditions, 4h	Average score 24, 48, 72h: Erythema: 0/0/0 Oedema: 0/0/0 (At the 60 minutes observation very slight erythema (barely perceptible) was observed) Result: Non-irritating	For the initial test in one animal, the test site was not examined immediately after the patch removal, however, this does not affect the outcome of the study	Anonymous (2007a)

Table 3.10 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritating
Justification for the value/conclusion	Based on the results of the GLP-study on rabbits (OECD TG 404, EC B.4), Ameisen Streu- und Gießmittel PROX is non-irritating to the skin.
Classification of the product according to CLP	No classification of Ameisen Streu- und Gießmittel PROX is required.

3.6.1.2 Eye irritation

No *in vitro* or human data on the biocidal product concerning eye irritation are available.

Table 3.11 Summary table of animal studies on serious eye damage and eye irritation

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 TG 405 (Acute Eye Irritation/Corrosion), EC B.5, GLP RL 1	Rabbit (Himalayan), 3 males	100 mg of the fine mortared test item SPU-00220-I was administered per eye: placed in the conjunctival sac of the right eye of each animal after gently pulling the lower lid away from the eyeball. The lids were then gently held together for about one second in order to prevent loss of the material. The left eye, which remained untreated, served as a control.	Average score: Cornea: 0/0/0 Iris: 0/0/0 Conjunctiva redness: 0/0.67/0.67 Conjunctiva chemosis: 0/0/0 Reversibility: Yes Result: Non-irritating	No use of topical anaesthetics and systemic analgesics; initial test is missing, but all animals were tested simultaneously. This does not affect the outcome of the study	Anonymous (2007b)

Table 3.12 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Non-irritating
Justification for the value/conclusion	Based on the results of the GLP-study on rabbits (OECD TG 405, EC B.5), Ameisen Streu- und Gießmittel PROX is non-irritating to the eye.
Classification of the product according to CLP	No classification of Ameisen Streu- und Gießmittel PROX is required.

3.6.1.3 Respiratory tract irritation

There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. Consequently respiratory irritation is not included in the testing strategies. Furthermore, there are no indications or data that any of the substances in the biocidal product causes respiratory tract irritation (no classification, STOT etc.). Therefore, no further data are considered relevant for the biocidal product.

Table 3.13 Data waiving

Data waiving	
Information requirement	There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation.
Justification	Data on respiratory irritation are not submitted, however taking account of any available information no evidence of respiratory irritation potential of Ameisen Streu- und Gießmittel PROX is given. The sum of substances classified H335 remains below the generic threshold of 10 % to justify the absence of classification of the b.p.

3.6.1.4 Skin sensitisation

No information or evidence on *in vitro* studies or human data on skin sensitisation properties available.

Table 3.14 Summary table of animal studies on skin sensitisation

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**
OECD TG 406 (Skin Sensitisation), EC B.6, GLP RL 1	Guinea pig (Dunkin-Hartley), males. vehicle control: 5 guinea pigs treatment group: 10 guinea pigs Positive control: 20 guinea pigs	Intracutaneous (induction): 10 % suspension of SPU-00220-I in aqua ad iniectabilia Topical (induction): 50 % suspension of SPU-00220-I in aqua ad iniectabilia Topical (challenge): 50 % suspension of SPU-00220-I in aqua ad iniectabilia	Challenge revealed no skin irritation in any animal and thus, the test item had no sensitising properties.	-	Anonymous (2007c)

Table 3.15 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Ameisen Streu- und Gießmittel PROX revealed no sensitising properties in guinea pigs in a test model according to MAGNUSSON and KLIGMAN skin maximisation test (Anonymous (2007c)).
Justification for the value/conclusion	No skin irritation was observed in the challenge group, and thus the test item had no sensitising properties.
Classification of the product according to CLP	No classification of Ameisen Streu- und Gießmittel PROX is required.

3.6.1.5 Respiratory sensitisation

Table 3.16 Data waiving

Data waiving	
Information requirement	There are no formally recognised and validated animal or *in vitro* tests for respiratory sensitisation. Relevant information with respect to respiratory sensitisation may be available from case reports, epidemiological studies, medical surveillance, reporting schemes.
Justification	No sensitisation or allergenicity is known or reported, no hypersensitivity or any evidence that the biocidal product can induce specific respiratory hypersensitivity is given. Further, since respiratory exposure via dust can be excluded (dust-free formulation), no further information is required.

3.6.1.6 Acute oral toxicity

No human data on the biocidal product concerning acute toxicity are available.

Table 3.17 Summary table of animal studies on acute oral toxicity

Summary table of animal studies on acute oral toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 423 (Acute oral toxic-acute toxic class method), EC B.1 tris, GLP RL 1	Rat, Crl: CD(SD), females, 6 per group	2 000 mg SPU-00220-I /kg b.w., single administration (limit test, oral gavage in 0.8 % aqueous hydroxy-propylmethylcellulose gel)	Rats did not reveal any signs of toxicity, all animals gained the expected body weight, no pathological findings were noted at necropsy.	>2 000 mg /kg	-	Anonymous (2007d)

Table 3.18 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (female rats) >2000 mg/kg bw
Justification for the selected value	Under the present test conditions, a single oral administration of 2000 mg Ameisen Streu- und Gießmittel PROX/kg bw to rats did not reveal any signs of toxicity.
Classification of the product according to CLP	No classification of Ameisen Streu- und Gießmittel PROX is required.

3.6.1.7 Acute inhalation toxicity

Table 3.19 Data waiving

Data waiving	
Information requirement	Testing by the inhalation route is appropriate, if exposure of humans via inhalation is likely
Justification	The performance of an acute inhalation toxicity study with the biocidal product is not considered to be required for the following reasons: inhalation toxicity data for the active substance are available, demonstrating absence of acute toxic effects by inhalation. Furthermore, none of the non-active ingredients of the biocidal product is known to present any hazard to human health by inhalation. By extrapolation from the existing data, it is therefore concluded that the biocidal product lacks any significant potential to harm human health by inhalation. Moreover, the recommended application modes of the biocidal product (scattering or pouring) exclude the possibility of aerosol or dust generation. The product itself is a fine granular formulation not forming dust. Therefore, in view of the limited vapour pressure of the active substance, its non-toxicity by inhalation, and the application mode of the biocidal product, exposure of humans to the active substance is considered negligible.

3.6.1.8 Acute dermal toxicity

No human data on the biocidal product concerning acute dermal toxicity are available.

Table 3.20 Summary table of animal studies on acute dermal toxicity

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**
OECD TG 402 (Acute dermal toxicity: fixed dose procedure), EC B.3, GLP RL 1	Rat, Crl: CD(SD), males and females, 5 per sex per group	Occlusive, in aqua irrigation solution-Amount(s) applied (volume or weight with unit): 10 mL/kg bw	Dermal administration of 2000 mg SPU-00220-I/kg bw for 24h did not reveal any toxic symptoms.	>2 000 mg/kg	The LD_{50} could not be calculated due to lack of mortality at the applied dose level.	Anonymous (2007e)

Table 3.21 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (male and female rats) >2 000 mg/kg bw
Justification for the selected value	Under the present test conditions, dermal administration of 2 000 mg Ameisen Streu- und Gießmittel PROX/kg bw to rats did not reveal any signs of toxicity.
Classification of the product according to CLP	No classification of Ameisen Streu- und Gießmittel PROX is required.

3.6.2 Information on dermal absorption

Table 3.22 Data waiving

Data waiving	
Information requirement	Dermal absorption
Justification	Experimental data on dermal absorption of etofenprox in Ameisen Streu- und Gießmittel PROX are not available. However, according to the ECHA Guidance on Information Requirements (ECHA, May 2018[3]) submission of experimental data is not always mandatory. Based on the proposal of Biocidal Products Committee (BPC-24) (March, 2018) the new EFSA guidance (2017) in place of the previous one (2012) for biocidal products and active substances is applied. According to the EFSA Guidance on dermal absorption (EFSA, 2017) a default dermal absorption value for estimation of potential systemic exposure can be used in human risk assessment. This is in accordance with the Technical agreements for Biocides (TAB, 09th of August 2021) which also states that the EFSA dermal absorption guidance is applied. The values were set following evaluation of human *in vitro* data and information on the chemical composition indicating a significant impact on dermal absorption. The default values recommended are based on the concentration status and formulation category of the biocidal product (EFSA Guidance Notes, Section 6, How proceed when there are no data on the formulation under consideration, p.19). Accordingly, for Ameisen Streu- und Gießmittel (1 % a.s. etofenprox, formulation type WG) a default dermal absorption value of 50 % is considered as the worst case and this value is applied for (in use) dilutions water-based/dispersed or solid-formulated.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)) (ECHA 2017b). Consequently, only the active substance was addressed in the human health risk assessment.

Other

The human health effects of Ameisen Streu- und Gießmittel PROX are considered to be completely determined by the active substance etofenprox. According to the rules laid down

[3] ECHA (2018): Guidance on the Biocidal Products Regulation Volume III Human health Part A: Information Requirements, ECHA-18-G-05-EN, May 2018.

in CLP Regulation 1272/2008 (EC), Ameisen Streu- und Gießmittel PROX requires labelling with the hazard statement H362 "May cause harm to breast-fed children".

3.6.4 Other

Not relevant. No new data are provided for re-assessment.

3.6.4.1 Food and feeding stuffs studies

The intended use descriptions of the biocidal product indicate that the uses must avoid exposure of food and feed.
The following instructions of uses will be applied on the product label:

N-127: 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.

N-130: Do not apply the product on or close to plants used as food or feed.

Therefore, no food and feed residues are to be expected.
As in the previous assessment reference to the CAR (Austria, 2013) of the active substance is made with regard to residue analytical methods. No new methods or studies are submitted.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant. No new data are provided for re-assessment.

3.6.4.3 Other test(s) related to the exposure to humans

Not relevant. No new data are provided for re-assessment.

3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, please refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

"Ameisen Streu- und Gießmittel PROX" is a biocidal product consisting of water dispersible granules based on sugar and containing etofenprox to be used for the control of *L. niger* outdoors by non-professionals via scattering or pouring (after dissolution in water). The content of the active substance in the product is 1 % (w/w), equivalent to 10 g/kg.

Besides the active substance etofenprox, no further substances of concern have been identified in the biocidal product regarding the risk characterisation for human health.

The following guidance documents are taken into account for the exposure and risk assessment on human health of Ameisen Streu- und Gießmittel PROX:

Relevant guidance documents consulted for human health risk assessment

- ECHA Biocides Human Health Exposure Methodology (ECHA, 2015)
- Recommendations of the Ad hoc Working Group on Human Exposure (HEAdhoc)
- Opinions of the Human Exposure Expert Group (HEEG)
- Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017 (ECHA 2017b)
- EFSA Guidance Document for dermal absorption (EFSA, 2017)

Relevant exposure models or exposure studies used for human health risk assessment

As no exposure studies performed with the product are available following models/guidance were used for exposure assessment:

- HEEG Opinion 13 (2011): HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance
- HEEG Opinion 2 (2008): HEEG opinion on the assessment of Potential & Actual Hand Exposure
- HEEG opinion 7 (2009): HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4
- HEAdhoc recommendation 6, version 4 (May 2020), scenario 51; Subsoil treatment model 2; scenario 48; Consumer spraying and dusting model 2; scenario 40
- RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 73): RIVM rapport 320005002 Pest control products fact sheet

Strategy for human health risk assessment

Etofenprox is an insecticide used to control ant infestations by acting via direct contact and ingestion. It acts on sodium channels of the insect nervous system by disturbing the normal neuro-transmittance.
The given biocidal product consisting of water dispersible granules based on sugar and containing etofenprox to be used for the control of *L. niger* (PT 18) outdoors by non-professionals via scattering or pouring (after dissolution in water).
Therefore AT CA performed a quantitative risk assessment identifying all realistic worst cases using above mentioned guidances.
In the Assessment Report Etofenprox Product-type 18 (Insecticide) of 27th September 2013 AELs were developed for short-, medium- and long-term exposure based on the most critical effects. The systemic AELs are considered appropriate for use in the quantitative risk assessment on human health of the biocidal product. No local effects were identified for

etofenprox.
Additionally, a default of 50 % dermal absorption (for granules and for dilution) of etofenprox as proposed in the new EFSA Guidance on dermal absorption (2017) is applied in the risk assessment.

Considerations on volatility of the active substance(s) and substance(s) of concern from the product
Exposure to vapours of etofenprox when handling the biocidal product is not expected. As a general rule a substance should be considered volatile only if it has a vapour pressure >10 mPa at 20°C. With a vapour pressure of 8.13×10^{-7} Pa at 25°C, the volatility of etofenprox is below this threshold. Nevertheless, potential inhalation exposure is assessed in a first screening approach using the criteria of HEEG Opinion 13 *"Assessment of Inhalation Exposure of Volatilised Biocide Active Substance"* for etofenprox. As the formation of mists, aerosols, fumes etc. is not expected, a worst-case inhalation long-term screening tool provided in HEEG 13 is applied.

Table 3.23 Input parameters for HEEG Opinion 13

Input parameters and description for HEEG Opinion 13 "Assessment of Inhalation Exposure of Volatilised Biocide Active Substance"

Inhalation of volatilised residues: toddler inhaling volatilised residues indoors. As worst case 24 h/day of inhalation exposure is assumed. This scenario also covers children and adults.

According to the HEEG Opinion 13 endorsed at TM IV 2011 and amended after TM III 2013 long-term exposure to volatilised residues can be neglected if the following tier 1 screening tool which is based on the toddler (inhalation rate of 8 m³/24 h and body weight of 10 kg) representing the worst case, is ≤1:

$$0.328 \bullet \frac{MW(g/mol) \bullet VP(Pa)}{AEL_{long-term}} \leq 1$$

This is true for etofenprox (0.009). Therefore long-term exposure to volatilised residues is negligible for adults, infants and children for this a.s. Thus inhalation exposure is not included in the risk assessment as recommended in HEEG opinion 13 (2011).

