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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Ant Bait 1R-trans phenothrin Biocidal Product Family

Product type(s) 18

1R-trans phenothrin as included in the Union list of approved active substances

Case Number in R4BP: BC-LR019221-36

Evaluating Competent Authority: Ireland

Date: 08th August 2020

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Overview of applications:

Application type	Ref MS	Case number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
NA-APP	*IE*	BC-LR019221-36	30/04/2019	Initial assessment	07
NA-MIC	*IE*	BC-VV054362-07	20/08/2020	Change to shelf-life of products	14, 16, 18, 29, 30, 33 & 48

Ref-MS information to the reader:	All changes made by the IE CA for NA-MIC BC-VV054362-07 are highlighted in yellow.

1 CONCLUSION

1.1SUMMARY OF DECISIONS AND RESTRICTIONS

1.1.1 Usage area

User	Application Method
Non-Professional	Single and double thermoformed bait capsules.

1.1.2. Pests and application rate

Target organisms are Black Ants (*Lasius niger)*. For all these products the claim "for the control of garden ants" is permitted.

The single thermoformed bait capsules from meta SPC 2 2b (J-70021) and 2c (IIRD-08002) with an application rate of 1 or 2 baits per $10m^2$. The double bait station meta SPC 3, 3 (TP-050-C1b & TP-050-C2), and also the single bait station products meta SPC 1 1a (TP-050-C1) and meta SPC 2 2a (TP-050-C2) with an application rate of 1 or 2 bait stations per $10m^2$.

1.1.3. Active substance details

The concentration of active substance (1R-trans phenothrin) at 0.073 %w/w to 0.105 %w/w. The source is Sumitomo Chemical (U.K.) Plc. Minimum purity 89%.

1.1.4 Summary of evaluation findings

Efficacy
The efficacy data presented in the dossier supports the label claim use of Ant Bait 1R-transphenothrin BPF products for the "control of ants indoors and outdoors". The label claim supplied by the applicant "Eliminates Ants. Lasts for 3 months" is supported by the laboratory palatability and mortality data and field trial data.
The label statement suggesting that after using the product for 1 week, a reduction in ant numbers should be noted by the user is not supported. The IE eCA concludes that the statement should be changed to "after 4 weeks, the disappearance of the ants should be noticed".

Mammalian Toxicology
Ant Bait 1R-trans phenothrin is not considered irritant or corrosive to skin, eyes or the respiratory tract. It is not considered to be sensitizing to either skin or the respiratory tract. It is not considered to be acutely toxic by the oral, inhalation or dermal routes. The product families do not require classification for human health hazards. T he Henkel products are for amateur use only so no professional exposure is expected. The bait products were regarded as safe for primary and secondary exposure.

Environment
Environmental classification of the Ant Bait 1R-trans phenothrin BPF products is based on their content of 1R-trans phenothrin.
On this basis Aquatic Classification applies to the products of the associated families:

- Aquatic chronic 2; H411'Toxic to aquatic life with long lasting effects'

- Meta SPC 1 – 1a (TP-050-C1); and
- Meta SPC 2 – 2a (TP-050-C2), Meta SPC 2 – 2b (J-70021), Meta SPC 2 – 2c (IIRD-08002).
- Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2)

An environmental risk assessment was performed for the intended use(s) of the Ant Bait 1R-trans Phenothrin BPF. An unacceptable risk was not identified for the environmental compartments considered once the product(s) are used appropriately and as directed.

1.1.5 Conclusion

The initial dossier for Ant Bait 1R-trans phenothrin was submitted to the Agency on August 28th 2015. The evaluation period for the product family by the reference member state (rMS) Ireland started on 31st March 2016 and the first draft PAR was sent to the respective concerned member states (cMS) for commenting in 30th March 2017.
The cMS DE initiated a formal referral to the Coordination Group (CG) in accordance with Article 35(2) of Regulation EU No.528/2912 (BPR) on June 30th 2017. The disagreement was related to the composition of the family, risk mitigation measurements (RMMs), efficacy and shelf-life.
In relation to the points agreed during CG discussions, the meeting agreed that the double ant bait product will be reformulated so that both mixtures in the bait box will have the same classification and can be placed in the same meta SPC.
Each mixture will be authorized as a single product with its own authorisation number. The double bait box will be considered as a special type of package containing two biocidal products. The meta SPC 3 containing both mixtures will have a combination of the ranges of the components of the two mixtures.
Considering the human health risk assessment, the meeting agreed to add an advice on paresthesia caused by pyrethroids (e.g. "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.").

Therefore, during the course of two teleconference meetings (09/08/2017 and 04/09/2017) and discussions at the Coordination Group (CG-25) on 26th September 2017, some of the referral points were closed satisfactory for all parties involved, except for the referral point relating to efficacy.

Therefore, at the CG-25 it was concluded that this particular point of the Article 35 (2) referral shall be referred to the Commission following the provisions of Article 36(1) of the BPR. It should be noted that the referral points were discussed in the presence of the applicant at both teleconferences and CG-25.

However, the overall conclusion of the IE CA is that sufficient information has been provided to verify the outcome and conclusions, thereby permitting the authorisation of "Ant Bait 1R-trans phenothrin" biocidal product family as product type 18 for meta SPCs 1, 2 and 3.

The Henkel products have been applied for and evaluated as baits with the purpose of controlling garden ants (*Lasius niger*).

Based on the assessment, the IE CA concludes that these products can be safely used by non-professional users.

The detailed grounds for the overall conclusion are described in the assessment report.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Ant Bait 1R-trans phenothrin Biocidal Product Family	Ireland

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Henkel AG & Co. KGaA
	Address	Henkelstrasse 67 Duesseldorf 40589 North-Rhine Westfalia Germany
Family authorisation number	IE/BPA 70240	
Date of the authorisation	30/04/2019	
Expiry date of the authorisation	30/04/2029	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	IGO srl
Address of manufacturer	Via Palazzo, 46 24061 – Albano Sant'Alessandro (Bergamo) ITALY Tel: +39 035 583.078
Location of manufacturing sites	IGO srl Via Palazzo, 46 24061 – Albano Sant'Alessandro (Bergamo) ITALY Tel: +39 035 583.078

Name of manufacturer	Consultoria Tecnica e Representaçoes, Lda. (CTR)
Address of manufacturer	Loteamento Industrial da Murteira, Lotes 23/24 2135-301 Samora Correia PORTUGAL
Location of manufacturing sites	Consultoria Tecnica e Representaçoes, Lda. (CTR) Loteamento Industrial da Murteira, Lotes 23/24 2135-301 Samora Correia PORTUGAL

1 Please fill in here the identifying product name from R4BP.

Name of manufacturer	Laboratorio Chimico Farmaceutico Sanmarinese
Address of manufacturer	Strada del Marano 95 47896 Faetano REPUBLIC SAN MARINO Tel: +39 (0)549 873111
Location of manufacturing sites	Laboratorio Chimico Farmaceutico Sanmarinese Strada del Marano 95 47896 Faetano REPUBLIC SAN MARINO Tel: +39 (0)549 873111

Name of manufacturer	HENKEL HOMECARE KOREA
Address of manufacturer	3 Gatbachi-ro, Danwon-gu, Ansan city, Gyeonggi-do, SOUTH KOREA
Location of manufacturing sites	HENKEL HOMECARE KOREA 3 Gatbachi-ro, Danwon-gu, Ansan city, Gyeonggi-do, SOUTH KOREA

Name of manufacturer	Godrej Consumer Products Ltd
Address of manufacturer	Pirojshanagar, Eastern Express Highway, Vikhroli (east), Mumbai - 400079 INDIA Tel: 91 22 25 188010
Location of manufacturing sites	Godrej Consumer Products Ltd 131/1-4, Cuddalore Road, Kattukuppam, Manapet (PO) , Pondicherry - 607402 INDIA

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

Active substance	Sumithrin (1R-trans-phenothrin)
Name of manufacturer	Sumitomo Chemical (London, UK)
Address of manufacturer	Sumitomo Chemical (U.K.) Plc Hythe House 200 Shepherds Bush Road London W6 7NL United Kingdom
Location of manufacturing sites	Misawa Works, Aza-Sabishirotaira, Oaza-Misawa, Misawa

	Aomori 033-0022, Japan.

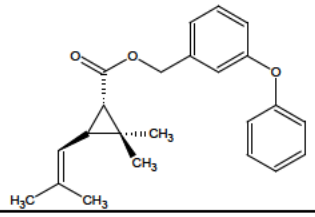
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	1R-trans phenothrin
IUPAC or EC name	m-phenoxybenzyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate
EC number	247-431-2
CAS number	26046-85-5
Index number in Annex VI of CLP	Not available
Minimum purity / content	89% (1R-trans phenothrin)
Structural formula	

2.1.2.2 Candidate(s) for substitution

1R-trans phenothrin is not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

This information is provided in the confidential annex.

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family[2]

This information is provided in the confidential annex.

2.1.2.5 Information on technical equivalence

Refer to the active substance supplier, Sumitomo Chemical (London, UK).

2.1.2.6 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

Gel/Paste, Water-based (ready-to–use)

2.1.3 Hazard and precautionary statements[2]

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

Level 2, Meta SPC 1

Classification	
Hazard category	Aquatic Chronic 2
Hazard statement	H411 Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	-
Hazard statements	H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	P101 If medical advice is needed, have product container or label at hand P102 Keep out of reach of children P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container to *domestic waste…in accordance with local/ regional/national regulation.*
Note	Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Level 2, Meta SPC 2

Classification	
Hazard category	Aquatic Chronic 2
Hazard statement	H411 Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	-
Hazard statements	H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	P101 If medical advice is needed, have product container or label at hand P102 Keep out of reach of children P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container to *domestic waste…in accordance with local/ regional/national regulation.*
Note	EUH208 Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction. Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Level 2, Meta SPC 3

Classification	
Hazard category	Aquatic Chronic 2
Hazard statement	H411 Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	-
Hazard statements	H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	P101 If medical advice is needed, have product container or label at hand P102 Keep out of reach of children P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container to *domestic waste…in accordance with local/ regional/national regulation.*
Note	EUH208 Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction. Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

2.1.4 Authorised use(s)

Level 2 - META SPC 1

2.1.4.1 Use description[3] - Meta SPC 1

Table 1. Meta SPC 1 - Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of the authorised use	This product is for the control of ants indoors and outdoors.
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 1'* ant baits are ready-to-use bait stations.
Application rate(s) and frequency	One or two baits every 10 m^2. This corresponds to AS concentrations 0.00525-0.0105g/10m^2 for the single bait containing (TP-050-C1), depending on whether 1 or 2 baits /10m^2 are used. Replace the ant bait every three months or when the ant bait is empty
Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use[4] - Meta SPC 1

1. Remove the flaps on the side of the bait station.
2. Place the bait station (sheltered from rain) on a flat surface near the nest or where there is evidence of ant trails.
3. Use one or two bait stations every 10 m^2.
4. After placing the bait stations do not move for at least one week.
5. After 4 weeks, the disappearance of the ants should be noticed.
6. Replace the bait station every three months or when the bait station is empty.

[3] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

[4] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.3 Use-specific risk mitigation measures – Meta SPC 1

Do not apply in places that may come into contact with food. Keep and place away from children and pets. Never let children play with the bait station. Do not force open bait stations.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment – Meta SPC 1

Most important symptoms and effects, both acute and delayed: Eyes: No adverse effects expected when used as directed. Skin: No adverse effects expected when used as directed. Inhalation: No adverse effects expected when used as directed. Ingestion: No adverse effects expected when used as directed. Potential environmental effects: Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Description of first aid measures: No special requirements. Observance of good industrial hygiene is recommended.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging – Meta SPC 1

Dispose of contents/container to domestic waste…in accordance with local/ regional/national regulation.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Meta SPC 1

Stable for 33 months under ambient storage conditions in polystyrene ant bait stations. Once activated replace bait stations after 3 months or when empty.

Level 2 - META SPC 2

2.1.4.7 Use description[5] - Meta SPC 2

Table 2. Meta SPC 2 Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of	This product is for the control of ants indoors and outdoors.

[5] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

the authorised use	
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 2'* ant baits are ready-to-use bait stations
Application rate(s) and frequency	One or two baits every 10 m^2 for product IIRD-08002 which corresponds to a dose rate of 0.0037-0.0073g/10m^2 and J-70021 which corresponds to a dose rate of 0.0049-0.0098 g/10m^2 depending on whether 1 or 2 bait stations are used per 10m^2. Product TP-050-C2 may be marketed as a single bait station and is used at a dose rate of 1 or 2 baits per 10m^2 (this correlates with a dose rate of 0.00525 to 0.0105 g/10m^2). Replace the ant bait every three months or when the ant bait is empty.
Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

2.1.4.8 Use-specific instructions for use[6] - Meta SPC 2

Instructions for single bait stations:

1. Remove the flaps on the side of the bait station.
2. Place the bait station (sheltered from rain) on a flat surface near the nest or where there is evidence of ant trails.
3. Use one or two bait stations every 10 m^2.
4. After placing the bait stations do not move for at least one week.
5. After 4 weeks, the disappearance of the ants should be noticed.
6. Replace the bait station every three months or when the bait station is empty.