	Parameters	**Value**	**Reference and justification**
Screening approach (worst case)	Molecular weight etofenprox	376.47 g/mol	Assessment Report Etofenprox PT 18, 2013
	Vapour pressure etofenprox	8.13×10^{-7} Pa at 25°C	Assessment Report Etofenprox PT 18, 2013
	AEL_long-term	0.011 mg/kg bw/d	Please see chapter 3.6.6.4

In addition, airborne exposure to the solid biocidal product is not expected. The granules of the biocidal product are coarse and considered nearly dust-free as study data show that the

concentration of residues released is very low with 2.1 mg gravimetric collected dust (0.007 % w/w of the sample) and the attrition resistance is high with 100 % (please refer to chapter 3.2. Physical, chemical and technical properties, Table 3.2, p. 22ff. above).

Strategy for livestock exposure and/or dietary risk assessment
Direct contact of biocidal product family to human and animal food or feed can be excluded due to the authorised use. The following instructions of use will be applied on the product label:

N-127: 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.

N-130: Do not apply the product on or close to plants used as food or feed.

Additionally the product is only to be applied where livestock's and pet's access can be excluded. A dietary risk assessment or a strategy for livestock exposure is therefore not necessary.

Strategy for the assessment of substance(s) of concern
Not relevant. No SoC is identified. Please refer to the confidential annex of the PAR for full composition of the biocidal product.

Strategy for disinfectant by-products assessment
Not relevant.

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3.24 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professionals bystanders/General public**	**Via food**
Inhalation	n/a	No	n/a	No	n/a
Dermal	n/a	Yes	n/a	Yes	n/a
Oral	n/a	No	n/a	Yes	n/a

3.6.6.3 List of exposure scenarios

Table 3.24 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Primary exposure		
Scenario [1]	***Pouring application including mixing and loading and cleaning step***	
1.1 Mixing and loading	Loading the granular biocidal product by measuring into dosing aid and mixing by filling water into watering can	Non-professionals
1.2 Application	Pouring of in-use dilution on ant nest entrance on hard surfaces outdoor	
1.3 Post-application	Rinse the watering can with a little water and apply the rinse water on the ant nest	
Scenario [2]	***Scattering application***	
	Scattering the granular biocidal product on ant nest entrance on hard surfaces outdoor	Non-professionals
Secondary exposure		
Scenario [3]	***Crawling on treated surfaces (pouring/scattering)***	
	Toddler is crawling on treated surface followed by mouthing	General public (toddler)
Scenario [4]	***Picking up a granule followed by mouthing/ingestion***	
	Toddler ingesting the biocidal product by picking up scattered granules	General public (toddler)
Combined exposure		
	The biocidal product is intended to be used by non-professional users outdoors in their private areas around buildings where ant nests occur. The product is to be applied either by drench application or by scatter application. Thus, a combined exposure is not foreseen.	n.r.

3.6.6.4 Reference values to be used in risk characterisation

Table 3.25 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	developmental neurotoxicity in rats	NOAEL 28.4 mg/kg bw/d	100	30 %	0.085 mg/kg bw/d
AELmedium-term	13-week, rat	NOAEL 20 mg/kg bw/d	100	30 %	0.06 mg/kg bw/d
AELlong-term	2-year, rat	NOAEL 3.7 mg/kg bw/d	100	30 %	0.011 mg/kg bw/d
AECdermal	not applicable				
AECinhalation	not applicable				
ARfD	not applicable				
ADI	not applicable				

[1]For etofenprox, the respective Assessment Report Etofenprox Product-type 18 (Insecticide) of 27th September 2013 is considered. The systemic AELs are deduced for short, medium and long term exposure.
As evaluated during EU review, the short term AEL of 0.085 mg/kg bw/d was derived from the developmental neurotoxicity NOAEL of 28.4 mg/kg bw/d in rats based on ocular lesions (haemorrhage effects) in weanlings; the medium term AEL was set at 0.06 mg/kg bw/d based on the 13-week NOAEL of 20 mg/kg bw/d in rats for liver and thyroid effects; the long term AEL of 0.011 mg/kg bw/d was derived from the 2-year NOAEL of 3.7 mg/kg bw/d in rats based on liver and thyroid effects. For derivation of systemic AELs, the external NOAELs were multiplied by a factor of 0.3 for correction of oral absorption rate and further, a safety factor of 100 for intra- and inter-variability was applied.

3.6.6.5 Specific reference value for groundwater

Applying worst case assumptions the PEC values in groundwater for direct exposure to soil were estimated at 0.033 µg/L and 0.028 µg/L for pouring and scattering, respectively (Summary table of PNEC, PEC and PEC:PNEC values).

The generic groundwater limit value is 0.1 µg/L. The predicted concentrations of etofenprox in groundwater hence fall below the official limit value. An acceptable risk for groundwater is therefore demonstrated.

3.6.6.6 Professional users (including industrial users and trained professional users)

Not relevant.

3.6.6.7 Non-professional users

The biocidal product is marketed as granules for non-professional use. It may be used via drenching application directly on the ant nest after dissolving the granules in a watering can. Furthermore it may be used via scattering the dry granules directly to the ant nest and the close surrounding.

The potential for **primary (direct) exposure** to occur will apply to non-professionals (i.e. consumers) by scattering the granules on the ant nest as well as by drenching application respectively. For both applications only dermal exposure is considered to be relevant, as exposure to hands is expected during the application phase when scattering the granules/preparing (mixing and loading), applying the diluted product and washing of watering can (post-application).
Inhalation exposure to etofenprox is unlikely due to the very low volatility of the active substance. Additionally it is not expected to be released to the air as gas or via particles (please see above: *"Considerations on volatility of the active substance(s) and substance(s) of concern from the product"*).
Oral exposure is considered to be negligible in comparison to dermal exposure. In addition users are asked to wash hands after usage (P264). Moreover the product is nearly dust-free and there is no non-respirable dust that might be swallowed/inhaled during the application which furthermore is outdoor.

Secondary (indirect) exposures to general public – especially toddlers and children - are not unlikely due to the application(s) of the product - assuming contact with treated surfaces or picking up scattered granules. Inhalation exposure due to gaseous release is expected to be not relevant due to the low vapour pressure of the a.s. and the outdoor use. Dermal and oral exposure might be relevant as reasonable worst case for secondary exposure, assuming toddlers/children being exposed to treated areas/scattered granules.

Table 3.26 Description and input parameters

Description of Scenario [1.1], [1.2] and [1.3]: Pouring application with mixing/loading and cleaning step
Brief description of scenario: Mixing and loading the granules of the biocidal product in a watering can and applying the diluted product with a watering can and cleaning of watering can. Exposure to skin is considered to occur during all phases of handling (mixing and loading, application and post-application). The biocidal product is intended for non-professional use for control of ants outdoors at private areas around buildings. For pouring application the required amount of granules is measured with the help of the clicked-on dosing aid and mixed with the according amount of water in a watering can. A concentration of 10 g biocidal product per litre is used per square meter. The application liquid is poured with an application rate of 1 L/m^2 on a spot (ant nest entrances on hard surfaces) with a maximum size of 1.5 m^2. After the application the watering can has to be rinsed with little water and the rinse water be applied on the ant nest. A harmonised approach for exposure assessment of pouring with a watering can ("Subsoil treatment model 2") is described in the HEAdhoc recommendation 6 version 4 in scenario no. 51 (ECHA 2020) as well as in Biocides Human Health Exposure Methodology document on page 203 (ECHA 2015). Therein mixing and loading is included. The assessment laid out in this PAR follows this approach. Subsoil treatment model 2 provides default exposure values for actual hand exposure inside gloves, for potential body exposure of the rest of the body (and for inhalation exposure). For calculation of potential hand exposure without gloves, the default value for hand exposure inside gloves is multiplied by 100 as suggested in the HEEG opinion No. 2 (2008, page 2). Taking into account these adaptions the model is considered appropriate also for non-professional exposure as a conservative scenario. In addition, exposure of hands during cleaning of the watering can is considered, although it represents only a minor part of the total dermal exposure. After application, cleaning is performed by filling tap water in the watering can and emptying the rinsing onto the ant nest. As no suitable model is available to assess the cleaning of a watering can, this step is assessed using the same model as during the application step presented above. However, a lower exposure time (5 min) and a dilution factor of 100 were taken into account. As an application/exposure duration including the mixing and loading step AT CA assumed 15 minutes as a reasonable estimate to achieve a conservative worst case value. As shown above inhalation exposure was demonstrated to be negligible.

Input parameters for Scenario [1] Pouring application with mixing/loading and cleaning step			
Dermal			
	Parameters	**Value**	**Reference and justification**
Tier 1 (no PPE)	Concentration of a.s. in biocidal product	1 % (w/w)	Product specifications (refer to SPC)
	Concentration of a.s. in application liquid	0.01 % (w/w)	Product specifications (refer to SPC)
	Application duration	15 min	Reasonable estimate
	Post-Application duration	5 min	Reasonable estimate
	Indicative exposure value hands in gloves	48.8 mg/min	HEAdhoc recommendation 6, version 4, scenario no. 51 (ECHA 2020)
	Indicative exposure value hands without gloves	4880 mg/min	Adapted (x 100): HEEG opinion No. 2, (EC, 2008)
	Indicative exposure value body	38.2 mg/min	HEAdhoc recommendation 6, version 4, scenario no. 51 (ECHA 2020)
	Body weight, adult	60 kg	HEAdhoc recommendation 14, appendix A (ECHA 2017a)
	Dermal absorption	50 %	Chapter 3.6.2
	Dilution factor cleaning step	100	Reasonable estimate
Inhalation, Oral			
Not relevant.			

Systemic Exposure

Exposure$_{\text{dermal Appl.}}$ = (indicative potential exposure value hands without gloves + indicative exposure body) x exposure duration application x concentration of the a.s. in the application liquid x dermal absorption / body weight adult

= (4880 mg BP/min + 38.2 mg BP/min) x 15 min x 0.01 % x 50 % / 60 kg
= **0.0615 mg/kg bw/d**

Exposure$_{\text{dermal Clean.}}$ =(indicative potential exposure value hands without gloves + indicative exposure body) x exposure duration cleaning x concentration of the a.s. in the in-use product / dilution factor cleaning step x dermal absorption / body weight adult

= (4880 mg BP/min + 38.2 mg BP/min) x 5 min x 0.01 % / 100 / 100 x 50 % /100 / 60 kg
= **0.0002 mg/kg bw**

Total systemic exposure = 0.0617 mg a.s./kg bw

Table 3.27 Description and input parameters

Description of Scenario [2] Scattering application of dry granules
Brief description of scenario: Non-professional user loading biocidal product by scattering granules from the packaging into dosing aid followed by scattering of granules on ant nest entrance on hard surfaces outdoor. Post-application exposure is not expected. Exposure to skin is considered to occur during handling. The biocidal product is intended for non-professional use for control of ants outdoors at private areas around buildings. For scatter application the required amount of granules will be applied directly into or directly around ant nest entrances on hard surfaces, using the provided dosing aid. An application rate of 8 g biocidal product per square meter is used. The maximal size of application is 1.5 m^2. A harmonised approach for exposure assessment of scattering coarse granules indoors is described in the HEAdhoc recommendation 6, version 4 (scenario no. 48, "Consumer spraying and dusting model 2"). The assessment laid out in this PAR follows this approach. In this model the exposure from scattering granules (directly from package or from bucket with spoon or beaker) is regarded as a worst case for outdoor application of the subject product. As an application/exposure duration scenario no. 48 of HEAdhoc recommendation 6, version 4 suggests 5 minutes for non-professional use, what is considered a realistic worst case value. As shown above inhalation exposure was demonstrated to be negligible. Additionally in scenario no. 40 (same model as in scenario no. 48) of the HEAdhoc recommendation 6 states, that inhalation exposure is negligible if a spoon is used (in this case: dosing aid).

Input parameters for Scenario [2] Scattering application of dry granules			
Dermal			
	Parameters	**Value**	**Reference and justification**
Tier 1 (no PPE)	Concentration of a.s. in biocidal product	1 % (w/w)	Product specifications (refer to SPC)
	Indicative exposure value hands/forearm	2.73 mg/min	HEAdhoc recommendation 6, version 4 (scenario no. 48)
	Indicative exposure value Legs/feet/face	2.74 mg/min	HEAdhoc recommendation 6, version 4 (scenario no. 48)
	Application/exposure duration	5 min	HEAdhoc recommendation 6, version 4 (scenario no. 40)
	Dermal absorption	50 %	Chapter 3.6.2
	Body weight, adult	60 kg	HEAdhoc recommendation 14, appendix A (ECHA 2017a)
Inhalation, Oral			
Not relevant.			

Calculations for Scenario 2

Systemic exposure

$Exposure_{dermal}$ = (indicative exposure value hands, forearms + indicative exposure value legs, feet, face) x application/exposure duration x concentration a.s. x dermal absorption / body weight adult

= (2.73 mg b.p./min + 2.74 mg BP/min) x 5 min x 1 % x 50 % / 60 kg
= 0.0023 mg/kg bw

Total systemic exposure = 0.0023 mg a.s./kg bw

Outcome of systemic exposure and risk characterisation

Table 3.28 Summary table: estimated systemic exposure and risk characterisation for non-professional users

Summary table: estimated systemic exposure and risk characterisation for non-professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.06 mg/kg bw/d (medium-term) AEL = 0.085 mg/kg bw/d (short term)	**Acceptable (Yes/No)**
Scenario [1] Pouring	Tier 1: no PPE	n/a	0.0617	n/a	0.0617	103% (73 %)	No (Yes)
Scenario [2] Scattering	Tier 1: no PPE	n/a	0.0023	n/a	0.0023	38% (3 %)	Yes (Yes)

n/a: not applicable

Using the medium-term NOAEL for potential repeated exposure in risk characterisation of Ameisen Streu- und Gießmittel PROX considering the use pattern would result in a slight exceedance of the AEL.