Instruction for single bait station (thermoformed capsule type):

1. Remove the transparent lid.
2. Place the bait station in a horizontal position on an even surface in paths used by the ants, or near the nest in positions protected from rain.
3. Use one or two bait stations every 10 m^2.
4. Activate the bait station, by pressing the gel capsule firmly downwards. Replace the transparent lid to avoid rain getting into the capsule.
5. After placing the bait stations do not move for at least one week.
6. After 4 weeks, the disappearance of the ants should be noticed.
7. Replace the bait station every three months or when the bait station is empty

6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.9 Use-specific risk mitigation measures – Meta SPC 2

Do not apply in places that may come into contact with food. Keep and place away from children and pets. Never let children play with the bait station. Do not force open bait stations.

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment – Meta SPC 2

Most important symptoms and effects, both acute and delayed: Eyes: No adverse effects expected when used as directed. Skin: No adverse effects expected when used as directed. Inhalation: No adverse effects expected when used as directed. Ingestion: No adverse effects expected when used as directed. Potential environmental effects: Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Description of first aid measures: No special requirements. Observance of good industrial hygiene is recommended.

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging – Meta SPC 2

Dispose of contents/container to domestic waste…in accordance with local/ regional/national regulation.

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Meta SPC 2

The Meta SPC 2 products IIRD8002 (Vapona Ant Bait) and J-70021 (Vapona Ant Bait Extra) can be given a shelf-life of 31 months under ambient storage conditions in polystyrene or Acrylonitrile-methylacrylate + PE/EVOH + Aluminium ant bait stations. The Meta SPC 2 product "Vapona Ant Bait C2" can be given a shelf-life of 33 months under ambient storage conditions in polystyrene or Acrylonitrile-methylacrylate + PE/EVOH + Aluminium ant bait stations. Once activated replace bait stations after 3 months or when empty.

Level 2 - META SPC 3

2.1.4.13 Use description[7] - Meta SPC 3

Table 3. Meta SPC 3 Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of the authorised use	This product is for the control of ants indoors and outdoors.
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 3'* are ready-to-use double bait stations
Application rate(s) and frequency	One or two baits every 10 m^2. This corresponds to AS concentrations of 0.00593-0.01186g/10m^2 for the double bait containing (TP-050-C1b & TP-050-C2) depending on whether 1 or 2 baits /10m^2 are used. Replace the ant bait every three months or when the ant bait is empty
Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

2.1.4.14 Use-specific instructions for use[8] - Meta SPC 3

- Remove the flaps on the side of the bait station.
- Place the bait station (sheltered from rain) on a flat surface near the nest or where there is evidence of ant trails.
- Use one or two bait stations every 10 m^2.
- After placing the bait stations do not move for at least one week.
- After 4 weeks, the disappearance of the ants should be noticed.
- Replace the bait station every three months or when the bait station is empty.

2.1.4.15 Use-specific risk mitigation measures – Meta SPC 3

Do not apply in places that may come into contact with food.
Keep and place away from children and pets.
Never let children play with the bait station.

[7] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

[8] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

Do not force open bait stations.

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment – Meta SPC 3

Most important symptoms and effects, both acute and delayed: Eyes: No adverse effects expected when used as directed. Skin: No adverse effects expected when used as directed. Inhalation: No adverse effects expected when used as directed. Ingestion: No adverse effects expected when used as directed. Potential environmental effects: Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Description of first aid measures: No special requirements. Observance of good industrial hygiene is recommended.

2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging – Meta SPC 3

Dispose of contents/container to domestic waste…in accordance with local/ regional/national regulation.

2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage – Meta SPC 3

Stable for 33 months under ambient storage conditions in polystyrene ant bait stations. Once activated replace bait stations after 3 months or when empty.

2.1.5 General directions for use

2.1.5.1 Instructions for use[9]

As for Section 2.1.4

2.1.5.2 Risk mitigation measures

As for Section 2.1.4

[9] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

As for Section 2.1.4

2.1.5.4 Instructions for safe disposal of the product and its packaging

As for Section 2.1.4

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

As for Section 2.1.4

2.1.6 Other information

Application codes Main/Primary target organisms to be controlled: 1.3.10 Hymenoptera: Formicidae: *Lasius niger* Developmental stages of target organisms to be controlled: II.1.5 Imagines, Adults Function/mode of action of a.s./b.p/type of effect: III.1.1 Ingestion (bait); III.2.1 Kill effect; III.3.1 Trophallaxis (e.g. in ants) Field of use: IV.1.1 indoor use, potential for contamination outdoor; IV.2.5 outdoor use, others (around buildings) User category: V.1 non-professional user/consumer Method of application: VI.6 Bait application; VI.7.2 in bait boxes Application aim: VII.2 Health protection Type of formulation: VIII.5.1.1 paste ready-for-use Protect from rain

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Single Bait Stations – Meta SPC 1 – 1a (TP-050-C1), Meta SPC 2 – 2a (TP-050-C2)					
Single bait station	Containing 5 g of bait	Polystyrene	Polystyrene	Non-professional	Yes
Double bait stations – Meta SPC 3 - 3 (TP-050-C1b in chamber 1 & TP-050-C2 in chamber 2)					
Double bait station with 2	**Chamber 1** (TP-050-	Polystyrene	Polystyrene	Non-professional	Yes

cavities containing bait	C1b) contains 5 g of bait; **chamber 2** (TP-050-C2) contains 0.65 g of bait				
Thermoformed capsules – Meta SPC 2 – 2b (J-70021), 2c (IIRD-08002)					
Thermoformed capsule	Containing 5 g of bait	transparent thermo-file PET/PE/EVOH/ PE	Sealing foil aluminium	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The studies performed to support the dossier are listed in the reference list contained in Annex 3.1.

2.1.8.2 Access to documentation

The applicant has provided a letter of access to the active substance supplier.

2.2 Assessment of the biocidal product (family)

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

Meta SPC 1

Table 4. Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of the authorised use	This product is for the control of ants indoors and outdoors.
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 1'* ant baits are ready-to-use bait stations.
Application rate(s) and frequency	One or two baits every 10 m^2. Replace the ant bait every three months or when the ant bait is empty

Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 2

Table 5. Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of the authorised use	This product is for the control of ants indoors and outdoors.
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 2'* ant baits are ready-to-use bait stations
Application rate(s) and frequency	One or two baits every 10 m^2. Replace the ant bait every three months or when the ant bait is empty
Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

Meta SPC 3

Table 6. Use # 1 – Control of ants indoors and outdoors

Product Type	PT 18
Where relevant, an exact description of the authorised use	This product is for the control of ants indoors and outdoors.
Target organism (including development stage)	Ants. Adult - *Lasius niger*
Field of use	For use in and around buildings.
Application method(s)	'*Meta SPC 3'* ant baits are ready-to-use double bait stations.
Application rate(s) and frequency	One or two baits every 10 m^2. Replace the ant bait every three months or when the ant bait is empty
Category(ies) of users	Non-professional use only
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

The Ant Bait 1R-trans phenothrin biocidal product family was initially designed to include products based on new formulations of ant bait with a lower content of 1R-trans phenothrin. This is in keeping with the concept of the use of the minimum effective dose to minimise the amount of chemicals reaching the environment.

The testing plan for the BPF was based on testing many of these new formulations (hereafter referred to as Henkel R & D formulations SG-24017-C1, SG-24017-C2, SG-24016 & SG-24021) as the lower content of AI presented a worse case for stability and analytical method development. During the evaluation phase of the BPF dossier it became apparent that these R & D formulations contained the very minimum concentration of AI for efficacy and loss of a very small amount of AI over the shelf life of the products resulted in a loss of efficacy such that these new formulation products were withdrawn from the final family structure of Ant Bait 1R-trans phenothrin BPF.
Consequently read-across to the R & D formulations with similar composition of non-active ingredients is shown in the table below.

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	1a (TP-050-C1) (Read across for TP-050-C1b)	Visual Determination	(1R-trans phenothrin) 0.093 (0.105)	Semi-solid (opaque)	Cortès, J 28-05-2015
	2a (TP-050-C2)		0.093 (0.105)	Thick and viscous liquid (opaque)	
	2b (J-70021) 2c (IIRD-08002)		0.087 (0.098) 0.065 (0.073)	Thick and viscous liquid (translucent)	
Colour at 20 °C and 101.3 kPa	1a (TP-050-C1) (Read across for TP-050-C1b)	Visual Determination	0.093 (0.105)	Whitish	Cortès, J 28-05-2015
	2a (TP-050-C2)		0.093 (0.105)	Brown	
	2b (J-70021) 2c (IIRD-08002)		0.087 (0.098) 0.065 (0.073)	Light brown	
Odour at 20 °C and 101.3 kPa	1a (TP-050-C1) (Read across for TP-050-C1b)	Olfactory Determination	0.093 (0.105)	Odourless	Cortès, J 28-05-2015
	2a (TP-050-C2)		0.093 (0.105)	Characteristic	
	2b (J-70021) 2c (IIRD-08002)		0.087 (0.098) 0.065 (0.073)	Honey-sweet	
Acidity / alkalinity	All products	N/A	N/A	Testing is not required as the formulations are designed to be neutral and are not designed to be applied as aqueous dilutions	
	2c (IIRD-08002)			pH = 5.80 @ 20°C (in 1% aqueous dilution)	Lee, L.L. (2015) Report TS-150-64
Relative density / bulk density	All products	Testing of the formulations is not technically feasible due to the consistency of the samples.			Lee, L.L. (2015) Report

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		The samples were too viscous so that it was not possible to fill up the densitometer cell by suction since the tubing was too small and narrow. In addition, due to the high viscosity air bubbles are created and remain in the formulation leading to unreliable and non-homogenous results. Therefore, this in-house test method was not deemed suitable for viscous samples whilst the CIPAC test method MT186 for solid material is not appropriate for semi-solid or liquid samples.			TS-150-64
Storage stability test – **accelerated storage**	SG-24017-C1 (Read across for TP-050-C1 and TP-050-C1b)	CIPAC method Storage **MT 46.3** Active determination **356/TC/(M)**	0.021 (0.019) (1R-trans phenothrin)	Stable after 2 weeks at 40°C (1.4% Loss). SG-24017-C1 bait contains 0.0198% w/w of Sumithrin® (0.0186% w/w 1R-trans phenothrin). Weight loss after 6 weeks storage is minimal, <2% from initial weight of bait before storage. Green closed packaging appearance (in regards to colour, shape and form) remained unchanged after 6 weeks storage at 45°C. Formulation of SG-24017-C1 bait became more viscous after storage study compared to initial sample. Direct qualitative isomer/chiral	Izyan, N. (2015) Report TS-15162R2

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				quantification was carried following CIPAC method and result was within ±2% with calculated values based on COA provided.	
	SG-24017-C2 (Read across for TP-050-C2)		0.021 (0.019)	Stable after 2 weeks at 54°C (0.7% Loss). SG-24017-C2 bait contains 0.0190% w/w of Sumithrin® (0.0178% w/w 1R-trans phenothrin). Weight loss for SG-24017-C2 ant bait sample after 2 weeks storage in 54°C oven was minimal, which was less than 1% from the initial weight of bait before storage. Blue bait station packaging appearance (in regards to colour, shape and form) remained unchanged after 2 weeks storage in 54°C oven. Formulation of SG-24017-C2 bait became more viscous and darker	Izyan, N. (2015) Report TS-15192

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				in colour after storage study compared to the initial sample. Direct qualitative isomer/chiral quantification was carried following CIPAC method and result within ±2% with calculated values based on COA provided.	
	SG-24016 (Read across for J-70021 & IIRD-08002)		0.021 (0.019)	Stable after 2 weeks at 54°C (5.6% Loss). The accelerated storage stability study (54°C for 2 weeks) was carried out by Henkel, with samples being supplied to the analytical lab in transparent glass bottles. Sumithrin® contents of both replicates were stable after 2 weeks of storage in 54°C oven with less than 6% deviation from the initial contents, variation of the 1R-trans-phenothrin in the range of ±5% versus the initial contents.	Izyan, N. (2015) Report TS-15235

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	SG-24017-C2 (Read across for TP-050-C2)		0.021 (0.019)	Stable after 6 weeks at 45°C (0.4% Loss). SG-24017-C2 bait contains 0.0263% w/w of Sumithrin® (0.0247% w/w 1R-trans phenothrin). Weight loss after 6 weeks is minimal, <1% from the initial weight of the bait before storage. Packaging appearance of the SG-24017-C2 syringe (in regards to colour, shape and form) remain unchanged after 6 weeks storage in 45°C oven. The formulation of the SG-24017-C2 bait however became more viscous and darker in color after the storage study compared to the initial sample. Direct qualitative isomer/chiral quantification was carried following the CIPAC method and the result was in close agreement (±3%) with the	Izyan, N. (2015) Report TS-15164R2

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				calculated values based on COA.	
Storage stability test – **long term storage at ambient temperature**	SG24017-C1 (Read across for TP-050-C1 and TP-050-C1b) SG-24017-C2 (Read across for TP-050-C2) SG-24016 (Read across for J-70021 & IIRD-08002)	Ambient Storage Stability	0.021 (0.019) (1R-trans phenothrin)	Final results scheduled for May 2020. 19 month interim data shows 6% weight loss. No change in colour; Loss of content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M) is around 3.3%.	Cortès, J. Interim report LR-C-411 (R10)
			0.021 (0.019)	Final results scheduled for May 2020. 19 month interim data shows 0.67% weight loss. No change in colour; Loss of content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M) is around 5.6%.	Cortès, J. Interim report LR-C-375 (R10)
			0.021 (0.019)	Final results scheduled for May 2020. 19 month interim data shows 7% weight loss. No change in colour; Loss of	Cortès, J. Interim report LR-C-410 (R10)