However, the underlying approach is over-conservative since since a low oral absorption of 30 % was taken into consideration for calculating internal AELs though this 30 % value was derived from bolus application to bile duct cannulated rates and the critical NOAELs were derived from feeding studies. The medium-term AEL is 0.06 mg/kg bw/d based on the rat sub-chronic feeding study (13-weeks) on liver and thyroid effects NOAEL of 20 mg/kg bw/d in rats. The derived AEL is considered conservative.
Moreover, the exposure models used for Scenario [1] are conservative as well. The product is not used on a daily basis.

Therefore, no risk is anticipated also for scenario [1] (pouring application), for which the ratio of estimated uptake/ AEL (%) is slightly above 100 %.
Considering the short term AEL of 0.085 mg/kg bw/d, which might be a more realistic reference value for this kind of use, the ratio of estimated uptake to AEL (%) is far below 100 %.

Conclusion

Based on the use pattern, chronic long-term exposure is not considered relevant.

The risk for non-professional users (Scenario [1] and [2]) is assessed for the use of Ameisen Streu- und Gießmittel PROX for ant control outdoors and considered acceptable (Estimated uptake/ AEL (%) safe if < 100 % of AEL).

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

Table 3.29 Description and input parameters

Description of Scenario [3] Crawling on treated surfaces
Brief description: A toddler is crawling on a treated surface. Exposure occurs via dermal route and subsequently orally via hand-to-mouth contact. In this scenario it is assumed a toddler is crawling on treated surface and is exposed to dislodged residues. As a conservative approach, it is assumed that the surface has been treated recently and there is neither decay or decomposition or even ingestion by the target organism of the active ingredient. Besides the dermal exposure also oral exposure might take place due to hand-to mouth contact and will be considered. A concentration of 10 g biocidal product per litre is used per square meter with a maximum size of 1.5 m^2. As transfer coefficient (exposure parameter used to describe the effectively contacted surface area per time) for surface to skin transfer a value of 2100 cm^2/h for toddlers was estimated in the HEADhoc recommendation No. 12 (ECHA, 2016). Although this default is for indoor treated surface it is assumed that it is also applicable in this case as the biocidal product is applied around houses on hard surfaces (e.g. terraces). As a conservative assumption an area of 10 m^2 (small terrace) was used which toddler is covering in one hour of exposure duration, wherein the treated area is located. Hence, the potential of dermal contact is reduced accordingly. Exposure duration of 1 hour: This is considered as a conservative assumption for contact time, as the ants will attack the toddler during this time to defend their nest and drive the toddler away, even if the value is reported in "Pest Control Products Fact Sheet" (RIVM report 320005002/2006, p. 73). In addition, the expected supervision of the parents is ignored. For surface transferable residues a value of 55 % (various types of surfaces – dried fluids) was used, taken from Biocidal product exposure methodology (ECHA, 2015, p. 171). According to the HEEG Opinion 7 for hand-to-mouth transfer it is assumed that 50 % of the product that ends up on the hands is taken up orally. As a worst case it is assumed, that all biocidal product is on the hands. Additionally to the conservative assumptions and parameters in this scenario: In general the risk of toddlers being exposed to the product is considered to be low due to the limited accessibility of the product in the ant nest. As well parents are expected to keep children away from treated areas as well as from ant nests.

Input parameters for Scenario [3] Crawling on treated surfaces			
Dermal			
	Parameters	**Value**	**Reference and justification**
Tier 1 (no PPE)	Application rate biocidal product	10 g/m^2	Product specifications (refer to SPC)
	Concentration of a.s. in biocidal product	1 % (w/w)	Product specifications (refer to SPC)
	Treated area (maximum)	1.5 m^2	Product specifications (refer to SPC)
	Area toddler is covering in 1h (terrace)	10 m^2	Estimation
	Exposure duration	1h	RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 73).
	Surface transferable residues (dried fluid on smooth glazed tile)	55 %	Biocidal product exposure methodology, p. 171 (ECHA 2015)
	Transfer coefficient	2100 cm^2/h	HEAdhoc recommendation No 12, 2016 (ECHA 2016)
	Dermal absorption	50 %	Chapter 3.6.2
	Body weight, toddler	10 kg	HEAdhoc recommendation 14, appendix A (ECHA 2017a)
Oral			
Tier 1 (no PPE)	Oral absorption	30 %	Chapter 3.6.6.4
	Hand to mouth transfer factor	50 %	HEEG Opinion 7, p. 3
Inhalation			
Not relevant.			

Calculations for Scenario 3
Systemic exposure

Total amount of a.s. on skin (all on hands)
= application rate b.p. x concentration a.s. x treated surface / area of terrace x surface transferable residues x transfer coefficient x exposure duration

= 10 000 mg/m^2 x 1 % x 1.5 m^2 / 10 m^2 x 55 % x 0.21 m^2/h x 1h
= **1.733 mg**

Of these 1.733 mg active substance 50% are taken up orally and dermally each. Additionally oral and dermal absorption values are taken into account.

$Exposure_{oral}$ = Total amount of a.s. on skin (all on hands) x uptake via mouthing x oral absorption / body weight

= 1.733 mg x 50 % x 30 % / 10 kg
= **0.0260 mg/kg bw oral uptake per event**

$Exposure_{dermal}$ = Total amount of a.s. on skin (all on hands) x uptake via mouthing x dermal absorption / body weight

= 1.733 mg x 50 % x 50 % / 10 kg
= 0.026 mg/kg per event
= 0.0433 mg/kg bw dermal uptake per event

Oral uptake	**+**	**dermal uptake**	**=**	**Total systemic exposure**
0.0260 mg/kg	**+**	**0.0433 mg/kg**	**=**	**0.0693 mg a.s./kg bw/event**

Description of Scenario [4] Picking up a granule followed by mouthing/ingestion

The biocidal product is intended for control of ants outdoors at private areas around buildings by scattering the required amount of granules directly into or directly around ant nest. Even if the product contains denatonium benzoate as a strong human aversive agent it cannot be excluded a toddler picks up followed by mouthing and or instant swallowing and ingestion.

In general the risk of toddlers being exposed to the product is considered to be low due to parental supervision who are expected to keep children away from treated areas as well as from ant nests, since this is an risk mitigation measure set (Avoid contact to treated surfaces/areas, in particular by children/toddler (N-321, modified). Furthermore, as already mentioned the biocidal product contains denatonium benzoate, a bittering agent, in order to minimise accidental ingestion by toddlers.

As no fitting model is known by the AT CA, a reverse reference scenario is calculated.

Input parameters for Scenario [4] Picking up a granule followed by mouthing/ingestion

Dermal			
	Parameters	**Value**	**Reference and justification**
Tier 1 (no PPE)	Concentration of a.s. in biocidal product	1 % (w/w)	Product specifications (refer to SPC)
	AEL_short-term*	0.085 mg/kg bw/d	Table 3.25: Reference values to be used in risk characterisation
	Oral absorption	30 %	Chapter 3.6.2
	Body weight, toddler	10 kg	HEAdhoc recommendation 14, appendix A (ECHA 2017a)
Inhalation, Oral			
Not relevant.			

*short term AEL was used since the scenario is considered to be accidentally and exposure does not occur frequently

Calculations for Scenario 4

Acceptable amount of active substance, which can be ingested by a toddler:

= AEL_short-term x body weight_toddler = 0.085 mg/kg bw x 10 kg = **0.85 mg a.s.**

1 g biocidal product contains 10 mg a.s. Hence 0.85 mg a.s. is equivalent to **85 mg biocidal**

product without considering oral absorption of 30 %.

Taking into account the product's relative density (tap density, chapter 3.2) with 0.95 g/cm^3 (950 mg/cm^3) 85 mg correspond to 0.089 cm^3. This corresponds to a sphere with a diameter of 0.554 cm.

Worst case estimation of the amount of granules this corresponds to:
With >99 % of the granules having a size of 1000 µm or smaller (please see "particle size distribution" in chapter 3.3, table 3.4 and/or Anonymous 2010a) for the worst case calculation of the weight of one granule a diameter of 1000 µm (=0.1 cm) was used. As shape of a granule a sphere was assumed. The biocidal product consists of over 96 % of sucrose therefore the density of sucrose was used for calculation (d =1.59 g/cm³).

= 4/3 x r^3 π x d
= 4/3 x 0.05^3 cm x 3.1415 x 1.59 g/cm³

= **0.00083 g per granule**
= **0.83 mg per granule**

Amount of granules:

= Maximum ingestion / worst case weight of a granule
= 85 mg / 0.83 mg/granule
= ~103 granules

Hence, a toddler would have to ingest over 100 granules of the biocidal product to reach AEL_short-term.

Summary of secondary exposure

Table 3.30 Summary table: estimated systemic exposure and risk characterisation for general public (toddler)

Summary table: estimated systemic exposure and risk characterisation for non-professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.06 mg/kg bw/d (medium-term) AEL short-term =0.085 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario [3]	Tier 1: no PPE	0.0260	0.0433	n/a	0.0693	115% (81.53 %)	No (Yes)
Scenario [4] Ingestion of b.p. granules – reverse scenario	Tier 1: no PPE	Reverse scenario	n/a	n/a	Reverse scenario	n/a	Yes

n/a: not applicable

If exposure of toddler to b.p. is supposed to be accidentally, there is no risk (Estimated uptake/ AEL (%) safe if <100 % of AEL), comparison of AEL (short –term) with estimated total uptake (mg/kg bw/day).

However, contact of children (toddlers) might not be limited to small number of days and might occur more frequently, thus, the AEL medium term is considered and a value of 115% is derived, indicating a risk to toddlers (Estimated uptake/ AEL (%) safe if >100 % of AEL).

Therefore, following risk mitigation measure is considered necessary.

Avoid contact to treated surfaces/areas, in particular by children/toddler. (N-321, modified)

Conclusion

The risk for secondary exposure is assessed after the use of Ameisen Streu- und Gießmittel PROX for ant control outdoors and considered is considered safe, if toddlers (children) are prevented to come frequently in contact with treated surfaces/areas. A risk mitigation measure (Avoid contact to treated surfaces/areas, in particular by children/toddler. (N-321, modified) is set. .

3.6.7 Monitoring data

Specific information on surveys or exposure studies (e.g. Tier-3 field studies) with the actual product or with a surrogate are not available.

3.6.8 Dietary risk assessment

Ameisen Streu- und Gießmittel PROX is intended to be applied outdoors in private areas directly onto ant nests or on terrace and sidewalk. In view of the intended use of Ameisen Streu-und Gießmittel PROX, by applying the biocidal product outside in private areas on ant nests or terrace and sidewalks, any contact to food or feedingstuff for livestock is not foreseen. Thus, dietary exposure to etofenprox resulting from use of Ameisen Streu- und Gießmittel PROX is considered as not relevant. Neither new data was provided for the renewal of the product nor new guidance had to be taken into account. Thus, the conclusion from the first product authorisation remains valid.

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Etofenprox is approved in PPP under Reg. (EC) No 1107/2009 (Reg. (EU) 2022/1480) and MRLs have been set according to Reg. (EU) 2021/590.

3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

Not relevant.

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

Not relevant.

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

Not relevant.

3.6.8.5 Maximum residue limits or equivalent

Etofenprox is approved in PPP under Reg. (EC) No 1107/2009 (Reg. (EU) 2022/1480) and MRLs have been set according to Reg. (EU) 2021/590.

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

Not required. The product only contains one active substance and no substance of concern with regards to human health.

3.6.10 Overall conclusion on risk assessment for human health

Table 3.31 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion**	**Set of RMMs**
[1]	Insecticide - adult ants – outdoor - non-professionals – pouring	Acceptable	None
[2]	Insecticide - adult ants – outdoor - non-professionals – scattering	Acceptable	None

[1] Use numbers in accordance with the list of all uses indicated under section 2.2.

Overall conclusion

The risk for non-professional users is assessed for the use of Ameisen Streu- und Gießmittel PROX for ant control outdoors.
The use of Ameisen Streu- und Gießmittel PROX with a content of 1 % (w/w) etofenprox for control ants outside in domestic areas by non-professional users has been shown to lead to acceptable exposure levels under the standard assumption that no PPE is used.

3.7 Risk assessment for animal health

Neither new data was provided for the renewal of the product nor new guidance had to be taken into account to assess the risk for animal health.

The biocide is not applied directly on animals or in their surroundings. However accidental exposure may happen to animals. The assessment indicating an unacceptable risk from secondary exposure to infants from application of aqueous solutions of the product may support also an unacceptable risk for companion animals and the need to further set risk mitigation measures.

Considering the specific situation of **scattering granules** containing sugar with an application rate of 8 g product/m^2 which corresponds to 80 mg etofenprox/m^2 a risk for pets is apparent: For a dog with 10 kg bw the short term limit value of 0.085 mg/kg bw/d would translate to 0.8 mg/10 kg bw/d. This means that with the uptake of all sugar granules from a 10 cm^2 spot treatment the dog would already consume 100 % of the human AEL. Smaller animals like cats may be at even higher risk. The human AEL could be increased by allometric scaling to dogs and cats, but this would increase the AEL by about a factor of 2, which is still within a critical range for the reverse exposure scenario. It is known that the bittering agent is no effective prevention for dogs and cats.

Therefore the following instruction and measures shall be taken:

Use instruction for Use 1 and 2:
N-127: 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.

Risk mitigation measure for Use 1 and Use 2:
N-221: Do not use near domestic animals or livestock.

3.7.1 Risk for companion animals

Please see above.

3.7.2 Risk for livestock animals

Please see above.

3.8 Risk assessment for the environment

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

The risk assessment is based on the list of endpoints as published in the assessment report (Assessment report for Etofenprox PT 18 (Insecticide), September 2013) for which AT was the rapporteur member state. The assessment report is available on the ECHA website. During the first evaluation of the biocidal product a new $PNEC_{soil}$ was applied (discussed and agreed at ENV WG-IV 2016) and used in the risk assessment. This PNEC was also applied in this dossier at renewal stage.