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M) is around 3%.	
Storage stability test – **long term storage at ambient temperature-Final Report Data**	SG24017-C1 (Read across for TP-050-C1 and TP-050-C1b) SG-24017-C2 (Read across for TP-050-C2) SG-24016 (Read across for J-70021 & IIRD-08002)	Ambient Storage Stability	0.021 (0.019) (1R-trans phenothrin)	Results of 37 months final data shows 9% average weight loss versus initial sample. No change in colour; Loss of content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M) is average -5.6%.	Cortès, J. Final report LR-C-411 (R9)
			0.021 (0.019)	Results of 36 months final data shows 0.9% average weight loss. No change in colour; Loss of content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M) is average -5.6%.	Cortès, J. Final report LR-C-375 (R9)
			0.021 (0.019)	Results of 39 months final data shows 10% average weight loss. No change in colour; Loss of	Cortès, J. Final report LR-C-410 (R9)

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				content of active substance (by GC and Chiral HPLC, CIPAC method 356/TC/(M)) is average -4.9%.	
Storage stability test – **low temperature stability test for liquids**	All products	Low temperature stability testing was not required. With the exception of product Meta SPC 1 - 1a (TP-050-C1) the physical state of the products means that they do not freeze below freezing point. For product Meta SPC 1 - 1a (TP-050-C1) and Meta SPC 3 - 3 (TP-050-C1b & TP-050-C2), which contain a higher percentage of water, the effect of low temperature will be mitigated by labelling. The labels will carry the statement **'protect from frost'**.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	SG24017-C1 (Read across for TP-050-C1 and TP-050-C1b) SG-24017-C2 (Read across for TP-050-C2) SG-24016 (Read across for J-70021 & IIRD-08002)	Accelerated storage stability	0,021 (0,019) 0,021 (0,019) 0,021 (0,019)1R-trans phenothrin)	The enclosed packaging ensures that the product is not exposed to light.	Izyan, N. (2015)
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	SG24017-C1 (Read across for TP-050-C1 and TP-050-C1b) SG-24017-C2 (Read across for TP-050-C2) SG-24016 (Read across for J-70021 & IIRD-08002)	Ambient Storage Stability	0.021 (0.019) 0.021 (0.019) 0.021 (0.019) (1R-trans phenothrin)	Results scheduled for May 2020.	N/A
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	SG24017-C1 (Read across for TP-050-C1 and TP-050-C1b)	Ambient Storage Stability	0.021 (0.019) (1R-trans phenothrin)	Results scheduled for May 2020. 19 month interim data shows no reactivity with	Cortès, J. Interim report LR-C-411 (R10)

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				the container.	
	SG-24017-C2 (Read across for TP-050-C2)		0.021 (0.019)	Results scheduled for May 2020. 19 month interim data shows no reactivity with the container.	Cortès, J. Interim report LR-C-375 (R10)
	SG-24016 (Read across for J-70021 & IIRD-08002)		0.021 (0.019)	Results scheduled for May 2020. 19 month interim data shows no reactivity with the container.	Cortès, J. Interim report LR-C-410 (R10)
Physical compatibility	All products	None of the products are to be used with other products, as specified on the labels. There is therefore no requirement to assess any potential interaction.			
Wettability	All products	Not relevant for any of the products			
Suspensibility, spontaneity and dispersion stability	All products	Not relevant for any of the products			
Wet sieve analysis and dry sieve test	All products	Not relevant for any of the products			
Emulsifiability, re-emulsifiability and emulsion stability	All products	Not relevant for any of the products			
Disintegration time	All products	Not relevant for any of the products			
Particle size distribution, content of dust/fines, attrition, friability	All products	Not relevant for any of the products			
Persistent foaming	All products	Not relevant for any of the products			
Flowability/Pourability/Dustability	All products	Not relevant for any of the products			
Burning rate — smoke	All products	Not relevant for any of the products			

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
generators					
Burning completeness — smoke generators	All products	Not relevant for any of the products			
Composition of smoke — smoke generators	All products	Not relevant for any of the products			
Spraying pattern — aerosols	All products	Not relevant for any of the products			
Physical compatibility	All products	None of the products are to be used with other products, as specified on the labels. There is therefore no requirement to assess any potential interaction.			
Chemical compatibility	All products	As above.			
Degree of dissolution and dilution stability	All products	Not relevant as the products are ready to use.			
Surface tension	All products	This test is only required for liquid products that contain more than 10% organic solvent (hydrocarbons) and is therefore not relevant for these products.			
Viscosity	All products	Testing is not technically possible due to the consistency of the samples. Testing is required for all liquid formulations; however testing is not technically possible for products 1a (SG-24017-C1) and 2a (TP-050-C1) which are semi-solid and will not pour from the bottle. Testing is not technically possible for the remaining products as they are thick and viscous liquids which would give inaccurate measurements in the test system. Preliminary testing (included in the study report for Acidity and attached in section 3.2) was performed and inaccurate or non-reliable results caused by bubbles trapped around the rotor were obtained. The results were not accepted and have therefore not been presented in the dossier.			

In addition to confirmation of the thermal stability of the ant baits containing 1R-trans phenothrin, the palatability of the bait matrices for all products has been confirmed after ageing at 54°C for 2 weeks and in efficacy studies using aged baits.
N/A not applicable

Conclusion on the physical, chemical and technical properties of the product
Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2) product was modified during the evaluation phase of the dossier. An explanation for this has been included in Annex 3.7. Consequently read-across of physical, chemical and technical properties has been implemented for this meta SPC.

Appearance: physical state, colour and odour were determined at 20°C and 101.3 kPa in accordance with the ECHA guidance and was acceptable.

Acidity/Alkalinity: determined according to CIPAC method MT75.3 where required with acceptable results. Determination for products 1a, 7a, 2a and 2b is not required as the product is designed to be neutral and is not applied as an aqueous solution.

Relative density/bulk density: Testing was not possible due to the nature of the formulations.

Storage stability, Accelerated storage: Studies were conducted according to CIPAC method MT 46.3 either for 2 weeks at 54°C or six weeks at 45°C. The studies were carried out on three R&D novel formulations (SG-24017-C1, SC-24017-C2 and SG-24016) which were based on a lower concentration of the active ingredient and therefore represented the worst case for stability. These were accepted as representative of all products.

Storage stability at ambient temperature: Studies on three R&D novel formulations (SG-24017-C1, SC-24017-C2 and SG-24016) which are based on a lower concentration of the active ingredient and therefore represented the worst case for stability, are ongoing.

Storage stability at low temperature: This is only an issue for products 1a (TP0050-C1) and 3 (TP-050-C1b & TP-050-C2). These products will carry the statement 'protect from frost' which is acceptable.

Where the statement 'not relevant for any of the products' is used in the table above the justification for the non-submission of data by the company is accepted.

Physical and chemical compatability: None of the products are to be used with other products, as specified on the label and as such ther is no requirement to assess compatability.

Surface Tension: The products are thick liquids and gels/pastes and as such surface tension tests are not required.

Viscosity: due to the nature of the product viscosity tests were not possible.

Final storage stability at ambient temperature: Studies on three R&D novel formulations (SG-24017-C1, SC-24017-C2 and SG-24016) which are based on a lower concentration of the active ingredient and therefore represented the worst case for stability. Studies were conducted according to CIPAC method 356/TC/(M) for 37, 36 and 39 months respectively in commercial packaging. These were accepted as representative of all products. No visual packaging or colour variations observed and weight loss of active ingredient within accepted tolerance (+/-10%) therefore a 36 month shelf life is supported.

2.2.3 Physical hazards and respective characteristics

Property	Products	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	All products	In consideration of the chemical structure of the active substance and non-active substances the Products do not have explosive properties			
Flammable properties	All products	Based on the chemical structure of the active ingredient and non-active ingredients the product does not contain functional groups which have flammable properties.			
Oxidising properties	All products	In consideration of the chemical structure of the active substance and non-active substances the Products do not have oxidizing properties			
Self-reactive substances and mixtures	All products	None of the components of the product are classified as self-reactive.			
Pyrophoric liquids	All products	None of the components of the product are pyrophoric liquids.			
Self-heating substances and mixtures	All products	None of the components of the product are self-heating substances.			
Organic peroxides	All products	None of the components of the product are organic peroxides.			
Corrosive to metals	All products	None of the components of the product are corrosive to metals.			
Auto-ignition temperatures of products (liquids and gases)	All products	Based on the on the chemical structure of the active ingredient and the properties of the non-active ingredients with monoethylene glycol (present in some of the formulations at 0.018%) being the only solvent apart from water, it is considered unlikely that the product will have an auto-ignition temperature low enough to present a hazard during manufacture and use.			

Conclusion on the physical hazards and respective characteristics of the product
It can be concluded that products in the Ant Bait 1R-trans phenothrin BPF are not classified and will not be labelled for physical hazards.

2.2.4 Methods for detection and identification

Please refer to the introduction in section 2.2.2 regarding read-across to R & D formulations. The matrices of meta SPC 1 – 1a (TP-050-C1) and meta SPC 3 – 3 (TP-050-C1b & TP-050-C2) and meta SPC 2 – 2a (TP-050-C2) may be read across from SG-24017-C1 and SG-24017-C2 respectively.

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

	Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Selectivity**	**Matrix**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
						Range	Mean	RSD		

)										
Active Substance 1R-trans phenothrin Calculated using the sum of all isomers of Phenothrin (SIP) and Trans and 1R isomer ratio	ANA104R1	This method is suitable to determine SIP content ranged from 0.002% w/w to 0.15% w/w in bait sample.	R^2 = 1.00	No overlapping peak	*IIRD-08002*	*98.5 – 99.50%*	*99.0 %*	*R = 0.505 %*	*Highest concentration (0.15% w/w SIP), Repeatability r = 0.202%* *Accuracy / recovery 98.9%* *Lowest concentration (0.002% w/w SIP),* *Repeatability r = 1.500%* *Accuracy / recovery 100.8%*	*Mahidon M., Method validation for determination of Sum of all Isomers of Phenothrin (SIP) content of ant bait (Document ID: MV13R1) Revision 1, prepared on 25th January 2016* *Reference document: ANA104R1* ***CIPAC method 356/TC/(M)** was used to determine the trans and 1R isomer ratio allowing the calculation of 1R-trans phenothrin content.*
					SG-24017-C1	*97.00 – 98.15%*	*97.6 %*	*r = 0.513 %*		
					SG-24017-C2	*96.80 – 98.15%*	*97.5 %*	r = 0.513 %		

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

Conclusion on the methods for detection and identificationof the product
The method validation (MV13R1) demonstrated that the analytical method for determination of Sum of all Isomers of Phenothrin (SIP) content of ant bait (ANA104R1) is fit for use to determine Sum of all Isomers of Phenothrin (SIP) content of ant bait.

Selectivity: No analyte interferences were detected. Chromatograms were included and were acceptable
Linearity: Linearity was demonstrated for the range covering the concentration in the products.
Precision / Repeatability: Repeatability was demonstrated for the lowest concentration in the products (0.019%w/w) with a relative standard deviation (%RSD) of 0.505%, which is acceptable.
Accuracy / Recovery: Accuracy was demonstrated for the lowest concentration in the products (0.019%w/w) with 99% accuracy, which is acceptable.

The test method is suitable to analyze ant bait sample prepared in various matrices like IIRD-08002 (Product Meta SPC 2- 2c), R&D formulations SG24017-C1 and SG-24017-C2.

As the validation was acceptable using matrice IIRD-08002 (Product Meta SPC 2- 2c), the method validation can read across to three other products (Meta SPC 2- 2b (J-70021)) with the same formulation type (honey/invert sugar base).

As the validation was acceptable using matrice SG24017-C1, the method validation can read across to products Meta SPC 1 -1a (TP-050 -C1) and Meta SPC 3 – 3 (TP-050-C1b chamber 1 formulation), with the same formulation type (sucrose base). Meta SPC 3 formulation in chamber 1 (TP-050-C1b) has the same composition as meta SPC 1 – 1a (TP-050-C1) with the exception of the addition of a preservation agent. A justification for this read across is presented in Annex 3.7.

As the validation was acceptable using matrice SG- 24017-C2, the method validation can read across to products meta SPC 2- 2a (TP-050-C2) and meta SPC 3 (TP-050-C2 chamber 2 formulation) with the same formulation type (honey/whole egg powder base)

The method validation also demonstrates the analytical method is suitable for the other analysis conducted such as the Accelerated Storage Stability analysis studies.

Selectivity:
Linearity:
Precision/Repeatability:
Accuracy/Recovery:

Methods for soil, air and water – no additional studies required as there are data contained within the active substance dossier.

Methods for monitoring – not required as the product will not come into contact with food producing animals, food of plant and animal origin or feeding stuffs.

Methods for animal and human body fluids and tissues – not required as this is a bait product which will not come into contact with food and feed or body fluids and tissues.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group 03: Pest control; the product is an insecticide (PT18).

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

Target organisms are Black Ants (*Lasius niger).*

2.2.5.3 Effects on target organisms, including unacceptable suffering

Ant Bait 1R-trans phenothrin BPF kills ants following ingestion.

2.2.5.4 Mode of action, including time delay

1R-trans phenothrin acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. The prolonged opening of sodium channels produces a protracted sodium influx which leads to repetitive firing of sensory nerve endings which may ultimately progress to hyper-excitation of the entire nervous system, conduction block and death of the insect.

2.2.5.5 Efficacy data

Level 3 product and test substance	**Test organism (s)**	**Test system / concentrations applied / exposure time**	**Test results: effects, mode of action, resistance**	**Reference**
Meta SPC 1 – 1a (TP-050-C1) 0.093% 1R-trans phenothrin	Black ants, (*Lasius niger)*	A field trial was performed in the UK to test the efficacy of fresh baits and 1, 2 and 3 month aged baits. Ant baits containing 0.093% active or control baits containing base formulation only, were placed beside ant nests and the number of visible ants beside the nest counted over a 1 minute period was recorded prior to treatment and again 2, 5, 10, 15, 20, 25 and 30 days post application. Statistical analyses were run using the % reduction at 29-30 days, however field tests were continued up to 39 days to verify and confirm the growing trend of ant activity reduction.	Statistical analysis concluded that TP-050 Double traps strongly reduces the ant activity, up to 89.61%, a level that cannot be distinguished statistically from 90% according the null hypothesis from Sokal & Rohlf (1995) in the time of 29-31 days. 95.6% reduction was noted for fresh baits at 3.5 weeks. The efficacy of the aged baits was confirmed. No signs of resistance were reported.	Heaven, H. (2015c) Field trial to determine the efficacy of TP-050 Ant Double Trap against black ants, *Lasius niger*, i2L Research Ltd. Study code 14/294C
		The efficacy studies performed with Meta SPC 2 – 2c (IIRD-08002) with 0.065% 1R-trans phenothrin provide additional support for efficacy.		

Level 3 product and test substance	**Test organism (s)**	**Test system / concentrations applied / exposure time**	**Test results: effects, mode of action, resistance**	**Reference**
Meta SPC 2 – 2a (TP-050-C2) 0.093% 1R-trans phenothrin	Black ants, (*Lasius niger)*	A field trial was performed in the UK to test the efficacy of fresh baits and 1, 2 and 3 month aged baits. Ant baits containing 0.093% active or control baits containing base formulation only, were placed beside ant nests and the number of visible ants beside the nest counted over a 1 minute period was recorded prior to treatment and again 2, 5, 10, 15, 20, 25 and 30 days post application. Statistical analyses were run using the % reduction at 29-30 days, however field tests were continued up to 39 days to verify and confirm the growing trend of ant activity reduction.	Statistical analysis concluded that TP-050 Double traps strongly reduce ant activity, up to an 89.6% level that cannot be distinguished statistically from 90% according the null hypothesis from Sokal & R ohlf (1995) in the time of 29-31 days. 95.6% reduction was noted for fresh baits at 3.5 weeks. The efficacy of the aged baits was confirmed. No signs of resistance were reported.	Heaven, H. (2015c) Field trial to determine the efficacy of TP-050 Ant Double Trap against black ants, *Lasius niger*, i2L Research Ltd. Study code 14/294C
Meta SPC 2 – 2b (J-70021) 0.087% 1R-trans phenothrin	Black ants, (*Lasius niger)*	The efficacy for this product may be based on read-across to the efficacy studies performed for products Meta SPC 2 - 2c (IIRD-08002). The composition of these products is identical with the exception of the active substance concentration and in addition both latter products are placed on the market in the same type of packaging. Product 2c (IIRD-08002) include a lower concentration (0.065%) of 1R-trans phenothrin and therefore efficacy data generated for products containing a lower concentration of active substance will support a product containing higher concentration of active substance.	-	-

Level 3 product and test substance	**Test organism (s)**	**Test system / concentrations applied / exposure time**	**Test results: effects, mode of action, resistance**	**Reference**
Meta SPC 2 – 2c (IIRD-08002) 0.065% 1R-trans phenothrin	Black ants, (*Lasius niger)*	A field trial was performed in the UK to test the efficacy of fresh baits and 1, 2 and 3 month aged baits. Ant baits containing 0.065% active or control baits containing base formulation only, were placed beside ant nests and the number of visible ants beside the nest counted over a 1 minute period was recorded prior to treatment and again 2, 5, 10, 15, 20, 25 and 30 days post application. A non-parametric statistical analyses of the % reduction in ant numbers exposed to IIRD-08002 with ageing interval as a factor was performed. Field tests were continued up to 39 days to verify and confirm the growing trend of ant activity reduction.	IIRD-08002 Ant Bait Capsules resulted in significantly higher reduction in ant numbers compared with the no active Capsules. The overall median reduction for IIRD-08002 Ant Bait Capsules was 98% at the end of the experimental period. 95% reduction was noted for 1 month aged baits at 3 weeks. The efficacy of the aged baits was confirmed. No signs of resistance were reported.	Heaven, H. (2015a) Field trial to determine the efficacy of IIRD-08002 Ant Bait Capsule against black ants, *Lasius niger*, i2L Research Ltd. Study code 14/294A

Level 3 product and test substance	**Test organism (s)**	**Test system / concentrations applied / exposure time**	**Test results: effects, mode of action, resistance**	**Reference**
Formulation SG-24016 no active. [This matrix is the same for J-70021 and IIRD-08002 and therefore it demonstrates the effect for these products also.]	Black ants, (*Lasius niger)*	Palatability lab test using ants caught in the wild. 2 treatments: bait with bittering agent, bait without bittering agent. 100 ants per replicate. 3 replicates per treatment. Ants acclimitized to surroundings for 5 days. Number of ants feeding on bait was counted every 10 mins for first hour, then every hour for 7 hours.	There was no significant difference between the number of ants feeding on the bait with bittering agent versus the number of ants feeding on the bait without bittering agent.	Abril, S. and Gómez, C. (2015) Denatonium Benzoate (safety bittering agent) effect on palatability in *Lasius niger*. Grpecat-universitat de girona Report

<table>
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<tr>
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<td>Insects:
Black garden ants (Lasius niger)</td>
<td>The aim of the laboratory choice test was to assess the palatability and efficacy of 31 months aged bait on black garden ants.
100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
The tests were carried out in 30cm x 25cm x 15cm plastic test arena with free-choice competition diet. A ssessment conducted at 1, 8 and 24 hours and then at 2, 5, 7, 9 and 14 days.
Ants kept at 25°C and 60% R.H. throughout.</td>
<td>Arena choice test: % mortality of ants
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<tr><td></td><td colspan="8">Days of exposure</td></tr>
<tr><td></td><td>0</td><td>0.04</td><td>0.33</td><td>1</td><td>2</td><td>5</td><td>6</td><td>7</td></tr>
<tr><td>Untreated control</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.3</td><td>1.8</td><td>1.8</td><td>2.0</td></tr>
<tr><td>IIRD-08002 0.065% 1R-trans-phenotrin</td><td>0.0</td><td>10.2</td><td>25.5</td><td>60.6</td><td>84.2</td><td>91.7</td><td>94.0</td><td>96.9</td></tr>
</table>
Under the conditions in the test arenas the formulation IIRD-08002 (0.065% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days Product stored at room temperature (25°C) for 31 months.
96.9% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td>
<td>Moreno, M. (2017a) Report No: RB-148.16</td>
</tr>
</table>

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<tr><th>Level 3 product and test substance</th><th>Test organism (s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects, mode of action, resistance</th><th>Reference</th></tr>
<tr><td>Meta SPC 2 - 2c (IIRD-08002) containing 0.065% 1R-trans-phenotrin Stored at room temperature (25°C) for 31months + a further 3 months storage after activation</td><td>Insects: Black garden ants (Lasius niger)</td><td>The aim of the laboratory choice test was to assess the palatability and efficacy of 31 months aged + a further 3 months storage after activation bait on black garden ants.
100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
The tests were carried out in 30cm x 25cm x 15cm plastic test arena with free-choice competition diet. Assessment conducted at 1, 8 and 24 hours and then at 2, 3, 4 and 7 days.
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Under the conditions in the test arenas the formulation IIRD-08002 (0.065% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days Product stored at room temperature (25°C) for 31 months+ a further 3 months storage after activation.
98.8% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td><td>Moreno, M. (2017a) Report No: RB-148.16.1</td></tr>
<tr><td>Meta SPC 1 – 1a (TP-50-C1) containing 0.093% 1R-trans-phenotrin Stored at room temperature (25°C) for 33months</td><td>Insects: Black garden ants (Lasius niger)</td><td>The aim of the laboratory choice test was to assess the palatability and efficacy of 33 months aged bait on black garden ants.
100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
The tests were carried out in 30cm x 25cm x 15cm plastic test arena with free-choice competition diet. A ssessment conducted at 1, 8 and 24 hours and then at 2, 5, 7, 9 and 14 days.
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Under the conditions in the test arenas the formulation TP--050-C1 (0.093% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days. Product stored at room temperature (25°C) for 33 months.
97.7% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td><td>Moreno, M. (2017b) Report No: RB-148.17</td></tr>
</table>

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<tr><td>Meta SPC 1 – 1a (TP-50-C1) containing 0.093% 1R-trans-phenotrin Stored at room temperature (25°C) for 33months + a further 3 months storage after activation</td><td>Insects: Black garden ants (Lasius niger)</td><td>The aim of the laboratory choice test was to assess the palatability and efficacy of 33 months aged bait + a further 3 months storage after activation on black garden ants.
100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
The tests were carried out in 30cm x 25cm x 15cm plastic test arena with free-choice competition diet. Assessment conducted at 1, 8 and 24 hours and then at 2, 3, 4 and 7 days.
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Under the conditions in the test arenas the formulation TP--050-C1 (0.093% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days. Product stored at room temperature (25°C) for 33 months + a further 3 months storage after activation.
100% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td><td>Moreno, M. (2017b) Report No: RB-148.17.1</td></tr>
<tr><td>Meta SPC 2 – 2a (TP-50-C2) containing 0.093% 1R-trans-phenotrin Stored at room temperature (25°C) for 33months</td><td>Insects: Black garden ants (Lasius niger)</td><td>The aim of the laboratory choice test was to assess the palatability and efficacy of 33 months aged bait on black garden ants.
100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
The tests were carried out in 30cm x 25cm x 15cm plastic test arena with free-choice competition diet. A ssessment conducted at 1, 8 and 24 hours and then at 2, 5, 7, 9 and 14 days.
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Under the conditions in the test arenas the formulation TP-050-C2 (0.093% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days.
Study conducted with aged product - stored at room temperature (25°C) for 31 months.
97.3% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td><td>Moreno, M. (2017c) Report No: RB-148.18</td></tr>
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100 worker ants were collected from field colonies used per replicate. 4 replicates per trial.
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<tr><td>TP-50-C2 0.093% 1R-trans-phenotrin</td><td>0.0</td><td>2.3</td><td>26.8</td><td>32.8</td><td>50.8</td><td>65.0</td><td>77.3</td><td>97.8</td></tr>
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Under the conditions in the test arenas the formulation TP-050-C2 (0.093% 1R-trans-phenotrin) achieved the required minimum 95% control of ants in 7 days.
Study conducted with aged product - stored at room temperature (25°C) for 33 months+ a further 3 months storage after activation.
97.8% mortality of Black garden ants (Lasius niger) was reached after 7 days.</td>
<td>Moreno, M. (2017c) Report No: RB-148.18.1</td>
</tr>
</table>

Conclusion on the efficacy of the product
The applicant presented the results from nine studies: two field efficacy studies and seven laboratory tests. Both field studies were carried out in the UK, the lab palatability whilst the laboratory choice studies were conducted in Spain. Detailed comments on these studies have been added as annotations to the studies included with the dossier on IUCLID. The field test protocols were largely in accordance with the available guidance for PT18 products for ant control (CA-Dec12-Doc.6.2.a – Final). Adult *Lasius niger* was the tested organism. TnG states that for bait products intended to control ants laboratory palatability choice tests (bait and alternative food) should achieve at least 95% control of insects at a given time point and field trials should demonstrate >90% reduction in ant numbers relative to untreated sites or pre-treatment levels in order to be considered sufficiently effective. The first suite of palatability trials (Abril and Gómez 2015) presented by the applicant differs slightly from the bait choice test suggested in the PT18 guidance in that the test organisms were not given a free choice between the food option with the bittering agent present or an alternative food source without the bittering agent present. In the palatability study supplied, six groups ("artificial nests") of ants were established in separate boxes in the lab, with the ants sourced from wild nests. Each box was either

given the bait with bittering agent present (n=3); or the bait without the bittering agent present (n=3). The difference in feeding between these two groups was assessed and it was concluded that because ants fed on either bait with a similar frequency, that the bait was palatable when bittering agent was added. Although the test was not strictly in agreement with the established guidance (CA-Dec12-Doc.6.2.a – Final), it did show that the *L. niger* showed no aversion to the bait with the bittering agent added.

The first field study (Heaven 2015c) demonstrates the efficacy of the double ant bait station containing 0.093% AS and included two different formulations (Meta SPC 1, TP-050-C1; Meta SPC 2, TP-050-C2). The first chamber contained a sugar based food source, whilst the second chamber contained a sugar and protein based food source.
The second field study (Heaven 2015a) demonstrates the efficacy of the single bait capsule Meta SPC 2 – 2c IIRD-08002, containing 0.065% AS.
All field studies also demonstrate the efficacy of aged baits (up to 3 months old), as statistical analysis showed that bait age did not have a significant effect on its attractiveness or effectiveness.