Under environmental conditions etofenprox is considered as hydrolytically stable. It has a vapour pressure of 8.13 x 10^{-7} Pa (25°C) and a Henry Law constant (calculated) of 0.0136 $Pa.m^3/mol$ indicating that volatilisation is not a significant pathway regarding the dissipation into the environment.

The log Kow of 6.9 indicating a bioaccumulation potential. Etofenprox is considered as "not readily biodegradable" (only 17 % of mineralisation after 28 days) however the results of simulation tests in different media showed that it will not persist in the environment.

In the aquatic degradation studies two major metabolites were detected: α–CO in the water phase by aqueous photolysis (63.6 % and 37.8 % of applied radioactivity in sterile buffer and natural water after 15 days) and 4'-OH in the sediment phase (max. of 21.4 % AR at day 7). The route of degradation in water/sediment systems of etofenprox is by hydroxylation to 4'-OH and further metabolised to EPMP. The active substance can also be degraded to α-CO and γ-CO and further to m-PB-acid or EPMP. It was also shown that there is a formation to mineralisation up to CO_2. Those metabolites were relevant in the environmental risk assessment (water and sediment compartment) in the CAR (AT, 2013) and hence were also taken into account in this dossier.

The route of degradation in the soil compartment was described by four different routes: Oxidation resulting in α-CO, hydroxylation of the benzene ring leading to 4'-OH, de-ethylation resulting in DE and cleavage of the ether linkage between the two benzene rings to give DP. None of the detected metabolites in the soil except CO_2 (38.2–45.6 %) and bound residues (42.8–54.5 %) exceeded 10 % AR. Etofenprox is not mobile in soil, it strongly adsorbs to soil particles and has a very low leaching potential.

The endpoints applied in the environmental risk assessment are summarised in the tables below.

Table 3.32 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment			
	Value	**Unit**	**Remarks***
	Etofenprox		
Fate and behaviour in the environment			
Molecular weight	376.47	g/mol	
Melting point	37.4 ± 0.1	°C	
Vapour pressure (at 25°C)	8.13E-07	Pa	
Water solubility (at 20°C)	0.0225 (bidist.water) 0.0052 (buffer pH 4) 0.012 (buffer pH 9)	mg/L	
Log Octanol/water partition coefficient (K_{ow})	6.9	Log 10	
Organic carbon/water partition coefficient (K_{oc})	28524	L/kg	Freundlich coefficient
Henry's Law Constant (at 25°C)	0.0136	$Pa/m^3/mol$	
Characterisation of biodegradability	not readily biodegradable	-	
Rate constant for STP	n.a.	h^{-1}	
Transformation fraction and maximum radioactivity	-	-	
DT_{50} for biodegradation in surface water	20.1	d (at 20ºC)	Whole system (water/sediment)
Transformation fraction and maximum radioactivity	-	-	
DT_{50} for hydrolysis in surface water	stable	d or h (at 12ºC /pH)	
DT_{50} for degradation in soil	22.8	d (at 12ºC)	
Transformation fraction and maximum radioactivity	-	-	
DT_{50} for degradation in air	6.2	hr	
DT_{50} for degradation in the sewer system	-	d or h (at 12ºC)	
DT_{50} for degradation in manure	-	d or h (at 12ºC)	

Predicted no effect concentrations (PNEC)			
Sewage treatment plant	2.25E-02	mg/L	*Based on a NOEC for respiration rate (set equal to the water solubility). The application of an assessment factor was not necessary.*
Surface water	5.4E-06	mg/L	*Based on three chronic studies and an assessment factor of 10. Daphnia are most sensitive.*
Marine water	-	mg/L	No studies with marine organisms are available. PNEC was not derived.
Sediment	6.3E-03	mg/kg wwt	*Based on a NOEC for reduced emergence rate and an assessment factor of 100.*
Marine sediment	-	mg/kg wwt	No studies with marine organisms are available. PNEC was not derived.
Soil	6.33E-03	mg/kg wwt	*Acute and chronic endpoints are available. Based on a $NOEC_{TWA}$ and an assessment factor of 50 (for further information refer to WGI-ENV-2016).*
Bird	33.3	mg/kg diet	Based on a NOEC from a reproduction study and an AF of 30.
Mammals	24.7	mg/kg diet	Based on a NOEC from a reproduction study and an AF of 30.

* The respective Assessment Report Etofenprox Product-type 18 (Insecticide) of 27th September 2013 is considered to provide the relevant data.
- not available

Table 3.33 Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment

Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment				
	Value		**Unit**	**Remarks***
	Metabolite 1 (α-CO in surface water)	**Metabolite 2 (4'-OH in sediment)**		
Fate and behaviour in the environment				
Molecular weight	390.5	392.5	g/mol	
Melting point			°C	
Vapour pressure (at 25°C)	3.02 x 10-7	6.8 x 10-9	Pa	
Water solubility (at 20°C)	0.0425	0.217	mg/L	
Log Octanol/water partition coefficient (K_{ow})	6.5	5.3	Log 10	
Organic carbon/water partition coefficient (Koc)	36870	11090	L/kg	
Henry's Law Constant (at 25°C)	1.14 x 10-3 3.93 x 10-3	2.38 x 10-7 1.71 x 10-7	Pa/m3/mol	acc. to AR Etofenprox 2013 Bond method (EPI Suite) Group method (EPI Suite)
Characterisation of biodegradability	-	-	-	
Rate constant for STP	-	-	h^{-1}	
Transformation fraction and maximum radioactivity	-	-	- %	
DT_{50} for biodegradation in surface water	-	-	d or h (at 12ºC)	
Transformation fraction and maximum radioactivity	-	-	-	
DT_{50} for hydrolysis in surface water	-	-	d or h (at 12ºC /pH)	
DT_{50} for degradation in soil	12-45	14-44	d (at 20ºC)	
Transformation fraction and maximum radioactivity	-	-	-	
DT_{50} for degradation in air	-	-	hr	
DT_{50} for degradation in the sewer system	-	-	d or h (at 12ºC)	
DT_{50} for degradation in manure	-	-	d or h (at 12ºC)	

Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment				
	Value		**Unit**	**Remarks***
	Metabolite 1 (α-CO in surface water)	**Metabolite 2 (4'-OH in sediment)**		
Predicted no effect concentrations (PNEC) ***[highlight in bold PNEC values derived from new endpoints]***				
Sewage treatment plant	-	-	mg/L	-
Surface water	4.4E-05	-	mg/L	*Based on an acute study with Daphnia magna and an assessment factor of 1000..*
Marine water	-	-	mg/L	No studies with marine organisms are available. PNEC was not derived.
Sediment	-	6.3E-03	mg/kg wwt	*Calculated according to the equilibrium partitioning method based on the PNECsw.*
Marine sediment	-	-	mg/kg wwt	No studies with marine organisms are available. PNEC was not derived.
Soil	-	-	mg/kg wwt	No major/relevant metabolite were detected in the soil degradation studies.
Bird	-	-	-	-
Mammals	-	-	-	-

* The respective Assessment Report Etofenprox Product-type 18 (Insecticide) of 27th September 2013 is considered to provide the relevant data.
- not available

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substance and available information for the non-active substances.

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substance was addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substances, refer to the respective section of the confidential annex.

3.8.2 Emission estimation

3.8.2.1 General information

Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario documents (OECD 2008, release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (ECHA 2017c,distribution in the environment), the Technical agreements for biocides (ECHA 2022) and the model SimpleTreat (concentrations for micro-organisms in the sewage treatment plant (STP) the STP's effluent) by using the default values for parameters, unless otherwise noted.

Release of active substance during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substance is added are disposed as solid waste and usually incinerated.

Emission to groundwater was assessed based on the substance's mobility in soils (K_{oc}) as described in the guidance. No higher tier modelling was deemed necessary.

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Compartments highlighted in bold are directly exposed.

Emission was calculated for each intended use based on the highest efficacious concentration, i.e. in-use concentration as specified in the SPC.

The risk assessment approach is summarised below.

Table 3.34 Environmental risk assessment

Environmental risk assessment					
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance(s)**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
[1]	Insecticide - adult ants – outdoor - non-professionals – pouring (100 % of the releases end up in soil)	OECD 2008, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008 ECHA 2022: Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021	Etofenprox: **0.1 g a.s./L/m²**	---	*[**Soil**]* *[Groundwater]*
[2]	Insecticide - adult ants – outdoor - non-professionals – scattering (100 % of the releases end up in soil)		Etofenprox: **0.08 g a.s./m²**	---	*[**Soil**]* *[Groundwater]*

The applicant has submitted an assessments for releases sent to sewers in a city environment, as was the case for the initial authorisation in Austria dated 13 September 2018 (Austria 2013).
Since professional use was not applied for this renewal of the product these assessments are no longer relevant according to Technical agreements for biocides entry 159 (ECHA 2022).
However, for the sake of completeness, the applicant's assessment for these scenarios are kept available in Appendix 4.1.3.

3.8.2.2 Emission estimation for the scenario(s)

For the environmental risk assessment, the relevant compartments for emissions have to be defined and an assessment of the potential residues in each area of importance has to be conducted. Emission Scenario Documents (ESDs) have been prepared for a number of product types, among them for products used as insecticides for household and professional uses (OECD 2008). The environmental risk assessment for the biocidal product Ameisen Streu- und Gießmittel PROX is based on this document.

The Emission Scenario Document for PT18 covers the following life-cycle steps as being potentially relevant for environmental emissions:

- Mixing/loading
- Application
- Releases from outdoor treated surfaces by weathering.

Ameisen Streu- und Gießmittel PROX is a ready to use product intended for the use against ant infestation around buildings (outdoors). The insecticidal product is supplied as ready to use granules which are applied on infested areas, or are to be dispersed in water and applied using a watering can.
The product is foreseen to be used on hard surfaces only – it must not be applied on soil.

Due to the characteristic of the active substance (non-volatile), emission to air is expected to be negligible. Therefore release to air is not calculated.

Due to this kind of formulation, the following release pathways can be excluded or identified to be relevant for environmental exposure:

Scenario 1 - Insecticide - adult ants – outdoor - non-professionals – pouring

- Mixing/loading
For the application of the dissolved product, the required amount of granular product is loaded from the package directly into a can and filled up with water, e.g. with the help of a garden hosepipe. According to the applicant considerable spillage of the granules is not anticipated due to the specific dosing insert the packaging is supplied with (please refer to Chapter 3.1 of this document).
However, spillage of the diluted product is possible according to the Emission Scenario Document for PT18, chapter 4.2.
When the product is only used outdoors, the mixing/loading step may be performed inside or outside a building nearby. In the present scenario, as worst case, it will be considered that when the product is applied outdoors, it is also prepared outside the building. In this case releases may occur directly onto the ground. The fate of the substance spilled on the ground depends on the location were the mixing/loading step is performed, i.e. either directly on unpaved soil or on hard surface like terraces. In the second case, insecticides will be washed with rain to the soil compartment around a terrace or to the rainwater/sewer system and reach the sewage treatment plant (STP). Releases can then occur to the surface water from STP discharge, to agricultural soil from sludge application and eventually to groundwater. The fractions of the product emitted on unpaved soil will eventually end up to groundwater.

Release to the STP or soil compartment around a terrace:
For the assessment of emission of Ameisen Streu- und Gießmittel PROX, this calculation is not applicable since the application area and the area, where the mixing and loading step is performed is identical (hard surface like terraces). Since the amount of product dispersed is intended to be applied completely during one treatment event, the quantity of product potentially released by spillage is already included in the calculation of emission during the application step.

Release directly onto unpaved ground:
Release of the product during the mixing and loading step might occur to an outdoor area of about 0.4 m^3. The fraction emitted to the ground is set at 20 L for an unspecific container volume of 5 liters (OECD 2008). This would result in 0.002 g a.s./0.4 m^3. However this amount can be neglected in comparison with the emissions calculated for the application step.

- Application and Weathering
The product Ameisen Streu- und Gießmittel PROX is used by non-professionals for the control of ants in close proximity to gardens and buildings, e.g. on terraces and pathways around houses. According to the Emission Scenario Document for PT18 it is proposed to assess two theoretical environments, one where 100 % of the releases end up in soil in a rural environment and another one where 100 % of the releases are sent to sewers in a city environment. However, according to Technical Agreements for Biocides entry 159, in case of non-professional use and spot application on paved surfaces like terraces no release to sewer/STP is assumed. Only releases to soil compartment around a terrace is considered relevant.

The specific application practice for Ameisen Streu- und Gießmittel PROX foresees pouring of the dissolved product on ant pathways or on nest entrances on hard surfaces only (on horizontal surfaces, e.g. terraces). The product must not be used for treatment on bar soil. Therefore, direct exposure of soil is only considered as a result of wash-off by rainfall from treated terraces after the application step. In view of the emission estimations of Ameisen Streu- und Gießmittel PROX by pouring the emission scenario for crawling insects (chapter 4.4.2.2 of the OECD 2008) is adopted, which proposes scenarios for the application step and further for wash-off of treated surfaces by rainfall.

Table 3.35 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Insecticide - adult ants – outdoor - non-professionals – pouring			
Quantity of product applied	0.01	kg/m²	
Fraction of active substance in the commercial product	0.01	–	
Area of surface (OECD: foundation) treated	1.5	m²/d	**Already accepted in the PAR (2018):** Adaption of the Emission Scenario Document for PT18 (OECD 2008) assumption is made. The typical area that is treated for ant control is adapted to 1.5 m² as treatment is only required for restricted infested zones.
Fraction emitted to soil during outdoor foundation pouring (OECD: spray) application	0.3	–	
Fraction emitted to soil by wash-off	0.5	–	

Calculations for Scenario 1 - Insecticide - adult ants – outdoor - non-professionals – pouring

Emission from outdoor pouring application on terraces are calculated according to Emission Scenario Document for PT18 as follows:

$$E_{spray,terrace} = Q_{prod} \times F_{AI} \times AREA_{treated} \times F_{spray,terrace}$$
$$=0.000045 \text{ kg/d}$$

Local emission from outdoor spray application on terrace due to wash-off are calculated according to Emission Scenario Document for PT18 as follows:

$$E_{spray,terrace,wash\text{-}off} = AREA_{treated} \times Q_{prod} \times F_{AI} \times F_{spray,wash\text{-}off}$$
$$= 0.000075 \text{ kg/d}$$

During pouring application on hard surfaces, a fraction of the solution actually applied on the surface may eventually reach the soil via run-off. It is assumed that 70 % of the product applied remains on the surface after application.
The quantity of substance that is washed off by rainfall is dependent to some extent on the type of surface that is treated (e.g. concrete, cement, tiles). It is assumed that 50 % of the applied substance is washed off the surface during the first rain event.