Following agreement in the meeting with the Coordination Group on August 9th 2017, Henkel initiated further efficacy laboratory tests to check the performance of the ant bait formulations IIRD-08002, TP-050-C1 and TP-050-C2 with aged samples. These were retained samples stored in ambient conditions for IIRD-08002 (batch: 5051G, Jan 2015, 31 months since production), TP-050-C1 (batch: 4336 CP 2417, Nov 2014, 33 months since production) and TP-050-C2 (batch: 4336 CP 2417, Nov 2014, 33 months since production). Summaries of these studies are included in Annex 3.5. The efficacy results for the aged formulations IIRD-08002, TP-050-C1 and TP-050-C2 (0.065 and 0.093%) was greater than 95% after 7 days. Based on these results it may be concluded that the palatability of the matrices of formulations supported in this dossier (understood as attractiveness for the bait) is not affected by 31 to 33 months of aging when stored at room temperature followed by storage for a further 3 months after activation. The efficacy of these product over their proposed shelf-life of 2 years was confirmed.

The applicant has applied for read-across from Heaven 2015a and Moreno 2017a, Report No: RB-148.16 to product J-70021 (Meta SPC 2- 2b). The IE eCA agrees that this product should be efficacious, as it has similar compositions of food ingredients and a higher concentration of AS than the actual product tested (IIRD-08002); therefore read-across is allowed to this product as proof of efficacy.

The applicant has applied for read-across from Heaven 2015c and Moreno, M. 2017b, Report No: RB-148.17 for chamber 1 formulation (TP-050-C1b) in meta SPC 3 - 3 (TP-050-C1b & TP-050-C2). A justification for this has been included in Annex 3.7 and is considered acceptable.
Discussions with regard to the methods employed in the laboratory and field trials and with regard to the statistical analyses of the results took place during the Efficacy Working Group (EFF WG) meeting on 25 April 2018 (EFF WG-II-2018). Following comprehensive discussion it was agreed that the information provided by the applicant and assessed by the refMS is sufficient to demonstrate that this biocidal product family is sufficiently effective when used as claimed. The conclusions reached by the refMS are considered valid and it can be concluded that the conditions of Article 19(1)(b) are met.

The IE eCA also asked the applicant for a justification why they wish to market a double bait station product whilst the results of their efficacy trials indicate that there is no difference between the efficacy of the double and single bait stations. The applicant has provided a literature review detailing the nutritional requirements of garden ants at different life-stages (uploaded to IUCLID under section 6.1 IE eCA annotation). The applicant reasoned that different ant life stages have certain nutritional requirements, and that the nutritional requirements of ants can change through the season. Given this scientifically reasoned justification, and the fact that both single and double bait products are efficacious, the IE eCA agrees to the authorisation of both types of bait.

The IE eCA considers that the following products from the biocide product family "Ant bait 1 R-trans phenothrin" are sufficiently effective for the use against ants in and around buildings when they are applied according to the stated application rate: the single thermoformed bait capsules from meta SPC 2 2b (J-70021) and 2c (IIRD-08002) with an application rate of 1 or 2 baits per $10m^2$. The double bait station meta SPC 3 – 3 (TP-050-C1b & TP-050-C2), and also the single bait station products meta SPC 1 – 1a (TP-050-C1) and meta SPC 2 – 2a (TP-050-C2), both having application rates of 1 or 2 bait stations per $10m^2$. It should be noted that the single bait stations contain 5g of bait. For all of these products the claim "for the control of garden ants" is permitted.

The applicant submitted a request for a shelf-life extension from 2 years to 3 years for the entire biocidal product family. New chemistry stability studies submitted by the applicant demonstrated that the 3 meta SPCs were covered for up to 36 months with AI degradations not exceeding 6%. No additional efficacy studies were submitted. However, the efficacy studies submitted and accepted at authorisation demonstrated acceptable levels of efficacy and palatability for up to 31 months storage for the IIRD-08002 product (Moreno, M. (2017a) Report No: RB-148.16.1) and 33 months for the TP-050-C1b and TP-050-C2 products (Moreno, M. (2017b) Report No: RB-148.17.1; Moreno, M. (2017c) Report No: RB-148.18.1). These 3 efficacy studies also demonstrated that after the storage period, the products could be activated (foil covering removed) for 3 months and still retained efficacy. It is the view of the IE CA that the "activation period" reflects the service-life of the products and cannot be used to justify an extension of a products shelf-life, as the 3-month activation period is detailed in the products use instructions. Therefore, the IE CA proposes a shelf-life extension of up to 31 months for product IIRD-08002 and 33 months for the products TP-050-C1b and TP-050-C2. As bridging is applied from these studies to cover several meta SPCs shelf-life is as follows:

- Meta SPC 1 product "Vapona Ant Bait C1" (TP-050-C1b) can be given a shelf life of 33 months.
- The Meta SPC 2 products IIRD8002 (Vapona Ant Bait) and J-70021 (Vapona Ant Bait Extra) can be given a shelf-life of 31 months based on the IIRD-08002 study. The Meta SPC 2 product "Vapona Ant Bait C2" can be given a shelf-life of 33 months (TP-050-C2).
- The Meta SPC 3 dual bait station product "Vapona Double Ant Bait" can be given a shelf-life of 33 months based on the studies conducted on the studies conducted on TP-050-C1b and TP-050-C2.

2.2.5.6 Occurrence of resistance and resistance management

The following text was provided by the applicant: "*Pyrethroid resistance is known to occur and measures, such as those detailed below, are known to be effective in reducing the occurrence of resistance*".
There were no instances of resistance observed during the efficacy trials conducted and summarised within this dossier.
Baits are only used where ants are observed, for example, next to ant nests or ant trails. Bait stations should last for up to 3 months approximately, and should be replaced when empty if ants remain active. Resistance in ants is a less common feature. Ant nests have one or few queens who lay eggs for a long period, and with a biocide that kills the colony members most of the time it is not anticipated that resistance will develop.

2.2.5.7 Known limitations

None are known to the applicant. However, IE eCA notes the importance of the removal of any other food source from the ants in order that the ant bait provides effective control of ants.

2.2.5.8 Evaluation of the label claims

The efficacy data presented in the dossier supports the label claim us use of Ant Bait 1R-transphenothrin BPF products for the "control of ants indoors and outdoors".
The label states that after 1 week a reduction in ant numbers should be noted by the user. The efficacy data does not conclusively prove this statement. [redacted] Therefore, the IE eCA concludes that the statement should be changed to "after 4 weeks, the disappearance of the ants should be noticed".
The label claim supplied by the applicant "Eliminates Ants. Lasts for 3 months" is supported by the efficacy studies.

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

Ant Bait 1R-transphenothrin BPF products are not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No classification proposed
Justification for the value/conclusion	Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components in the bait mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the components and their concentration in the bait mixtures.
Classification of the product according to CLP and DSD	As neither the active substance nor the components of the biocidal product family bait products are classified for skin irritation, the products included in the Ant Bait 1R-trans phenothrin BPF do not meet the criteria for skin irritation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	No classification proposed
Justification for the value/conclusion	Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components in the bait mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the components and their concentration in the bait mixtures.
Classification of the product according to CLP and DSD	As neither the active substance nor the components of the biocidal product family bait products are classified for eye irritation, the products included in the Ant Bait 1R-trans phenothrin BPF do not meet the criteria for eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Testing for respiratory tract irritation has not been performed as the Ant Bait 1R-trans phenothrin BPF products are non-volatile and contained within sealed bait stations or marketed for use as a ready-to-use syringe for cracks and crevices containing thick and viscous liquid bait which is non-volatile.
Classification of	No classification proposed

the product according to CLP and DSD	

Skin sensitization
Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components in the bait mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the components and their concentration in the bait mixtures.

For product Meta SPC 1 – 1a (TP-050-C1), as neither the active substance nor the components of the biocidal product family bait products are classified for skin sensitisation, the mixture does not meet the criteria for classification for skin sensitisation.
For products Meta SPC 2 – 2a (TP-050-C2), Meta SPC 2 – 2b (J-70021), Meta SPC 2 – 2c (IIRD-08002) & Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2) from the information available on the bait mixtures they will not be classified for skin sensitisation but will carry the EUH208 warning on the label due to the inclusion of 1,2-benzisothiazol-3(2H)-one (BIT) preservative above 1/10 of the specific concentration limit of 0.05%.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No classification proposed
Justification for the value/conclusion	For product Meta SPC 1 – 1a (TP-050-C1), as neither the active substance nor the components of the biocidal product family bait products are classified for skin sensitisation, the mixture does not meet the criteria for classification for skin sensitisation. For products Meta SPC 2 – 2a (TP-050-C2), Meta SPC 2 – 2b (J-70021), Meta SPC 2 – 2c (IIRD-08002) Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2) from the information available on the bait mixtures they will not be classified for skin sensitisation but will carry the EUH208 warning on the label due to the inclusion of 1,2-benzisothiazol-3(2H)-one (BIT) preservative above 1/10 of the specific concentration limit of 0.05%.
Classification of the product according to CLP and DSD	No classification proposed

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No classification proposed
Justification for the value/conclusion	Testing of the product is not deemed necessary. Classification may be based on read across to the active substance by means of a letter of access and reference to the components and their concentration in the mixture. As neither the active substance nor the components of the biocidal product family/product is classified for respiratory sensitisation, the mixture does not meet the criteria for classification for respiratory sensitisation.
Classification of the	No classification proposed

product according to CLP and DSD	

Acute toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	No classification proposed
Justification for the selected value	Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components in the bait mixtures sufficient to allow classification of the mixture according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the non-active substance components and their concentration in the bait mixtures. As neither the active substance nor the components of the biocidal product family bait products are classified for acute oral toxicity, the products included in the Ant Bait 1R-trans phenothrin BPF do not meet the criteria for classification for acute toxicity by the oral route.
Classification of the product according to CLP and DSD	No classification proposed

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No classification proposed
Justification for the selected value	Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components in the bait mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the non-active substance components and their concentration in the bait mixtures. In addition the BPF products are water based pastes held within a plastic cartridge packaged and used in a way that does not result in respirable particles or vapour and the vapour pressure of the active ingredient is very low (2.37 x 10-5 Pa at 20°C & 4.17 x 10-5 Pa at 25°C). As neither the active substance nor the components of the product are classified for acute inhalation toxicity, the bait mixtures do not meet the criteria for classification for acute toxicity by the inhalation route.
Classification of the product according to CLP and DSD	No classification proposed

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No classification proposed
Justification for the selected	Testing of the Ant Bait 1R-trans phenothrin BPF has not been performed as there are valid data available on each of the components

value	in the bait mixtures sufficient to allow classification according to Regulation (EC) No 1272/2008 (CLP) and synergistic effects between the components are not expected. On this basis classification may be based on read across to the 1R-trans phenothrin Annex I dossier and with reference to the non-active substance components and their concentration in the bait mixtures. In addition the BPF products are water based pastes held within a plastic cartridge packaged and used in a way that does not result in dermal exposure when following the label instructions. As neither the active substance nor the components of the biocidal product family bait products are classified for acute dermal toxicity, the products included in the Ant Bait 1R-trans phenothrin BPF do not meet the criteria for classification for acute toxicity by the dermal route.
Classification of the product according to CLP and DSD	No classification proposed

Information on dermal absorption

No data are available for the dermal absorption of the Ant Bait 1R-trans phenothrin BPF products, therefore according to ECHA Guidance for Human Health Risk Assessment, Volume III, Part B, Version 1.0, Dec 2013, (pages 37-41) a default value of 100% skin absorption is generally used unless molecular mass is above 500 and log P is outside the range [-1, 4], in which case a value of 10% skin absorption is chosen (De Heer et al, 1999). However for the purpose of estimating dermal absorption for biocidal active substance and products, using default values on the basis of physicochemical properties, the principles described in the OECD Guidance on Dermal Absorption (OECD 2004 and OECD 2011) as well as the approach and default values described in the EFSA Guidance Document for dermal absorption (EFSA, 2012) should also be considered. It is considered that a default value of 100% is excessive for the formulated ant-bait products and a lower value may be used for the Tier 1 assessments as justified in the discussion below.

The phys-chem data to be considered for dermal absorption (active substance data from the 1R-trans phenothrin Assessment Report) are shown below.

Physical state: Liquids and substances in solution are taken up more readily than dry particulates. Dry particulates will have to dissolve into the surface moisture of the skin before uptake can begin. Absorption of volatile liquids across the skin may be limited by the rate at which the liquid evaporates off the skin surface (Pryde and Payne, 1999).

Ant-bait products: pastes

Molecular weight: Less than 100 favours dermal uptake. Above 500 the molecule may be too large. 1R-trans phenothrin - 350.46

Structure: As a result of binding to skin components the uptake of chemicals with the following groups can be slowed: certain metal ions, particularly Ag^{+}, Cd^{2+}, Be^{2+} and Hg^{2+} acrylates, quaternary ammonium ions, heterocyclic ammonium ions, sulphonium salts. A slight reduction in the dermal uptake of chemicals belonging to the following substance classes could also be anticipated for the same reason: Quinines, dialkyl sulphides, acid chlorides, halotriazines, dinitro or trinitro benzenes. 1R-trans phenothrin is not included in any of the above groups

Water solubility: The substance must be sufficiently soluble in water to partition from the stratum corneum into the epidermis. Therefore if the water solubility is below 1 mg/l, dermal uptake is likely to be low. Between 1-100 mg/l absorption is anticipated to be low to moderate and between 100-10,000 mg/l moderate to high. However, if water solubility

is above 10,000 mg/l and the log P value below 0 the substance may be too hydrophilic to cross the lipid rich environment of the stratum corneum. Dermal uptake for these substances will be low.
1R-trans phenothrin: 0.002 mg/L at 21°C
Log P: For substances with log P values <0, poor lipophilicity will limit penetration into the stratum corneum and hence dermal absorption. Values <−1 suggest that a substance is not likely to be sufficiently lipophilic to cross the stratum corneum, therefore dermal absorption is likely to be low. Log P values between 1 and 4 favour dermal absorption (values between 2 and 3 are optimal) particularly if water solubility is high. Above 4, the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis, but uptake into the stratum corneum will be high. Above 6, the rate of transfer between the stratum corneum and the epidermis will be slow and will limit absorption across the skin. Uptake into the stratum corneum itself may be slow.
1R-trans phenothrin: 6.8 at pH 7
Vapour pressure: The rate at which gases and vapours partition from the air into the stratum corneum will be offset by the rate at which evaporation occurs therefore although a substance may readily partition into the stratum corneum, it may be too volatile to penetrate further. This can be the case for substances with vapour pressures above 100-10,000 Pa (ca. 0.76-76 mm Hg) at 25°C, though the extent of uptake would also depend on the degree of occlusion, ambient air currents and the rate at which it is able to transfer across the skin. Vapours of substances with vapour pressures below 100 Pa are likely to be well absorbed and the amount absorbed dermally may be more than 10% of the amount that would be absorbed by inhalation.
Not applicable for 1R-trans phenothrin
Surface tension: If the surface tension of an aqueous solution is less than 10 mN/m, the substance is a surfactant and this will enhance the potential dermal uptake. Surfactants can also substantially enhance the absorption of other compounds, even in the absence of skin irritant effects.
Not applicable for 1R-trans phenothrin
Skin irritation / corrosivity: If the substance is a skin irritant or corrosive, damage to the skin surface may enhance penetration.
Ant-bait products: not classified for irritation
Dermal toxicity data: Signs of systemic toxicity indicate that absorption has occurred. However, if steps have not been taken to prevent grooming, the substance may have been ingested and therefore signs of systemic toxicity could be due to oral rather than dermal absorption.
Ant-bait products: no information on formulated products
Skin sensitisation data: If the substance has been identified as a skin sensitizer then, provided the challenge application was to intact skin, some uptake must have occurred although it may only have been a small fraction of the applied dose.
Ant-bait products: no information on formulated products
Trace elements: If the substance is a cationic trace element, absorption is likely to be very low (<1%). Stable or radio-isotopes should be used and background levels determined to prevent analytical problems and inaccurate recoveries.
Ant-bait products: Not applicable for the formulated ant-bait product
Toxicokinetics of 1R-trans phenothrin: Rate and extent of oral absorption, rapid, 60% based on urinary excretion. Rate and extent of dermal absorption: 4.5% by 24 hours (1% w/v formulation) based on an in-vitro human dermal absorption study.
Note that the molecular weight of 1R-trans phenothrin is less than 500 and although the LogP is >4, the default value of 10% cannot be used. The water solubility is very low (2 µl/L at 21°C) and LogP >6 would indicate that dermal uptake is likely to be low as it will not easily be taken up into the stratum corneum or partition from the stratum corneum to the epidermis.

The EFSA and OECD guidance documents (OECD 2004, OECD 2011 & EFSA 2012) note that a default value of 75% may be used for products containing ≤ 5% active substance (section 6). The EFSA guidance also suggests that consideration of the oral absorption should be taken into account when setting a default dermal absorption value as the dermal absorption in unlikely to be higher than oral absorption for active substances although for formulated products this correlation is less reliable. For the ant-bait products which are not classified as irritating and whose components are primarily food based and unlikely to enhance dermal penetration it should be noted that use of the default value of 75% is protective when the oral absorption of 1R-trans phenothrin is 60 %.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Ant Bait 1R-trans phenothrin BPF products
Value(s)*	default value of 75%
Justification for the selected value(s)	The EFSA and OECD guidance documents (OECD 2004, OECD 2011 & EFSA 2012)

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

There are no non-active components of the biocidal product family products that are substances of concern in the Ant Bait 1R-trans phenothrin BPF.

The following product members of the Ant Bait 1R-trans phenothrin BPF Meta SPC 2 – 2a (TP-050-C2), Meta SPC 2 – 2b (J-70021), Meta SPC 2 – 2c (IIRD-08002), Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2), contain a non-active component that is classified according to Regulation (EC) No 1272/2008. It is not defined as a substance of concern at the concentration levels present in these products, nevertheless the product labels carry the EUH208 hazard statement 'Contains 1,2-Benzisothiazol-3(2H)-one, may produce an allergic reaction' and the products are suitably labelled to avoid dermal contact due to the EUH208 supplemental hazard information.

Available toxicological data relating to a mixture
There are no non-active components of the biocidal product family/products that are substances of concern in the Ant Bait 1R-trans phenothrin BPF.

2.2.6.2 Exposure assessment

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

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

* Accidental exposure

Ant Bait 1R-trans phenothrin Baits Stations

Ant Bait 1R-trans phenothrin Baits Stations are supplied ready-to-use by non-professional users.

There is a double ant bait station which contains product Meta SPC 3 – 3 (TP-050-C1b in chamber 1 & TP-050-C2 in chamber 2), each containing 0.093% 1R-trans phenothrin. Thus the double ant bait station contains approximately 5.65g product formulation (5.25 mg of 1R-trans phenothrin) in total.

Single ant bait stations products contain Meta SPC 1 – 1a (TP-050-C1) or Meta SPC 2 – 2a (TP-050-C2) each containing 0.093% 1R-trans phenothrin. The bait station contain up to 5 g product formulation which represents a worst case of 4.65 mg 1R-trans phenothrin.

Single Ant Bait Capsules contain products Meta SPC 2 – 2b (J-70021) or Meta SPC 2 – 2c (IIRD-08002) containing 0.087% and 0.065% 1R-trans phenothrin respectively. The capsules contain 5 g product formulation which represents a worst case of 4.35 mg 1R-trans phenothrin.

Primary Exposure:

Dermal Exposure: The bait stations are designed to prevent exposure such as dermal contact during the opening of the packaging or during the placing and activation of the stations. On this basis primary dermal exposure is considered to be negligible and will not be considered further.

Secondary Exposure:

Ant Bait 1R-trans phenothrin BPF baits are packaged in bait stations designed to prevent access to the bait to all except the intended pest (ants). Although the stations are used in and around buildings and domestic properties where adults, children and companion animals will inevitably be present during the three month working life of the product, the risk of accidental exposure can be considered negligible due to the design of the bait stations. Whilst secondary exposure to the bait formulation is unlikely the following potential secondary exposure scenarios are considered:

short-term dermal exposure – infant comes into contact with residue of the bait and is dermally exposed;

short-term oral exposure – infant comes into contact with residue of the bait and ingests *via* hand to mouth.

List of scenarios

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
Second. exposure 1.	Short-term dermal & oral exposure	Bait station product Secondary exposure. Infant crawling in the vicinity of the bait station comes into contact with residue of the bait transported by ants and is dermally and orally exposed (via hand to mouth contact).	Non-professional / General public

Industrial exposure

Operator exposure is considered under the requirements of The Chemical Agents at Work Directive (98/24/EEC, within Directive 89/391/EEC), and controlled using engineering controls and PPE and RPE as appropriate, according to Directive 89/656/EEC. These regulations competently control operator exposure to the constituents of the formulation and, therefore, no further assessment is required.

Professional exposure

Not applicable for Ant Bait 1R-trans phenothrin BPF products which are consumer products.

Non-professional exposure

Scenario [Secondary exposure 1]

Description of Scenario [Secondary exposure 1]			
Infant crawling in the vicinity of the bait station comes into contact with residue of the bait transported by ants and is dermally and orally exposed (*via* hand to mouth contact). An assessment has been conducted to determine the potential exposure to children crawling in the vicinity of a bait station with a worst case assumption that 3% of the bait could be present on the outside of the bait station as a result of ant activity (Guidance on the Biocidal Products Regulation, Volume III Human Health, Part B Risk Assessment, April 2015). This scenario is considered to be short-term dermal and oral exposure. It is anticipated such exposures would be sporadic and that normal washing, undertaken at least once a day would remove contamination from the skin.			
	Parameters[1]	Value Typical Use (2 baits)	Value Maximum Use (6 baits)
Tier 1	Weight of bait (g)	5	5
	Percentage active ingredient	0.105	0.105
	Percentage of bait an infant is potentially exposed to	3	3
	Typical number of baits used in a 10 m^2 area#	2	-
	Maximum number of baits used in 10 m^2 area##	-	6
	Dermal absorption (default value based on dilute formulation)	75%	75%
	Oral absorption (CAR, Ireland March 2013)	60%	60%
	Dermal uptake*	90%	90%
	Oral uptake*	10%	10%
	Infant body weight (HEEG Opinion, TM11 2013)	8 kg	8 kg

	Bait Exposure period (days)	30 days	30 days
	# from label information ## anticipated worst case * the model assumes that as a worst case an infant will be exposed to 90% of the available bait residue *via* dermal exposure and 10% *via* oral exposure due to hand to mouth contact (TNG, 2002)		
Tier 2[2]	N/A		
Tier 3	N/A		

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.
N/A not applicable

Summary of Secondary Exposure Scenario 1

Intended use (MG/PT)	Exposure scenario	Inhalational uptake	Total Internal Dermal Dose (mg/kg bw)	Total Internal Oral Dose (mg/kg bw)
MG3/ PT18	Scenario 1, Tier 1 Infant crawling in the vicinity of a bait station	N/A	Typical use (2 baits):- 9.84E-04 mg 1R-trans phenothrin/kg bw/day Maximum use (6 baits):- 2.95E-03 mg 1R-trans phenothrin/kg bw/day	Typical use (2 baits):- 7.88E-05mg 1R-trans phenothrin/kg bw/day Maximum use (6 baits):- 2.36E-04 1R-trans phenothrin/kg bw/day

N/A = Not applicable

Calculations for Scenario [Primary and Secondary exposure]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [Secondary exposure 1]	1	N/A	Typical use (2 baits) 9.84E-04 Maximum use (6 baits) 2.95E-03	Typical use (2 baits) 7.88E-05 Maximum use (6 baits) 2.36E-04	Typical use (2 baits) 1.06E-03 Maximum use (6 baits) 3.19E-03

N/A not applicable

Combined scenarios
Combined scenarios are not applicable for Ant Bait 1R-trans phenothrin BPF products.

Exposure of the general public

Exposure to the general public is considered in the secondary exposure scenarios reported above.

Dietary exposure

Dietary exposure is not applicable for Ant Bait 1R-trans phenothrin BPF products.

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

Exposure associated with production, formulation and disposal of the biocidal product are not applicable for Ant Bait 1R-trans phenothrin BPF products.

Aggregated exposure

Aggregated exposure is not applicable for Ant Bait 1R-trans phenothrin BPF products.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
Second. exposure 1.	Non-professionals / General public	1 / no PPE	~~Typical use (2 baits) 0.0028 Maximum use (6 baits)~~ Typical use (2 baits) 1.06E-03 Maximum use (6 baits) 3.19E-03

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Developmental toxicity study in rabbits#	30 mg/kg bw/d	100	60%; 18 mg/kg bw/d	0.18 mg/kg bw

AELmedium-term	52 week toxicity study in dogs#	8.2 mg/kg bw/d	100	60%; 4.92 mg/kg bw/d	0.05 mg/kg bw
AELlong-term	Not required				
ARfD	Not required				
ADI	Not required				

[1] AF of 10 for interspecies and 10 for intraspecies as defined in the Competent Authority Report: Ireland March 2014, PT18 Assessment Report for 1R-trans phenothrin.
Competent Authority Report: Ireland March 2014, PT18 Assessment Report for 1R-trans phenothrin

Maximum residue limits or equivalent
Residue limits are not required for Ant Bait 1R-trans phenothrin products.

Risk for industrial users
Not applicable for Ant Bait 1R-trans phenothrin BPF products.

Risk for professional users
Not applicable for Ant Bait 1R-trans phenothrin BPF products.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 (secondary exposure) Infant crawling in the vicinity of a bait station	Tier 1	4.92	0.05	Typical use (2 baits) 1.06E-03 Maximum Use (6 baits) 3.19E-03	0.02/2% 0.06/6%	Yes Yes

Non-professional Exposure (Consumer)
The bait is provided in preformed bait stations and there should be no significant potential exposure following non-professional use. 1R-trans-phenothrin is not very volatile (4.17 x 10^{-5} Pa at 25°C) and the amount of active ingredient incorporated into the bait (0.073-0.105%) coupled with the small amount that would be applied when used in and around buildings, result in an insignificant exposure *via* inhalation.
During the task of placing the bait stations there will be no contact with the product *via* the skin, therefore dermal and oral exposure during placing is not expected.
Secondary (Indirect) Exposure
An assessment has been conducted to assess the potential exposure to children crawling in the vicinity of a bait station (Scenario 1) with a worst case assumption that 3% of the bait could be present on the outside of the bait station for the life of the bait station (1 month). The results from this assessment demonstrate that there is no significant risk *via* dermal or oral exposure (MOE ≥4716). Exposure *via* inhalation is expected to be negligible as 1R-trans-phenothrin is of low volatility (4.17 x 10^{-5} Pa at 25°C) and the amount of active ingredient incorporated into the bait (0.021-0.105%) and the number of bait stations typically placed at one time are not expected to result in a significant risk *via* inhalation.