Total emissions (application plus wash-off) are calculated according to Emission Scenario Document for PT18, equation 51, as follows:

$$E_{spray,crawlinginsects} = E_{spray,terrace} + E_{spray,terrace,wash\text{-}off}$$

Note: The parameter "$E_{spray,soil}$" (see OECD 2008, equation 51) is omitted here, since it describes direct spraying to soil (soil treatment), which is not relevant for the pouring application onto terraces for Ameisen Streu- und Gießmittel PROX.

$$E_{spray,crawlinginsects} = Elocal_{soil,washoff} = 0.00012 \text{ kg/d}$$

Table 3.36 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	-	No direct release in this sub-scenario considered.
Freshwater	-	No direct release in this sub-scenario considered.
Seawater	-	No direct release in this sub-scenario considered.
Air	-	No direct release in this sub-scenario considered.
Soil	0.00012	

Scenario 2 - Insecticide - adult ants – outdoor - non-professionals – scattering

- Mixing/loading
Ameisen Streu- und Gießmittel PROX represents a ready to use granular formulation. Mixing and loading is therefore not necessary. The granules are coarse and nearly dust-free. In addition, the vapour pressure of etofenprox is low with 8.13×10^{-7} Pa (at 25°C) so that exposure to vapours can be ruled out. An exposure of environmental compartments during this life-cycle step is therefore considered not relevant.

- Application and Weathering
As discussed above (scenario 1) the Emission Scenario Document for PT18 proposes to assess two theoretical environments, one where 100 % of the releases end up in soil in a rural environment and another one where 100 % of the releases are sent to sewers in a city environment. However, according to Technical Agreements for Biocides entry 159, in case of spot application on paved surfaces like terraces only direct emission to soil as a result of wash-off by rainfall is considered relevant.

Application of the granular biocidal product onto ant nest entrances is comparable to "spot application" as identified in the Emission Scenario Document for PT18, chapter 4.3.4.1. It is acknowledged that an emission scenario is specified for spot application of granules and powders in the Emission Scenario Document for PT18. Emission factors are associated with this scenario, and model formulae for calculating active substance concentrations in the receiving compartments are given. The dimensions of the receiving compartment are defined in the Emission Scenario Document for PT18 by Figure 4.3-6.
The Emission Scenario Document for PT18 supposes a soil cube of 1/8 m³ under the application spot, to which the biocidal product is released.
Such a scenario is considered not suitable for the application of Ameisen Streu- und Gießmittel PROX on ant nest entrances for the following reasons: *(1) The "application spot" and the "receiving compartment", as specified in the ESD, are in this specific case the same and cannot be distinguished. When the spot "ant nest entrance" is treated, the biocidal product is intended to be released to that area designated as "receiving compartment" in the ESD by the ants, being the restricted area that is harbouring the nest below the application spot. Therefore, the "receiving compartment" cannot be identified, as it is defined as the target application site itself (the nest). (2) The spatial scale of the "receiving compartment" as defined in the ESD is extremely small. With respect to the protection targets of an environmental risk assessment, i.e. local populations and their ecological function, the relevant soil volume surrounding the target application site is negligible; (3) with particular reference to the previous argument, it is important to consider that etofenprox is relatively quickly degraded in soil with a DT_{50} of 22.8 days under standard European conditions (12°C). Therefore, longstanding pollution need not be expected.*
In addition, the product application is limited to infested hard surfaces areas, e.g. terraces. These areas are typically adjoining or close to inhabited buildings. The soil below the hard surfaces cannot be considered as a natural environment. Therefore direct exposure of soil is considered as a result of wash-off by rainfall from the treated (hard) surfaces after the application step.
In view of the emission estimations of Ameisen Streu- und Gießmittel PROX by scattering the emission scenario for crawling insects (chapter 4.4.2.2 of the OECD 2008) is used, which proposes scenarios for the application step and further for wash-off of treated surfaces by rainfall.

Table 3.37 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: Insecticide - adult ants – outdoor - non-professionals – scattering			
Quantity of product applied	0.008	kg/m²	
Fraction of active substance in the commercial product	0.01	–	
Area of surface (OECD: foundation) treated	1.5	m²/d	**Already accepted in the PAR (2018):** Adaption of the Emission Scenario Document for PT18 (OECD 2008) assumption is made. The typical area that is treated for ant control is adapted to 1.5 m² as treatment is only required for restricted infested zones.
Fraction emitted to soil by wash-off	0.9	–	**Already accepted in the PAR (2018):** The quantity of substance applied is not reduced via run-off. In line with the Emission Scenario Document for PT18 (spot application), it is considered that the fraction released during powder application to the environment is 90 %.

<u>Calculations for Scenario 2- Insecticide - adult ants – outdoor - non-professionals – scattering</u>

In this case only emission to the soil due to wash-off was considered to be relevant, since emission of a solid substance via run-off is negligible. It is assumed that 90 % of the applied granulate is washed off the surface during the first rain event.

Local emission from outdoor application on terrace due to wash-off are calculated according to Emission Scenario Document for PT18 as follows:

$$\mathbf{E_{spray,terrace,wash\text{-}off} = Elocal_{soil,washoff} = AREA_{treated} \times Q_{prod} \times F_{AI} \times F_{spray,wash\text{-}off}}$$
$$\mathbf{= 0.0001\ kg/d}$$

Table 3.38 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	-	No direct release in this sub-scenario considered.
Freshwater	-	No direct release in this sub-scenario considered.
Seawater	-	No direct release in this sub-scenario considered.
Air	-	No direct release in this sub-scenario considered.
Soil	0.0001	

3.8.3 Exposure calculation and risk characterisation

The predicted environmental concentration in the receiving soil as a result of wash-off to soil by rainfall ($PEClocal_{soil,washoff}$) is calculated based on 4.25 m³ soil volume (adaption of the Emission Scenario Document for PT18 (OECD 2008) assumption for $V_{soil,washoff}$ is made).

The PEC of etofenprox in the receiving soil around treated terraces is estimated as follows:

Calculation of the concentration in the receiving soil as a result of wash-off to soil by rainfall			
Parameter	**Definition**	**Scattering**	**Pouring**
Emission from outdoor application on terraces [kg/d]	$Elocal_{soil,washoff}$	0.0001	0.00012
Soil volume for wash-off at [m³]	$V_{soil,wash-off}$	4.25	
Bulk density of wet soil [kg/m³]	RHO_{soil}	1700	
Concentration in the receiving soil as a result of wash-off to soil by rainfall [mg/kg$_{wwt}$]	**$Clocal_{soil,washoff}$ = $Elocal_{soil,washoff}$ / ($V_{soil,washoff}$ × RHO_{soil})**	**0.0138**	**0.0166**

Groundwater (Scenario 1 and 2):
According to the Guidance on the BPR: Volume IV Environment (Parts B+C) (ECHA 2017c), the concentration of a substance in groundwater is equivalent to the concentration in the pore water of the potentially affected soil volume.
The concentration in pore water can be calculated assuming simple adsorption processes following the Guidance on the BPR:

$$PEClocal_{porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{k_{soil-water} \times 1000}$$

With:

$$k_{soil-water} = F_{water,soil} + F_{solid,soil} \times \frac{k_{p,soil}}{1000} \times RHO_{solid}$$

$$k_{p,soil} = F_{OC,soil} \times k_{OC} = 0.02 \times 28524 = 570.48$$

Accordingly, $k_{soil\text{-}water}$ is calculated as 855.92, and

$PEClocal_{porewater}$ = 0.028 µg/L (Scattering); 0.033 µg/L (Pouring)

Table 3.39 Summary table of PNEC, PEC and PEC:PNEC values

Summary table of PNEC, PEC and PEC:PNEC values	
	Active Substance
PNEC values	
PNECstp (mg/L)	2.25E-02
PNECwater (mg/L)	5.4E-06
PNECsed (mg/kg wwt)	6.3E-03
PNECsoil (mg/kg wwt)	6.33E-03
SCENARIO 1	
PEC values	
PECair	-
PECstp(mg/L)	-
PECwater (mg/L)	-
PECsed (mg/kg wwt)	-
PECsoil (mg/kg wwt)	1.66E-02
PECgw(μg/L)	3.3E-2
PEC/PNEC values	
PEC/PNECstp	-
PEC/PNECwater	-
PEC/PNECsed	-
PEC/PNECsoil	**2.62E+00**
SCENARIO 2a	
PEC values	
PECair	-
PECstp(mg/L)	-
PECwater (mg/L)	-
PECsed (mg/kg wwt)	-
PECsoil (mg/kg wwt)	1.38E-02
PECgw(µg/L)	2.8E-2
PEC/PNEC values	
PEC/PNECstp	-
PEC/PNECwater	-
PEC/PNECsed	-
PEC/PNECsoil	**2.18E+00**

Atmosphere

Conclusion: In view of the physicochemical properties of all components of the biocidal product, and the use of the biocidal product, emissions of etofenprox to air are regarded to be insignificant. The low reported vapour pressure with 8.13E-07 Pa and Henry Law of 0.0136 Pa.m^3/mol for the active substance etofenprox indicating a low potential being harmful to the air compartment (Austria, 2013). Furthermore the calculated half-life for etofenprox with 6.2h is below the trigger of 2 days which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere (Austria. 2013). Thus, the PEC of etofenprox in air is considered to be negligible and no risk is conceivable for the atmosphere.

Sewage treatment plant (STP)

Emissions to the STP compartment were not considered as relevant (please refer to chapter 3.8.2 Emission estimation).

Aquatic compartment

Emissions to the aquatic compartment (surface water and sediment) were not considered as relevant (please refer to chapter 3.8.2 Emission estimation).

Terrestrial compartment

The risk characterisation for the terrestrial compartment was calculated for direct exposure to soil.

The PEC/PNEC values for the direct exposure to soil (pouring and scattering) are >1 indicating an unacceptable risk for terrestrial organisms.

Conclusion:

In order to reduce the risk of the terrestrial compartment to an acceptable level the following risk mitigation measures shall be applied:

N-119 modified: ”**Apply only on hard surface under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water** ”.

“**To reach nests located under terraces, pour the product carefully in cracks and crevices or between tiles seals and avoid run off of product to surrounding soil”.**

Groundwater

Conclusion:

Applying worst case assumptions the PEC values in groundwater for direct exposure to soil were estimated at 0.033 µg/L and 0.028 µg/L for pouring and scattering, respectively (refer

to Summary table of PNEC, PEC and PEC:PNEC values).
The generic groundwater limit value is 0.1 µg/L. The predicted concentrations of etofenprox in groundwater hence fall below the official limit value. An acceptable risk for groundwater is therefore demonstrated.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

Non-target animals are potentially at risk in two ways: a) from direct consumption of a biocidal product (primary poisoning) or b) through eating organisms that have taken up/accumulated a poison (secondary poisoning).

Primary poisoning

The direct consumption of Ameisen Streu- und Gießmittel PROX by non-target organisms is unwanted but conceivable, in particular for the ready to use product (granular formulation). Contrary to Ameisen Streu- und Gießmittel PROX in solution the ready to use product that is scattered from the package directly onto the ant nest entrance or on hard surface (e.g. terrace, sidewalk) may be consumed by non-target animals e.g. mice or birds.
For the application by pouring of the aqueous solution the potential exposure is limited to a short time as the liquid is evaporated or infiltrating the target location (ant's nest entrance). Because of the use instruction "Please ensure that no puddles form on the ground." only the possibility of poisoning via consumption of the granular formulation is contemplated in the following. Therefore, a risk assessment for primary poisoning via consumption of the granular formulation was evaluated for bees, birds and mammals.

Primary poisoning bees

Etofenprox is highly toxic to bees. Technical etofenprox highlights a 96h acute oral LD_{50} value of 0.0238 µg etofenprox/bee and a 72h contact LD_{50} of 0.0145 µg a.s./bee (Austria, 2013). As the product is also used outdoor and since the $LD50_{contact}$ for honeybees for etofenprox is below the discussed and agreed threshold of 11 µg/bee (for further details refer to the final minutes of ENV WG-III 2021) the warning sentence "This biocidal product contains etofenprox which is dangerous to bees" (in line with CA-Dec20-Doc.4.1_rev2 and ENV TAB 244) will be included in the SPC section 6. The warning sentence is an interim solution until the ECHA guidance for bees becomes available.

However, the product Ameisen Streu- und Gießmittel PROX gets applied very locally and spot wise into or directly around ant nest entrances on hard surfaces. This is a limited area and only forager bees could be affected and not the whole colony. On the population level the risk for bees is therefore not considered significant.

The exposure risk for consumption of the granular formulation for bees can be considered not relevant due to its small scale application. Furthermore the granule formulation will not be applied on soil covered with plants or flowering plants and the ants will quickly begin to carry the product into the nest to make them inaccessible.
For the application by pouring of the aqueous solution the potential exposure is also limited to a short time as the liquid is evaporated or infiltrating the target location (ant's nest entrance). Furthermore a use specific instruction "Please ensure that no puddles form on the ground." shall be applied in the SPC.

To protect bees and other pollinators from moist sugar granules mixed with an insecticide, the following sentence has been inserted in the use instructions: "To protect bees and other pollinators, cover bait granules, for example with a flower pot or tile."

Conclusion:

The exposure to bees and other pollinators can be considered negligible due to the small-scale application in time and space and if the use instructions/proposed RMMs on the label are followed.

Primary poisoning birds and mammals

Primary poisoning, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases according to the Emission Scenario Document for PT18 (OECD 2008):

- Insecticides are applied together with food attractant, or
- Insecticides are applied as granular formulation.