Non-professional inhalation exposure to the occupants of the Premises

Occupants of treated premises could be exposed to vapours volatilised from the gel on treated surfaces. Adults, children and infants could inhale the vapours of Henkel's 0.105 % gel when in enclosed unventilated spaces. This would be a long-term exposure scenario and in a worst-case situation, occupiers could be exposed to air saturated with these vapours for 24 hours a day

Parameter	Value	Reference
Vapour Pressure of d-trans-phenothrin at 25 °C (Pa)	4.17×10^{-5}	
Molecular Weight of d-trans-phenothrin (g/mol)	350.46g/mol	
Gas Constant	8.31451	
Temperature (Kelvin)	298	25°C
Adult inhaltation rate (m^3/day)	15.2	Exposure Factors Sourcebook for European Populations. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium, Technical Report No 79 (2001).
Child inhaltation rate (m^3/day)	14.00	
Infant inhaltation rate (m^3/day)	4.5	
Adult Body Weight (kg)	60	
Child Body Weight (kg)	34.4	
Infant Body Weight (kg)	10	

SVC (g/m^3) = $\frac{\text{Vapour pressure (Pa) x Molecular weight}}{\text{Gas constant x Temperature (Kelvin)}}$

$= \frac{4.17 \times 10^{-5}\ 350.46}{8.31451 \times 298}$

$= 5.89 \times 10^{-6}\ g/m^3 =$ 0.006 mg/ m^3

Exposure	Adult	Child	Infant
Saturated vapour concentration d-trans-phenothrin (mg/m3)	0.006	0.006	0.006
Daily inhalation exposure (mg/day)	0.0912	0.084	0.027
Daily systemic exposure to (mg a.s./kg/day)	0.00152	0.00244186	0.0027

The exposure to the SVC has been calculated and found to be acceptable.

Conclusion

Primary Exposure

The Henkel products are for amateur use only so no professional exposure is expected. The products are prefilled bait stations that require no application and do not allow for bait contact. The bait stations have not been modelled from primary exposure because their design precludes this.

Secondary Exposure

Assessment to Determine the Potential Risk from Exposure to bait stations was undertaken.The risks are considered to be acceptable for infants, children and adults resident or visiting treated premises. The exposure scenario envisages a worst case event with 3% of the bait from a bait station being available for human exposure over the lifetime of the bait. As the ConsExpo fact sheet on insecticides suggest that exposure from bait stations is negligible we conclude that 3% from 6 bait stations represents worst case.

At this worst case the level the exposure to the infant (the most sensitive inhabitant) represents about 6% of the AEL

Combined scenarios

Combined scenarios are not applicable for Ant Bait 1R-trans phenothrin BPF products.

Local effects

Local effects are not applicable for Ant Bait 1R-trans phenothrin BPF products.

Risk for the general public

Exposure to the general public is considered in the secondary exposure scenarios reported above.

Risk for consumers via residues in food

Risk to consumers *via* residues in food are not applicable for Ant Bait 1R-trans phenothrin BPF products.

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

This is not applicable to Ant Bait 1R-trans phenothrin BPF products which do not contain any substances of concern.

2.2.7 Risk assessment for animal health

A risk assessment for animal health is not applicable for Ant Bait 1R-trans phenothrin BPF products.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

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

No new information or studies were submitted for Ant Bait 1R-trans phenothrin BPF. All information for this authorisation is based on the active substance, 1R-trans Phenothrin.

The ecotoxicological properties of the Ant Bait 1R-trans phenothrin BPF products are derived from the properties of the active ingredient and other components of the product. Information on the ecotoxicity of 1R-trans phenothrin is presented in the Annex I dossier.

Only one other component of the formulation (BIT) is classified on the basis of its environmental toxicity (H400) with a M factor of 1; however the concentration of BIT in the biocidal product does not trigger a classification.

Environmental classification of the Ant Bait 1R-trans phenothrin BPF products is based on their content of 1R-trans Phenothrin and is performed in accordance with the criteria for CLP Regulation (EC) No. 1272/2008.

Aquatic Compartment
Products in the Ant Bait 1R-trans phenothrin BPF have been classified according to the rules laid down in CLP Regulation (EC) No. 1272/2008 with read across to 1R-trans phenothrin; taking into consideration the percentage of active substance included in the formulation and reference to the components and their concentration in the bait mixtures.
On this basis Aquatic Classification applies to the products of the associated families:

- Aquatic chronic 2; H411'Toxic to aquatic life with long lasting effects'
  - Meta SPC 1 – 1a (TP-050-C1); and
  - Meta SPC 2 – 2a (TP-050-C2), Meta SPC 2 – 2b (J-70021), Meta SPC 2 – 2c (IIRD-08002).
  - Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2)

The available toxicity data (acute and chronic) of 1R-trans Phenothrin on aquatic organisms is summarized in the following table.

Toxicity Data for Aquatic Species (extracted from the List of Endpoints, Competent Authority Report for 1R-trans Phenothrin, March 2013)

Species	Time-scale	Endpoint	Toxicity
Fish			
Fish - Rainbow Trout (*Salmo gairdneri*)	96h	LC_{50}	0.0027 mg/l
Invertebrates			
Daphnia - Cladoceran (*Daphnia magna*)	48h	EC_{50}	0.0043 mg/l
Algae			
Algae - Green Alga *Pseudokirchneriella subcapitata*	72h	EbC_{50} NOErC	>0.011 mg/l 0.0036 mg/l
Micro-organisms			
Activated Sludge -	3h	EC_{50}	>100 mg/l

Atmosphere
1R-trans phenothrin can be considered to be low volatility on the basis of its vapour pressure and Henry's law constant. Atmospheric exposure is therefore insignificant and there are no other constituents of the product that are of concern to the air environmental compartment at their concentration in the bait mixtures.

Terrestrial Compartment
The only potential for exposure of the terrestrial compartment relates to the possibility that sewage sludge containing the active ingredient may be spread on agricultural land in

the event that it enters a STP. In this event, ecotoxicological data on the active substance are adequate for determining the resulting risk to organisms in the terrestrial compartment (Annex I dossier, Document IIA, Section 4.2).

Predicted No Effect Concentrations (PNECs)

PNEC	Value
$PNEC_{STP}$	10 mg/l
$PNEC_{freshwater}$	0.000047 mg/l
$PNEC_{sediment,freshwater}$	0.129 mg/kg wwt
$PNEC_{soil}$	0.0104 mg/kg wwt
$PNEC_{oral,\ predator}$	10 mg/kg food (mammals & earthworms)
	1.87 mg/kg food (birds)

Further Ecotoxicological studies

There are no new ecotoxicological studies available for Ant Bait 1R-trans phenothrin BPF.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	No new information or studies were submitted for Ant Bait 1R-trans phenothrin BPF. All information for this authorisation is based on the active substance, 1R-trans Phenothrin.
Justification for the value/conclusion	The risk assessment is based on the data obtained from the active substance 1R-trans Phenothrin (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, 1R-trans phenothrin CAS 188023-86-1, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Ireland, March 2013. A non-active preservative component of the formulation, Parmetol D11 (BIT), is classified as H400 'Very toxic to aquatic life' in the frame of the Directive 91/414/EEC on the basis of its environmental toxicity. The concentration of BIT does not trigger a classification in the biocidal product(s). The concentration of this agent used in the Ant Bait 1R-trans Phenothrin products does not contribute to the classification of the biocidal product. No other substance(s) of concern were identified. The effects of Ant Bait 1R-trans phenothrin Biocidal Product Family are considered to outweigh those of the non-active components of the product and the effects assessment for the Ant Bait 1R-trans phenothrin Biocidal Product Family can be extrapolated from the effects assessment of the active substance 1R-trans phenothrin.

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

There is no new information available for Ant Bait 1R-trans phenothrin BPF.

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

All formulation types – bait stations
Testing of the biocidal product family/product when packaged in bait stations was not performed. The Ant bait is contained in plastic prefilled sealed bait stations which are specifically designed to enable ant access to the bait when placed near ant nests or trails but will prevent access to larger non-target organisms. The bait stations are disposed of when empty.

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

All formulation types – bait stations
Testing of the biocidal product family/product when packaged in bait stations was not performed. The Ant bait is contained in plastic prefilled sealed bait stations which are specifically designed to enable ant access to the bait when placed near ant nests or trails but will prevent access to larger non-target organisms. The bait stations are disposed of when empty.

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

This is not relevant for the Ant Bait 1R-trans phenothrin BPF.

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

Please see section 2.2.7.2 Exposure assessment.

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

There is no new information available for Ant Bait 1R-trans phenothrin BPF.

Leaching behaviour (ADS)

This is not relevant for the Ant Bait 1R-trans phenothrin BPF.

Testing for distribution and dissipation in soil (ADS)

There is no new information available for Ant Bait 1R-trans phenothrin BPF.

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

There is no new information available for Ant Bait 1R-trans phenothrin BPF.

Testing for distribution and dissipation in air (ADS)

1R-trans phenothrin can be considered to be low volatility on the basis of its vapour pressure and Henry's law constant. Atmospheric exposure is therefore insignificant and there are no other constituents of the product that are of concern to the air environmental compartment at their concentration in the bait mixtures. On this basis new information Ant Bait 1R-trans phenothrin BPF was not required.

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

Ant Bait 1R-trans phenothrin BPF are bait products and are not sprayed during application or intended for use at or near surface waters.

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

Ant Bait 1R-trans phenothrin BPF are bait products and are not sprayed during application and have no potential for large scale formation of dust. A risk to bees and non-target arthropods is not considered in accordance with the proposed uses (i.e. bait station).

2.2.8.2 Exposure assessment

Ant Bait 1R-trans Phenothrin BPF are intended for use for the control of crawling insects, specifically ants. This assessment addresses the overall environmental exposure and risk assessment of the active substance, 1R-trans Phenothrin. From studies conducted using the active substance and described in detail in the Competent Authority Report: Ireland CAR, March 2013, the following environmental characteristics were established. One other constituent, present in some of the formulations, the preservative BIT, is classified as 'Very toxic to aquatic life' H400 with a M factor of 1. However, BIT is not present at a concentration sufficient to contribute to the environmental classification of the BPF for which it is present.

Degradation of 1R-trans Phenothrin in the Aquatic Compartment (Including Sediment)

- 1R-trans Phenothrin is not readily biodegradable.

- In natural water/sediments systems, the dissipation of 1R-trans Phenothrin from the water phase to the sediment phase was dominated by sorption. The average whole system DT_{50} was 6.77 days at 25°C (= 19.15 days at 12°C). However the degradation was best described by DFOP kinetics with a DT_{90} > 1000 days. Indee the rate of decline in the whole system slowed to almost a complete stop after about 20 days.

- Bound residues increased to maximum 39.1% of AR at the end of the study after 91 days, mineralisation was moderate with a maximum of 43.7% of AR after 91 days.

- 1R-trans Phenothrin is hydrolytically stable at environmentally relevant pH (5 - 7) and temperature (25°C). The aqueous $DT_{50,photolysis}$ of 1R-trans Phenothrin is 9.1 to 13.9 hours.

- The experimental bioconcentration factor (BCF) for fish is 2,849 L/kg, based on the fitted uptake and elimination rate constants. No experimental data are available on terrestrial bioconcentration. The BCF for earthworms, estimated according to QSAR by Jager 1998, is 75,716 L/kg.

Degradation of 1R-trans Phenothrin in the Terrestrial Compartment

- For biodegradation in soil, DT_{50} of 1R-trans Phenothrin at 25°C is 9.6 days (SFO kinetics). The DT_{50} of 1R-trans Phenothrin is 27.2 days at 12°C.

- Highest mineralisation accounted for 51.6% of AR after 120 days. In soil only one significant metabolite was detected - 3-phenoxybenzyl alcohol, maximum 12.9% of AR; DT_{50} < 11 days at 25°C.

- The average Koc of 1R-trans Phenothrin is 125,892.5 L/kg. Sorption of 1R-trans Phenothrin is related to organic carbon content (OC).

Degradation of 1R-trans Phenothrin in the Air Compartment

1R-trans Phenothrin has a very low predicted vapour pressure (2.37×10^{-5} Pa at 20°C). It is therefore expected that exposure to the air compartment will be negligible.

Metabolites in the Environment

The Applicant did not perform an exposure assessment for the metabolites of 1R-trans Phenothrin. Instead they referred to the PECs generated for the parent compound with the following justification:

"*The Final CAR for 1R-trans Phenothrin addressed the non-relevance of metabolites in the environment as follows:*
The Q(S)AR model, ECOSAR was used to assess d-trans-Phenothrin and its major environmental metabolites, PBalc, PBacid and HO-trans-PHN with respect to the ecosystem. Fish 96h and 14 days, daphnia 48h, algae 96h and chronic fish, daphnia and algae were all assessed. The PBalc and PBacid metabolites are significantly (>100x) less toxic than the parent compound and the HO-trans-PHN metabolite is also less toxic than the parent compound. Therefore it is acceptable that the $PNEC_{aquatic}$ *value derived for d-trans-Phenothrin will provide a sufficient level of protection. Consequently, the acceptable environmental risk assessment for 1R-trans-phenothrin is also indicative of no unacceptable risk from its metabolites.*"

In addition the RMS evaluator points out that PECs for metabolites presented in the final CAR were all significantly lower than those for the parent compound. Therefore we do not object to the Applicant's approach.