The latter is the case in Ameisen Streu- und Gießmittel PROX.

As recommended in the Emission Scenario Document for PT18, for granular insecticides, if granules are based on an organic carrier having a nutritional value then the emission scenario document for biocides used as rodenticides (ESD for PT 14) is applying for the calculation of the risk for primary poisoning.
In compliance with the ESD for PT14 the estimated theoretical exposure (ETE) for direct consumption of granular formulation may be calculated using the following equation:

ETE =(FIR/bw) x C x AV x PT x PD

Ameisen Streu- und Gießmittel PROX contains 10 g etofenprox per kg, thus the value for C is 10000 mg/kg. Default values for bodyweight and mean food intake were taken from the ESD for PT 14 (cf. Table below). In a first tier the ETE values are calculated assuming the standardised worst-case scenario for the rest of the parameters.

For birds the PT-value (Tier 2) is refined considering that birds are highly mobile and feed small portions on diverse places all over their habitat. Based on the assumption that 50 % of the diet/grit comes from a local and 50 % of the diet comes from a regional area the PT-value for birds is set at 0.5.

Calculation of the estimated theoretical exposure (ETE) for direct consumption of granular formulation								
Parameter	**Definition**	**Value**						
		Dog	**Pig**	**Pig, young**	**Tree sparrow**	**Chaffinch**	**Woodpigeon**	**Pheasant**
Concentration of active substance in fresh diet [mg x kg^{-1}]	C	10000			10000			
Food intake rates [g x d^{-1}]	FIR	12*	12*	12*	7.6	6.42	53.1	102.7
Body weight [g]	bw	10000	80000	25000	22	21.4	490	953
Avoidance factor (AV=1, no avoidance) [-]	AV	1			1			
Proportion of diet obtained in treated area [-]	PT	1			Tier 1: 1 Tier 2: 0.5			
Proportion of food type in the diet [-]	PD	1			1			
Estimated theoretical exposure [mg x kg_{bw}^{-1}x d^{-1}]	**ETE =C x (FIR/bw) x AVx PT x PD**	**12**	**1.5**	**4.8**	Tier 1: 3455 Tier 2: **1727.5**	Tier 1: 3000 Tier 2: **1500**	Tier 1: 1084 Tier 2: **542**	Tier 1: 1077 Tier 2: **538.5**

* For the calculation 12 g granules was used assuming a treatment of 1.5 m² per terrace at a rate of 8 g/m².

Summary table of estimated theoretical exposition (ETE)			
		ETE (Tier 1)	**ETE (Tier 2)***
		[mg/kg*d^{-1}]	[mg/kg*d^{-1}]
All scenarios	Dog**	12	-
	Pig**	1.5	-
	Pig, young**	4.8	-
	Tree sparrow	3455	1.727.5
	Chaffinch	3000	1500
	Woodpidgeon	1084	542
	Pheasant	1077	538.5

* For birds the PT-value (Tier 2) is refined considering that birds are highly mobile and feed small portions on diverse places all over their habitat. Based on the assumption that 50 % of the diet/grit comes from a local and 50 % of the diet comes from a regional area the PT-value for birds is set at 0.5.

** For the calculation 12 g granules was used assuming a treatment of 1.5 m² per terrace at a rate of 8 g/m².

Summary table on calculated ETE/LD50 values for Ameisen- Streu und Gießmittel PROX primary poisoning birds and mammals							
LD_{50} mammals [mg/kg bw] >2000 mg				LD_{50} birds [mg/kg bw]: >2000 mg			
	Dog	**Pig**	**Young Pig**	**Tree sparrow**	**Chaffinch**	**Wood-pigeon**	**Pheasant**
ETE/LD50 Tier 1	6E-3	7.5E-4	2.4E-3	**1.72**	**1.5**	0.54	0.54
ETE/LD50 Tier 2	Tier 2 not calculated			0.86	0.75	0.27	0.27

The calculated PEC/LD_{50} ratios for all calculated mammal species and the bird species woodpigeon and pheasant are below 1 indicating an acceptable risk for primary poisoning.

The PEC/LD_{50} values for the smaller bird species tree sparrow and chaffinch (Tier 1) are >1, indicating unacceptable risk. However, birds are highly mobile species and the assumption that 100 % of their daily food originates from only one local scale can be considered to be an overestimation. Therefore a refinement (Tier 2) for those two bird species was calculated (assuming that 50 % of the daily food is obtained in the treated area) which results in PEC/LD_{50} values <1, indicating acceptable risk. The assumption of the Tier 2 is more realistic. In addition, small bird species which are characteristic of the lawn/garden, have mixed diet, this fact will reduce the risk further.

Furthermore, the toxicity data are "greater than" values (oral LD_{50} ≥2000 mg/kg (mallard duck). At the highest concentration tested no mortality was observed and it was not possible to determine a LD_{50} value. Only one bird out of 40 died in the tested group 2 (at the dose level of 320 mg/kg active substance), all other surviving birds remained in apparent good health throughout the study. Therefore, the mortality rate can be expressed as 2.5 %. The validity criteria state that the mortality in the control group should not exceed 10 % at the end of the test. For this reason the mortality is statistical not significant and as it occurs at the lowest dose tested, the effect is not dose related, too. Thus it can be concluded that no effects could be determined in the acute toxicity test with birds and the value can therefore be considered a NOEC value.

Conclusion:
The risk estimation for mammals and larger bird species indicates an acceptable risk for primary poisoning. The risk of primary poisoning also shows a safe use even for small bird species when the toxicity data are well interpreted (oral NOEC 2000 mg/kg) and the mobility of small birds in general, the proportion of ants in the food of bird species which are characteristic for the lawn/garden, and the application in limited proportions on a small scale are taken into account.

3.8.4.2 Secondary poisoning

The Emission Scenario Document for PT18 (OECD 2008) states that during the outdoor use of insecticides, the most important route of exposition is the intake of contaminated feed. Non-target animals have potentially a risk of secondary poisoning in the following ways:

(1) By consumption of worms from contaminated soil,
(2) By consumption of contaminated vegetation and
(3) Through eating treated insects that have ingested the poison.

In consideration of the intended use of the product Ameisen Streu- und Gießmittel PROX the assessment of secondary poisoning via consumption of contaminated insects (ants) or earthworms is carried out (i.e. calculation of ETE for (1) and (3)). A risk for secondary poisoning by consumption of contaminated vegetation is not considered applicable for scattering or pouring applications of insecticides.

Secondary poisoning by contaminated feed (earthworms)

Mammals and birds may consume contaminated worms. The assessment of secondary poisoning via the consumption of worms was calculated by the applicant according to the Guidance on the BPR: Volume IV Environment (Parts B+C) (ECHA 2017c).
As input parameter the concentrations in the receiving soil compartment as a result of wash-off by rainfall are included as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. A reduction of the concentrations in soil or pore water due to use of the biocide on a limited area was not considered. For calculating the bioconcentration factor, an octanol/water partition coefficient of log K_{ow} = 6.9 was taken.

Calculation of the predicted environmental concentration in earthworms			
Parameter	**Definition**	**Scattering**	**Pouring**
Local concentration in soil [mg/kg_{wwt}]	$PEClocal_{soil}$	0.0138	0.0166
Octanol/water partition coefficient [-]	K_{ow}	7943282	
Density of earthworm [kg_{wwt}/L]	$RHO_{earthworm}$	1	

Bioconcentration factor for earthworm on wet weight basis [$L/kg_{wet\ earthworm}$]	$BCF = (0.84 + 0.012\ K_{ow})/RHO_{earthworm}$	95320	
Fraction of gut loading in worm [kg/kg]	F_{gut}	0.1	
Conversion factor for soil concentration wet-dry weight soil [kg_{wwt}/kg_{dwt}]	$CONV_{soil}$	1.133333	
Predicted Environmental Concentration in pore water [mg/L]	$PEClocal_{soil,porewater}$	0.000028	0.000033
Predicted Environmen-tal Concentaration in earthworms [$mg/kg_{wet\ earthworm}$]	$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut}\ x\ CONV_{soil}}{1 + F_{gut}\ x\ CONV_{soil}}$	**2.40**	**2.83**

According to the ESD for PT 18, for direct emissions to soil the $C_{earthworm}$ has to be replaced by the estimated theoretical exposure (ETE). For the assessment of secondary poisoning via the consumption of contaminated worms, ETE may be calculated using the following equation:

$ETE = C \times (FIR/bw) \times AV \times PT \times PD$

For the food chain from earthworm to earthworm-eating birds and mammals, it is considered that estimated residues in earthworms should be converted to daily dose by multiplying with 1.4 and 1.1 for mammals and birds respectively.

In a first tier the ETE values are calculated assuming the standardised worst-case scenario for the rest of the parameters.

Calculation of the estimated theoretical exposure (ETE) for earthworm-eating mammals and birds				
Parameter	**Pouring**		**Scattering**	
	Mammals	**Birds**	**Mammals**	**Birds**
Predicted Environmental Concentration in earthworms [mg x kg^{-1}]	2.83		2.40	
Food intake rates per body weight [d^{-1}]	1.4	1.1	1.4	1.1
Avoidance factor of contaminated food (AV=1, no avoidance) [-]	1		1	
Proportion of diet obtained in treated area [-]	1		1	
Proportion of food type (vegetation or insects) in the diet of specie of concern [-]	1		1	
Estimated theoretical exposure [mg x kg_{bw}^{-1}x d^{-1}]	**3.96**	**3.11**	**3.36**	**2.64**

Secondary poisoning by contaminated feed (ants)

For insectivorous species, the estimated theoretical exposure (ETE) is calculated. The ETE corresponds to the PEC_{oral} per day. The theoretical exposure of vertebrates is a function of the estimated concentration of the insecticide found in food sources of insectivorous birds

and mammals. Concentrations in insects (i.e. ants) are derived from the exposure scenario established for plant protection products in the EU (EC, 2002[4]).
In table 5.2-1 of the ESD for PT 18 insectivorous mammals are always assumed to eat large insects. Therefore an assessment for mammals is not considered applicable. Small birds are assumed to prefer small insects, so the residues for small insects are the default values in the case of birds in order to cover the worst case.

The total application rate of biocidal product per square meter was calculated for the treatment of 1.5 m² on a terrace with a size of 30 m² by scattering and pouring with 8 g/m² or 10 g/L/m² biocidal product, respectively.

In a second step, the concentration of etofenprox in fresh diet is assessed for acute and short-term exposure, and the estimated theoretical exposure is calculated for the corresponding indicator species (insectivorous birds).

According to the guidance document table 5.2-7 typical residues in contaminated small insects are 52 mg/kg wet weight for the acute situation and 29 mg/kg wet weight for the short term toxicity assessment. Food intake rates per body weight for small insectivorous birds of 1.04 and 0.2 are listed in the table.

They have to be multiplied by the actual application rate (T_{appl}) to obtain the concentration per wet weight.

In a first tier the ETE values are calculated assuming the standardised worst-case scenario for the rest of the parameters.

[4] European Commission, 2002: Guidance document on risk assessment for birds and mammals under council directive 91/414/EEC; SANCO/4145 2002

Calculation of the etofenprox concentration in the fresh diet					
	Definition	**Scattering**		**Pouring**	
		Acute	**Short-term**	**Acute**	**Short-term**
Application rate [kg x m^{-2}]	T_{appl}	0.4E-5		0.05E-5	
Residue per unit dose [mg x kg^{-1}]	RUD	52	29	52	29
Predicted environmental concentration in ants [mg × kg^{-1}]*	**C_{ant} =RUD x T_{appl} x 10^{-4}**	**2.1E-8**	**1.2E-8**	**2.6E-8**	**1.45-8**
Food intake rates per body weight-Small insectivorous bird I [d^{-1}]	FIR /bw	1.04		1.04	
Food intake rates per body weight- Small insectivorous bird II [d^{-1}]	FIR /bw	0.2		0.2	
Avoidance factor of contaminated food (AV=1, no avoidance) [-]	AV	1		1	
Proportion of diet obtained in treated area [-]	PT	1		1	
Proportion of food type (vegetation or insects) in the diet of specie of concern [-]	PD	1		1	
Estimated theoretical exposure- Small insectivorous bird I (e.g. Wren) [mg x kg_{bw}^{-1}x d^{-1}]	**ETE =C_{ant} x (FIR/bw) x AV x PT x PD**	**2.2E-8**	**1.25E-8**	**2.7E-8**	**1.5E-8**
Estimated theoretical exposure- Small insectivorous bird II (e.g. Tree sparrow) [mg x kg_{bw}^{-1}x d^{-1}]		**4.02-9**	**2.4E-9**	**5.2E-9**	**2.9E-9**

Table 3.40 Summary table of secondary poisoning

Summary table of secondary poisoning				
Scenario	**Concentration in compartment [mg/kg$_{wwt}$]**	**PEC$_{oral\ predator}$ [mg/kg diet]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
Secondary poisoning via contaminated ANTS				
Scenario 1a: Pouring acute toxicity	1.66E-02	2.6E-08	7.8E-10	-
Scenario 1a: Pouring short term toxicity	1.66E-02	1.45E-08	4.35E-10	-
Scenario 2a: Scattering acute toxicity	1.38E-02	2.1E-08	6.3E-10	**-**
Scenario 2a: Scattering short term toxicity	1.38E-02	1.2E-08	3.6E-10	**-**
Secondary poisoning via contaminated EARTHWORMS				
Scenario 1a: Pouring	1.66E-02	2.83	0.08	0.11
Scenario 2a: Scattering	1.38E-02	2.4	0.07	0.09

Conclusion:

The calculated PEC/PNEC values for the ingestion via contaminated earthworms for vertebrates are <1 indicating an acceptable risk for secondary poisoning via earthworms.

The PEC/PNEC values for secondary poisoning via contaminated ants are <<1 indicating acceptable risk for secondary poisoning of mammals and birds via contaminated ants.

3.8.5 Mixture toxicity

3.8.5.1 Screening step

Screening Step 1: Identification of the concerned environmental compartments

An exposure is likely to the following compartments: soil (direct) and groundwater (indirect).

Screening Step 2: Identification of relevant substances

Only the active substance etofenprox is relevant for mixture toxicity.

Screening Step 3: Screen on synergistic interactions

Synergistic effects of the active substance etofenprox and the co-formulants are not expected.

Table 3.41 Screening step

Screening step	
1	Significant exposure of environmental compartments? Y
2	Number of relevant substances >1? N
3	Indication for synergistic effects for the product or its constituents in the literature? N

Conclusion:

A mixture toxicity assessment is not relevant according to the outcome of the screening steps.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Guidance is still under development.

It is considered that an assessment of aggregated exposure is not relevant with regard to overlap in time and space based on the decision scheme included in the Guidance on BPR: Vol IV Environment (Parts B+C).

3.8.7 Overall conclusion on the risk assessment for the environment

Table 3.42 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1	Insecticide - adult ants – outdoor - non-professionals – pouring	Acceptable with further restriction or risk mitigation measures (RMM)	N-119 modified: Apply only on hard surface under a roof on areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water. To reach nests located under terraces, pour the product carefully in cracks and crevices or between tiles seals and avoid run off of product to surrounding soil.
2	Insecticide - adult ants – outdoor - non-professionals – scattering	Acceptable with further restriction or risk mitigation measures (RMM)	N-119 modified: Apply only on hard surface under a roof on in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. To protect bees and other pollinators, cover bait granules, for example with a flower pot or tile, ensuring that the ants still get access to the bait.

[1] Use numbers in accordance with the list of all uses indicated under section 2.2.
[2] Title of the specific use, as indicated in the SPC
[3] The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2.

3.9 Assessment of a combination of biocidal products

The biocidal product Ameisen Streu- und Gießmittel PROX is not intended to be used with other biocidal products.

3.10 Comparative assessment

Background
The biocidal product "Ameisen Streu- und Gießmittel PROX" contains the active substance etofenprox, which meets the criteria for substitution pursuant to Article 10 (1) of the Biocides Regulation (EU) No 528/2012 (BPR) and thus it becomes a candidate for substitution (CFS). Etofenprox is considered to be bioaccumulative and toxic. Therefore it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006. Consequently, in line with Article 23(1) of the Biocides Regulation the Austrian Competent Authority has performed a comparative assessment for the biocidal product „Ameisen Streu- und Gießmittel PROX", based on the „Technical Guidance Note on comparative assessment of biocidal products" (CA-May15-Doc.4.3.a).

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 12th May 2023), accessible on http://www.biozide.at/, which is maintained by the Environment Agency Austria („Umweltbundesamt GmbH") on behalf of the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology („BMK"). This was done due to the lack of a tool in the current version of R4BP3 to search SPCs, pursuant to the „Technical Guidance Note on comparative assessment of biocidal products" (CA-May15-Doc.4.3.a).

Authorised uses for the relevant biocidal product in the application
The biocidal product „Ameisen Streu- und Gießmittel PROX" belongs to product type 18 and contains the active substance etofenprox. "Ameisen Streu- und Gießmittel PROX" is an insecticidal product to be used by non-professional users for the control of black ants (*Lasius niger;* adults forager) in areas around buildings where they interfere with the interests of homeowners. The water dispersible granules may be used as dry granules by scattering or by pouring with a watering can after dilution in water.

Use1: Pouring

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Scientific name: Formicinae: *Lasius sp.* Common name: Black ants Development stage: Adults, forager
Field of use	Outdoor Outdoor use around buildings in private areas on sheltered hard surfaces (e.g. sheltered terraces).
Category(ies) of users	General public (non-professional)
Application method(s)	Method: Pouring Detailed description: Pouring of an aqueous solution of the granules (10 g/L) on ant nest entrances on sheltered hard surfaces (e.g. terraces).

Use 2: Scattering

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Scientific name: Formincinae: *Lasius sp.* Common name: Black ants Development stage: Adults, forager
Field of use	Outdoor Outdoor use around buildings in private areas on sheltered hard surfaces (e.g. sheltered terraces).
Category(ies) of users	General public (non-professional)
Application method(s)	Method: Scattering Detailed description: Scattering of the ready to use granules into or directly around ant nest entrances on sheltered hard surfaces (e.g. terrace)

Summary of the authorised uses:
PT18: Insecticide – *Lasius niger* (adults, forager) – outdoor use around buildings in private areas – pouring/scattering – general public (non-professional)

As stated in CA-May15-Doc.4.3.a – Final, elements 1 to 5 in the table above should be considered as the critical ones. But the AT CA mentions, that in (33) of Note for Guidance it is stated that, if an *„eCA considers that an application method makes that the BP is used in practice for very different purposes or under very different circumstances […], some application methods could be considered as separate uses to be covered under the comparative assessment."* Furthermore, according to (57) *„at least three different and independent active substances/mode of action combinations should remain available through authorised BPs for a given use […] in order to consider that the chemical diversity is adequate."*
Therefore the application method might be taken into consideration as the exposure differs depending on the application methods.

Mapping of existing alternatives to the relevant biocidal product in Austria:

Identified eligible alternative biocidal products:

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 12th May 2023), as already mentioned above.

Note: Biocidal products based on CFS are not considered eligible alternatives. Meaning, that authorised biocidal products in AT based on imidacloprid, lambda-cyhalothrin, spinosad, fipronil, 1R-trans-phenothrin, permethrin, etofenprox and lambda cyhalothrin are excluded from further steps in this comparative assessment.

Only biocidal products authorised for non-professional control of *Lasius niger* are taken into account in the next steps.
According to the information available for non-professional use against the relevant target organism five products based on deltamethrin, two products based on alpha-cypermethrin,

and one product based on silicion dioxide as well as one product based on a combination of transfluthrin, cyfluthrin and piperonyl butoxide are authorised.

The biocidal products based on alpha-cypermethrin are not considered to be eligible alternatives, as both are for indoor use of animal housings each.

The biocidal product based on the combination of active substances (transfluthrin, cyfluthrin and piperonyl butoxide) is for indoor use only and is therefore not an eligible alternative either.

Two out of the five biocidal products based on deltamethrin are for indoor use only as well.

So just four biocidal products based on 2 active substances (3 deltamethrin and one silicon dioxide) remain as eligible alternatives: "Blattanex Ungeziefer & Ameisenfrei", "Spezial Pumpspray", „Blattanex Ameisen & Ungeziefer Staub", and "InsectoSec BPF Biofa".

Taking into account the above mentioned information it becomes evident, that chemical diversity of active substances in authorised biocidal products for the control of the relevant target organisms in order to minimise the occurrence of resistance **is not given yet.**

Identified eligible non-chemical alternatives

Eligible non-chemical alternatives are non-chemical means of control and prevention methods. These should already exist on the EU market and the eCA, on basis of the available information, considers that there is robust evidence that the alternative does not give rise to concern in terms of safety for humans, animals or the environment and has demonstrated sufficient effectiveness under field conditions.

According to the AT CA, there are no known non-chemical alternatives.

3.10.1 Screening phase

Description of the assessment of the adequate chemical diversity in authorised biocidal products to minimise the occurrence of resistance and conclusion.

Chemical diversity
Article 23(3)(b) BPR 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 authorised biocidal products is adequate to minimise the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As proposed as general rule in "CA-May15-Doc.4.3.a" at least three different and independent active substance/mode of action - combinations should be available through authorised biocidal products for a given use to provide adequate chemical diversity as stipulated by Article 23(3)(b) BPR.

Mode of action:
Etofenprox belongs to the phenylpyrazole chemical family. It is an insecticide acting by direct contact and ingestion. The mode of action is disrupting the insect central nervous system by blocking GABA-gate chloride channels and glutamate-gated chloride (GluCl) channels. So

the toxic properties of etofenprox are based on its effect on sodium channels in the insect's nervous system resulting in knock-down or death of the target organism.

Note: Deltamethrin also acts via disturbance of neuro-transmittance by effecting the sodium channels.

Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but can benefit from derogation in accordance with Article 5(2) of the BPR

The active substance etofenprox is neither carcinogenic, mutagenic or reprotoxic, nor is it a PBT or vPvB substance and therefore it does not meet any of the exclusion criteria in Article 5(1) of Regulation (EU) No 528/2012. But as mentioned before, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 and thus it becomes a candidate substitution pursuant to Article 10(1) of the BPR.

Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria listed in Article 5 (1) but can benefit from derogation in accordance with Article 5 (2) of the BPR

The active substance etofenprox is neither carcinogenic, mutagenic or reprotoxic, nor is it a PBT or vPvB substance and therefore it does not meet any of the exclusion criteria in Article 5(1) of Regulation (EU) No 528/2012. But as mentioned before, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 and thus it becomes a candidate substitution pursuant to Article 10(1) of the BPR.

Conclusion of the screening phase:

Stop comparative assessment. Taking into account the available information summarized here, the Austrian Competent Authority concludes that the chemical diversity of active substances in authorised biocidal products to minimise the occurrence of resistance is not given yet.

In line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance (CA-May15-Doc.4.3.a – Final) and since etofenprox does not meet the exclusion criteria as outlined in Article 5(1) of the BPR, it is valid to conduct no further investigation at this point; comparative assessment is stopped and finalized at this stage.

The biocidal product *"Ameisen Streu- und Gießmittel PROX"* will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

3.10.2 Tier IA

Not applicable.

3.10.3 Tier IB

Not applicable.

3.10.4 Tier II

Not applicable.

3.10.5 Overall conclusion

Stop comparative assessment. Taking into account the available information summarized here, the Austrian Competent Authority concludes that the chemical diversity of active substances in authorised biocidal products to minimise the occurrence of resistance is not given yet.

In line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance (CA-May15-Doc.4.3.a – Final) and since etofenprox does not meet the exclusion criteria as outlined in Article 5(1) of the BPR, it is valid to conduct no further investigation at this point; comparative assessment is stopped and finalized at this stage.

The biocidal product "Ameisen Streu- und Gießmittel PROX" will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Cf. to chapter 3.6.6.

4.1.2 Dietary assessment

Cf. to chapter 3.6.8

4.1.3 Environment

Outdoor spot applications on paved surfaces; release via STP

The applicant has submitted an assessments for releases sent to sewers in a city environment, as was the case for the initial authorisation in Austria dated 13 September 2018 (Austria 2013).
Since professional use has not been applied for this renewal of the product these assessments are no longer relevant according to Technical Agreements for Biocides entry 159.
However, for the sake of completeness, the applicant's assessment for these scenarios are kept available in this chapter:

Table Environmental risk assessment; release via STP

Environmental risk assessment				
Scenario assessed	**ESD applied**	**Maximum in-use concentration of the active substance(s)**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
Insecticide - adult ants – outdoor - non-professionals – pouring (100 % of the releases are sent to sewers in a city environment)	OECD 2008, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents,	Etofenprox: **0.1 g a.s./L/m²**	---	*[**STP**]* *[Freshwater]* *[Sediment]* *[Soil]* *[Groundwater]*

Environmental risk assessment				
Scenario assessed	**ESD applied**	**Maximum in-use concentration of the active substance(s)**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
Insecticide - adult ants – outdoor - non-professionals – scattering (100 % of the releases are sent to sewers in a city environment)	number 18; ENV/JM/MONO(2008)14; 17-Jul-2008 ECHA 2022: Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021	Etofenprox: **0.08 g a.s./m²**	---	*[**STP**]* *[Freshwater]* *[Sediment]* *[Soil]* *[Groundwater]*

Scenario pouring - Insecticide - adult ants – outdoor - non-professionals - release via STP

Direct release to the STP by treatment on hard surfaces:
An emission scenario was considered that takes into account the primary emission to the wastewater compartment and hence, secondary emission to the aquatic surface water, the sediment compartment and soils via application of sewage sludge. In absence of a specialized scenario the soil emission scenario for crawling insects (chapter 4.4.2.2 of the OECD 2008) was used.

Table: Input parameters for calculating the local emission; release via STP

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Insecticide - adult ants – outdoor - non-professionals – pouring			
Quantity of product applied	0.01	kg/m²	

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Insecticide - adult ants – outdoor - non-professionals – pouring			
Fraction of active substance in the commercial product	0.01	–	
Area of surface (OECD: foundation) treated	1.5	m²/d	**Already accepted in the PAR (2018):** Adaption of the OECD 2008 assumption is made. The typical area that is treated for ant control is adapted to 1.5 m² as treatment is only required for restricted infested zones.
Fraction emitted to STP during outdoor foundation pouring (OECD: spray) application	0.3	–	
Fraction emitted to soil by wash-off	0.5	–	
Emission from outdoor pouring application on terraces	0.00012	kg/d	
Number of buildings connected to STP	4000	[-]	
Simultaneity factor	0.00815	[-]	

Calculations:

During pouring application on hard surfaces, a fraction of the solution actually applied on the surface may eventually reach the STP via run-off. It is assumed that 70 % of the product applied remains on the surface after application.

The quantity of substance that is washed off by rainfall is dependent to some extent on the type of surface that is treated (e.g. concrete, cement, tiles). It is assumed that 50 % of the applied substance is washed off the surface during the first rain event.

To take into account simultaneous use of an insecticide, it is agreed to assume an average number of 4,000 houses per STP catchment and a simultaneity factor ($F_{simultaneity}$), which is based on the use pattern of the product.
According to the properties of the product Ameisen Streu- und Gießmittel PROX and its intended use, the interval between applications is considered once every four weeks. In addition the product is only used during season of ant activity (worst case: 9 month). This would result in up to 9-10 applications per year.

Therefore, the product application frequency is assumed on a "3 to 11 applications per year" basis. As stated in section 2.7 of the OECD 2008 a simultaneity factor of 0.815 % has been derived ((1.9 x 32.15) + (37.82 x 0.54))/100) for this application pattern.
In this assessment, it is considered that this simultaneity factor covers both the pouring application and the granular treatment, as the number of applications is considered independent from the type of application.
Since the emission from outdoor pouring application on terraces (scenario 1) is higher than for scattering application of the granular (120 mg/d vs. 108 mg/d), thus the assessment of exposure of the STP is covered by scenario 1 (using $Elocal_{STP,washoff}$ =120 mg/d) as a worst case.

Table Resulting local emission to relevant environmental compartments; release via STP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.0039	
Freshwater	-	No direct release in this sub-scenario considered.
Seawater	-	No direct release in this sub-scenario considered.
Air	-	No direct release in this sub-scenario considered.
Soil	-	No direct release in this sub-scenario considered.

Scenario scattering - Insecticide - adult ants – outdoor - non-professionals **-** release via STP

Table Input parameters for calculating the local emission; release via STP

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Insecticide - adult ants – outdoor - non-professionals – scattering			
Quantity of product applied	0.008	kg/m²	
Fraction of active substance in the commercial product	0.01	–	
Area of surface (OECD: foundation) treated	1.5	m²/d	**Already accepted in the PAR (2018):** Adaption of the OECD 2008 assumption is made. The typical area that is treated for ant control is adapted to 1.5 m² as treatment is only required for restricted infested zones.
Fraction emitted to STP by wash-off of surface	0.9	–	**Already accepted in the PAR (2018):** The quantity of substance applied is not reduced via run-off. In line with the OECD 2008 (spot application), it is considered that the fraction released during powder application to the environment is 90 %.
Emission from outdoor pouring application on terraces	0.00012	kg/d	
Number of buildings connected to STP	4000	[-]	
Simultaneity factor	0.00815	[-]	

Calculations:

Direct release to the STP by treatment on hard surfaces:
For the calculation of emission to the STP via terraces, which may have a connection to the sewer system, the emission scenario for crawling insects (chapter 4.4.2.2 of the OECD 2008) was used in the absence of a specialised scenario.

To take into account simultaneous use of an insecticide, it is agreed to assume an average number of 4,000 houses per STP catchment and a simultaneity factor ($F_{simultaneity}$), which is based on the use pattern of the product.
According to the properties of the product Ameisen Streu- und Gießmittel PROX and its intended use, the interval between applications is considered once every four weeks. In addition the product is only used during season of ant activity (worst case: 9 month). This would result in up to 9-10 applications per year.
Therefore, the product application frequency is assumed on a "3 to 11 applications per year" basis. As stated in section 2.7 of the OECD 2008 a simultaneity factor of 0.815 % has been derived ((1.9 x 32.15) + (37.82 x 0.54))/100) for this application pattern.
In this assessment, it is considered that this simultaneity factor covers both the pouring application and the granular treatment, as the number of applications is considered independent from the type of application.
Since the emission from outdoor pouring application on terraces (scenario 1) is higher than for scattering application of the granular (120 mg/d vs. 108 mg/d), thus the assessment of exposure of the STP is covered by scenario 1 (using $Elocal_{STP,washoff}$ = 120 mg/d) as a worst case.

Table Resulting local emission to relevant environmental compartments; release via STP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.0035	
Freshwater	-	No direct release in this sub-scenario considered.
Seawater	-	No direct release in this sub-scenario considered.
Air	-	No direct release in this sub-scenario considered.
Soil	-	No direct release in this sub-scenario considered.

The assessment PECS is calculated according to the Guidance on the BPR: Volume IV Environment (Parts B+C) (ECHA 2017c) and the distribution of the active substance etofenprox in the environment after release to the sewer system given in the CAR on etofenprox Product-type 18 (Austria 2013).
In compliance with the CAR on etofenprox Product-type 18 (Austria, 2013), the main metabolite in surface water is α–CO. The highest percentage of α–CO, relatively to the amount of etofenprox initially applied, was determined to be 63.6 % Therefore, the PECs of etofenprox were multiplied by 63.6 % to estimate the PECs of the metabolite α–CO.
The main metabolite in sediment is 4'-OH. The highest percentage of 4'-OH, relatively to the amount of etofenprox initially applied, was determined to be 21.4 %. The PECs of etofenprox were multiplied by 21.4 % to estimate the PECs of the metabolite 4'-OH.
The results of the assessment are summarised in the table below:

Table Summary table of PNEC, PEC and PEC:PNEC values

Summary table of PNEC, PEC and PEC:PNEC values			
	Active Substance	**Metabolite 1 (α-CO in surface water)**	**Metabolite 2 (4'-O in sediment)**
PNEC values			
PNECstp (mg/L)	2.25E-02	-	-
PNECwater (mg/L)	5.4E-06	4.4E-05	-
PNECsed (mg/kg wwt)	6.3E-03	-	1.2E-02
PNECsoil (mg/kg wwt)	6.33E-03	-	-
Scenario pouring			
PEC values			
PECair	-	-	-
PECstp(mg/L)	3.14E-5	-	-
PECwater (mg/L)	2.99E-6	1.90E-6	-
PECsed (mg/kg wwt)	1.865E-3	-	3.98E-4
PECsoil (mg/kg wwt)	5.2E-3	-	-
PECgw(µg/L)	1.0E-3	-	-
PEC/PNEC values			
PEC/PNECstp	1.40E-03	-	-
PEC/PNECwater	5.54E-01	4.32E-02	-
PEC/PNECsed	2.96E-01	-	3.32E-02
PEC/PNECsoil	8.2E-01	-	-
Scenario scattering			
Covered by scenario pouring as worst case.			

Secondary poisoning via contaminated fish

As given in the assessment report (Austria 2013), with a log P_{ow} of 6.9, etofenprox is potentially bio-accumulating, hence also a potential for secondary poisoning via the consumption contaminated FISH may be given.
The assessment of secondary poisoning is calculated according to the Guidance on the BPR: Volume IV Environment (Parts B+C) (ECHA 2017c).

The concentration of contaminant in food (fish of fish-eating predators ($PECoral_{predator}$) is calculated from the PEC for surface water. Since no measured data for the BMF is available, it is based on default values according to the Guidance for BPR: Volume IV, Part B. The measured BCF of 2565 L/kg (corrected for a whole body lipid content of 5 %) is used as precedence trigger for the default BMF. Therefore, a BMF of 2-3 is considered to be appropriate.

Summary table of estimated theoretical exposition (ETE)		
Parameter	**Definition**	**Etofenprox**
Predicted environmental concentration in surface water [mg/L]	PEC_{water}	2.99E-6
Bioconcentration factor for fish on wet weight basis [L/kg$_{wet\ fish}$]	BCF_{fish}	2565
biomagnification factor in fish [-]	BMF	2
Predicted Environmental Concentration in fish [mg/kg$_{wet\ fish}$]	$PEC_{oral,\ predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$	**0.015**

Table Summary table of secondary poisoning

Summary table of secondary poisoning			
Scenario	**$PEC_{oral\ predator}$ [mg/kg diet]**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Aquatic environment			
Secondary poisoning via contaminated FISH			
Outdoor spot applications on paved surfaces; release via STP	0.015	4.5E-05	6.1E-04

Tables with input parameters and output from FOCUS PEARL for groundwater

No Tier 2 (FOCUS PEARL) calculation required. Thus, not relevant.

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the active substance is available.

4.3 List of studies for the biocidal product

The studies sponsored by Spiess-Urania Chemicals GmbH were transferred directly to the applicant Certis Europe B.V. in relation with a merge of both companies and subsequent change of authorisation holder. All rights and obligations relating to the product authorisation of Ameisen Streu- und Gießmittel were transferred from Spieß Urania Chemicals GmbH to Certis Europe B.V..
Please note that due to merger of Certis Europe BV and Belchim crop protection in June 2022 the new company name of Certis Europe B.V. is Certis Belchim B.V.

Author (s)	**Year** **Report date**	**Reference No. *(Annex III requirement)* / IUCLID Section No.**	**IUCLID Document name**	**Title. Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Anonymous	2007b	3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density (liquids) and bulk, tap density (solids).001	Pour and Tap Density of SPU-00220-I Report No. 20071165/01-PCTD	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes
Anonymous	2007a	3.4.1 Storage stability tests	Storage stability tests.001	Physico-chemical properties of the formulation SPU-00220-I after Accelerated Stroage at 54 °C for 2 Weeks Report No. 20071165/01-PCAS	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes

Anonymous	2010a	3.4.1 Storage stability tests	Storage stability tests.002	Final report to the shelf life test of the test item SPU-00220-I at ambient temperature according to Technical – Monograph No. 17 Report No. T06STI01	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2014a	3.8 Surface tension	Surface tension.001	Final report to the determination of the Surface Tension of the test item SPU-00220-I Report No. T14ASI01	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2014b	4.1 Explosiveness	Justification_Explosives.001	Explosive properties of SPU-00220-I Report No. Wa-151014-00220	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2007d	4.2 Flammability	Flammability.001	Flammability (solids) A.10. Autoflammability (Solids - Determination of relative self-ignition temperature) A.16 Report No. 20070270.01	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes

Anonymous	2014c	4.4 Oxidising properties	Justification_Oxidising properties.001	Oxidising properties of SPU-00220-I, EEC method A.17 Report No. Wa-141014-00220	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2007c	5 Methods of detection and identification	Methods of detection and identification.001	Validated method of analysis for the determination of Etofenprox in SPU-00220-I Report No. WA-25-05-07-00220	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2020	5 Methods of detection and identification	Methods of detection and identification.002	Development and validation of analytical method for the determination of Etofenprox in aqueous dilutions of SPU-00220-I Report No. S14-04659	unpublished	Certis Belchim B.V. Certis Europe B.V.	Yes	Yes
Anonymous	2008	6.7 Efficacy data to support these claims	Efficacy data to support these claims.001	Simulated use trial to determine the efficacy of ant granules (SPU-00220-I) against black ants, Lasius niger Report No. 08/09	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2009a	6.7 Efficacy data to support these claims	Efficacy data to support these claims.002	Efficacy of SPU-00220-I against black ants Report No. BIO050/09	unpublished	Certis Belchim B.V. Spiess-Urania	No	Yes

						Chemicals GmbH		
Anonymous	2009b	6.7 Efficacy data to support these claims	Efficacy data to support these claims.003	Field efficacy of drench applications of Etofenprox GR 1 against Lasius spp. Report No. BES ID 03193	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2010b	6.7 Efficacy data to support these claims	Efficacy data to support these claims.004	Field trial of the efficacy of an insecticide product against garden ants Report No. 1393/0710R	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2018	6.7 Efficacy data to support these claims	Efficacy data to support these claims.005	Biological Test Report - Efficacy of SPU 00220-I with 1.0 % Etofenprox tested fresh (<1 year old) and aged (2 years old) against Black ants, Lasius niger. Report No. BIO110-18	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes
Anonymous	2007a	8.1.1 Skin irritation / corrosion	Skin irritation / corrosion.001	Acute dermal irritation/corrosion test (patch test) of SPU-00220-I in rabbits Report No. 21310	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes

Anonymous	2007b	8.1.2 Eye irritation	Eye irritation.001	Acute eye irritation/corrosion test of SPU-00220-I in rabbits Report No. 21311	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes
Anonymous	2007c	8.3.1 Skin sensitisation	Skin sensitisation.001	Examination of SPU-00220-I on the skin sensitisation test in guinea pigs according to Magnusson and Kligman (maximisation test) Report No. 21312	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes
Anonymous	2007d	8.5.1 Acute toxicity: oral	Acute toxicity: oral.001	Acute oral toxicity study of SPU-00220-I in rats Report No. 21308	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	Yes	Yes
Anonymous	2011	8.5.2 Acute toxicity: inhalation	Justification_Acute toxicity: inhalation.001	Acute inhalation toxicity - Justification for non-submission Report No. 00220 30606	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes
Anonymous	2007e	8.5.3 Acute toxicity: dermal	Acute toxicity: dermal.001	Acute dermal toxicity study of SPU-00220-I in CD rats Report No. 21309	unpublished	Certis Belchim B.V. Spiess-Urania	Yes	Yes

						Chemicals GmbH		
Anonymous	2014	10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged	Foreseeable routes of entry into the environment.001	Estimation of distribution in the environment of Etofenprox Report No. 231014-01	unpublished	Certis Belchim B.V. Spiess-Urania Chemicals GmbH	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

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- McCleverty J. A. and Meyer T.J. 2003: Comprehensive Coordination Chemistry II, vol 9, 552-553, (ISBN: 978-0-08-043748-4)

4.4.2 Guidance documents

- RIVM 2006, report 320005002: Pest Control Products Fact Sheet to assess the risks for the consumer, Updated version for ConsExpo 4

- Austria 2013, Assessment report Etofenprox, Product type 18 (Insecticide), September 2013, Available at: https://dissemination.echa.europa.eu/Biocides/ActiveSubstances/0030-18/0030-18_Assessment_Report.pdf

- COM 2020, CA-Dec20-Doc.4.1 Warning sentence and RMM for bees_finalrev2

- COM 2021, CA-March21-Doc.4.3_Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment

- EC 2008 HEEG, Opinion 2 *HEEG opinion on the assessment of Potential & Actual Hand Exposure*

- EC 2009 HEEG, Opinion 7 *HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4*

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- ECHA 2015, *Biocides Human Health Exposure Methodology*, Version 1, October 2015

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- ECHA 2018, Guidance on the Biocidal Products Regulation, Volume II, Efficacy – Assessment and Evaluation Parts B+C, Version 3.0

- ECHA 2020, HEAdhoc Recommendation no. 6 *Methods and models to assess exposure to biocidal products in different product types, version 4*

- ECHA 2022, Technical Agreements for Biocides Environment (ENV), Release date: 14. October 2022

- OECD 2008, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008

- ECHA 2018, Guidance on the Biocidal Products Regulation, Volume I, Identity/physico-chemical properties/analytical methodology Parts A+B+C

4.4.3 Legal texts

- Commission implementing regulation (EU) No 408/2014 of 23 April 2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 10/06/2021 concerning Biocide Product Regulation

- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

- Commission implementing regulation (EU) No 1036/2013 of 24 October 2013 approving etofenprox as an existing active substance for use in biocidal products for product- type 18

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.