Relevant environmental compartments
In accordance with the report compiled by the OECD Task Force on Biocides Product Type 18, entitled, "Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods for household and professional uses" (17th July 08), the receiving compartments for the use of a bait contained in a bait station indoors and outdoors are as follows:-

Receiving Compartments Following Indoor Application

Step	"Intermediate" receiving compartments	"Final" receiving compartments
Bait station: Mixing loading step[1]	Not applicable	Not applicable
Bait station: Application step[2]	Not applicable	Not applicable
Bait station: Cleaning step[3]	Not applicable	Not applicable

1. The bait stations products are ready to use and therefore there is no mixing and loading step.
2. There should be no emission from the application step as the bait is contained within a bait station.
3. It is assumed that no release will occur during the service life (cleaning) stage for baits deployed in bait stations (ESD page 64).
4. It is assumed that 3% may be exposed to cleaning (wet or dry methods) and 0.03% cleaning efficiency (ESD page 64)

Receiving Compartments Following Outdoor Application

Main Scenario	Sub scenario	Environmental compartments					Secondary poisoning
		Air	STP	Soil	Surface Water	Ground Water	
Bait station1,2	Ant bait stations (rural/urban)	-	(++)	++	(+)	+	+

++ Compartment primarily exposed
+ Compartment secondarily exposed (surface water from STP discharge, agricultural soil from sludge application, groundwater further to soil exposure, vertebrates eating contaminated insects)
(+) Compartment potentially exposed.
1 There should be no emission from the application step as the bait is contained within a bait station.
2 It is assumed that no release will occur during the service life (cleaning) stage for baits deployed in bait stations (ESD page 64).

Bait station indoor use

In accordance with the guidance given in the Emission Scenario Document (ESD) PT18 for household and professional uses, it is expected that the nature and use of the supported product(s) (household ready-to-use bait stations) would result in negligible environmental exposure to 1R-trans Phenothrin. Therefore PEC values for the aquatic, atmospheric and terrestrial compartments are all considered to be effectively zero.

There is no potential for environmental exposure via emission to the applicator, as the product(s) are pre-prepared and ready to use. A cleaning event is not considered to result in exposure: the ESD (Table 3.3-8) assumes that there is no exposure to cleaning for solid or gel baits in bait stations. Potential for exposure via waste disposal following use of the product(s) is beyond the scope of this assessment and would be covered by the Hazardous Waste Directive.

It is on this basis that the environmental exposure to 1R-trans Phenothrin arising from the use phase of these bait station product(s) is anticipated to be negligible and that PEC values for the various environmental compartments are considered to be effectively zero.

Bait station outdoor use

These products are for use in and around buildings. A maximum of two baits is to be placed every 10m^2. The following extracts from the ESD for PT18 (p130) describe the exposure routes:

"*releases may occur from the transport of product by contaminated insects or following flooding from a rain event... about 80% of the product is consumed by the insects whereas 20% remain in the bait station and can be emitted into the environment.*

Fspot,bait = 0.2

...Although exposure of STP is possible, it is thus considered that the relevant scenario for outdoor use of baits is the exposure of surrounding garden soil following wash-off of the terrace by rainfall."

The biocidal product family consists of three meta-SPCs and 5 individual products. The amount of active substance in each product is illustrated as follows:

Meta SPC	Product Name	Description	Product Mass (g)	% active substance	Quantity of active substance per product (g)
1	TP-050-C1	Single bait station	5	0.105	0.00525
2	IIRD-08002	Thermoformed bait capsule	5	0.073	0.00365
	J-70021	Thermoformed bait capsule	5	0.098	0.00490
	TP-050-C2	Single bait station	5	0.105	0.00525
3	TP-050-C1b + T P-050-C2	Dual bait station	5.65	0.105	0.00593

Clearly the dual bait station product leads to the highest exposure. Therefore it can be used in a risk envelope approach to cover the exposure of the other 4 products. According to equation 58 of the PT18 ESD (p147) the emission may be calculated as follows:

$E_{spot, soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot, soil}$

where $F_{spot, soil}$ is equal to $F_{spot, bait}$ and the other variables are as follows:

Variable / parameter	Symbol	Unit	Value	S / D / O / P
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	5.65	S
Fraction of active substance in product	F_{AI}	[-]	0.0105	S
Number of application sites	N_{sites}	[-]	2	S
Number of application	N_{appl}	[-]	1	S
Fraction emitted to STP during outdoor bait application	$F_{spot\ bait}$	-	0.2	D

So $E_{spot, soil} = 5.65 \times 0.0105 \times 2 \times 1 \times 0.2 = 0.002373$ g

Soil concentration is then calculated by equation 60:

$C_{spot, soil} = E_{spot, soil} / (Area_{exposed} \times Depth_{soil} \times RHO_{soil})$

where: $Area_{exposed} = 10m^2$, $Depth_{soil} = 0.5m$, $RHO_{soil} = 1700kg/m^3$

So $C_{spot, soil} = 0.002373 / (10 \times 0.5 \times 1700) = 2.79E\text{-}07$ g/kg = **2.79E-04 mg/kg**

Although groundwater is not considered a significant compartment in this scenario, $PEClocal_{porewater}$ may still be calculated using equation 67 from the Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0, April 2015:

$$\mathbf{PEClocal_{soil,pore\ water}} = (PEC_{soil} * RHO_{soil})/(K_{soil\text{-}water} * 1000)$$

Ksoil-water in turn is evaluated using equations 24, 23 and 22 as well as using the defaults listed in Table 5 of the ECHA guidance and the K_{OC} for 1R-trans-*trans* Phenothrin of 125892.5 L/kg

$PEClocal_{soil,porew}$ = **1.26E-04 µg/L**

Secondary poisoning: Bait Stations
The proposed use pattern of the supported product(s) (ready-to-use bait stations) and the design of the products act to mitigate the potential for secondary poisoning, which is considered negligible.

Primary and secondary poisoning

The ready-to-use ant bait station(s) are intended for use by the general public. The utilisation of these products takes places during spring and summer, when target organism populations increase. They are intended to have a curative action. The insecticides used in ant bait stations act by ingestion/contact and are carried back to the nest by contaminated animals.

Primary poisoning
According to the ESD for type 18 products, Primary poisoning, *i.e.* the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

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

Although not a granular formulation, these products contain significant levels of food attractants and therefore some consideration should be undertaken in terms of primary poisoning. Bait stations for ant control, placed in and around the home in inaccessible places, are designed to have small openings allowing access by target pest but should not permit access to bait by birds and mammals. In addition, the bait boxes are designed to be tamper resistant to minimise environmental release.

The Emission Scenario Document, Page 149, indicates "It is not believed that powder, gels or any other insecticides are in the form that could be sufficiently appetent to birds or mammals so they would be at risk." In conclusion, the areas of application and the nature of the supported products are such that the possibility of primary poisoning is considered negligible.

Secondary poisoning

The risk of poisoning for birds and mammals eating contaminated insects rather than reflecting risk of accumulation in the food chain from diffuse exposure. The Emission Scenario Document, Page 102, indicates "The risk of secondary poisoning for birds and mammals consuming insects or vegetation is considered in 0" for spot application and Page 149, indicates "It is not believed that powder, gels or any other sort of insecticides are in a form that could be sufficiently appetent to bird or mammals so they would be at risk".

During the outdoor use of household or professional insecticides, the most important route of exposition is the intake of contaminated feed. Non-target animals have potentially a risk of secondary poisoning in three principal ways: 1). consumption of worms from contaminated soil; 2). consumption of contaminated vegetation; and 3).through eating treated insects that have accumulated the poison. Therefore, herbivorous, insectivorous and earthworms-eating animals are most at risk to be accidentally poisoned and these three types of dietary food are highly represented among mammals and birds. A risk for secondary poisoning by consumption of contaminated vegetation is only applicable for spraying application of insecticides.

The presented Estimated Theoretical Exposition (ETE) calculation follows ESD PT18 household and professional use (No. 18) Insecticides, acaricides and products to Control other Arthropods for Household and Professional Uses, 2008 . The ETE corresponds to the PEC_{oral} per day. The risk is assessed as the ratio between the estimated daily intake (ETE)

and the predicted no-effect concentration for oral intake for the non-target organism (PEC_{oral}).

$$ETE = C \times (FIR/bw) \times AV \times PT \times PD \quad \text{(Equation 68)}$$

The Tier 1 & 2 risk assessments for birds and mammals has been conducted following the OECD Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (2008) ENV/JM/MONO(2008)14.

Limited public literature suggests that an average Black ant may weigh 5 - 10 mg (based upon 1935 study data weighing a fixed number of ant workers) and, if it is presumed to eat around 10% of its own body weight per day as bait, each ant could contain 1 mg bait, equivalent to 1.05 µg (0.105%) Ant Bait 1R-trans Phenothrin. It can be assumed that an individual ant will not live longer than 24 h after first consuming the bait, though individual colony members will continue to seek and consume the bait over a period of 7-10 days.

The concentration of Ant Bait 1R-trans Phenothrin in ants as a food source, assuming no metabolism or excretion, would therefore be (1.05 µg / 10 mg) = 105 mg/kg. The estimated theoretical exposure (ETE) for relevant indicator species that may consume insects in the garden environment is calculated as follows:-

Ants: The relevant indicator species considered relevant for the lawn/garden environment as potential consumers of insects are defined in Table 5.2-7 of the ESD :

- Medium insectivorous bird (Blackbird); FIR/bw = 0.44
- Omnivorous bird (Magpie); FIR/bw = 0.20
- Medium insectivorous mammal (Hedgehog); FIR/bw = 0.18
- Large insectivorous mammal (Badger); FIR/bw = 0.18
- (*Note that the indicator species 'Small insectivorous mammal (Pipistrelle)' has been excluded as this mammal feeds exclusively on flying insects*).

Tier 1

As a first Tier evaluation, ETE values are calculated assuming no avoidance of the food type (AV=1), that all the focal species diet is obtained in the treated area (PT=1) and that ants are the only item in the diet (PD=1):-

- Medium insectivorous bird (Blackbird); ETE = 105 mg/kg x 0.44 = 46.2 mg/kg bw/d
- Omnivorous bird (Magpie); ETE = 105 mg/kg x 0.20 = 21 mg/kg bw/d
- Medium insectivorous mammal (Hedgehog); ETE = 105 mg/kg x 0.18 = 18.9 mg/kg bw/d
- Large insectivorous mammal (Badger); ETE = 105 mg/kg x 0.18 = 18.9 mg/kg bw/d

As expected the Tier 1 evaluation leads to an exceedance of the respective PNEC values for birds and mammals as the initial evaluation makes many worst case assumptions, leading to the overall assumption that the bird or mammal spends 100% of its feeding time in the treated area, where it feeds exclusively on ants that have consumed bait, and that there is no avoidance due to the presence of the bait in the ants. Further refinement is required as these assumptions are extremely unlikely to occur in the practical use

situation; none of them are likely to occur, and it is implausible that all would occur at the same time.

Tier 2
Ant Bait 1R-trans Phenothrin Biocidal Family Products (bait stations) are designed to be placed in and around the home in inaccessible places. The supported products are not in a form that is considered sufficiently appetent or accessible to birds or mammals. In addition, it is extremely unlikely that wild bird and mammal species will spend the whole of their feeding time in the treated area. Use of ant baits by non-professionals is restricted to a very small part of the garden environment but wild species have a very wide variety of habitats in which they can feed that are not within the treated area.

According to the PT18 ESD, the median size garden to be considered for secondary poisoning is 500 m^2 therefore placement of 2 – 6 bait stations represents (2 x 0.25 m^2 – 6 x 0.25 m^2 =) 0.5 – 1.5 m^2 per household. The fraction of diet obtained in the treated area (PT) can therefore be assumed to be ≤ 0.003. Furthermore, ants are not a preferred food source for many wild birds and mammals as worker ants are low in calorific value and are not an easy food source, as the soldier ants defend the nest vigorously when it is attacked. It is highly improbable that any wild bird or mammal will feed entirely on ants, and of those it does feed on, it is unlikely that all will contain residues at the maximum level assumed in the Tier 1 calculation.

When taking account of the fraction of diet into consideration refined ETEs can be calculated as follows:-

- Medium insectivorous bird (Blackbird): ETE = 105 x 0.44 x 0.003 = 1.386E-2 mg/kg bw/d
- Omnivorous bird (Magpie): ETE = 105 x 0.20 x 0.003 = 6.3E-2 mg/kg bw/d
- Medium insectivorous mammal (Hedgehog): ETE = 105 x 0.18 x 0.003 = 5.67E-2 mg/kg bw/d
- Large insectivorous mammal (Badger): ETE = 105x 0.18 x 0.003 = 5.67E-2 mg/kg bw/d

The values of the estimated daily uptake ETE for assessment of secondary poisoning via consumption of contaminated insects for selected indicator species is shown in the table below. These values are still considered to be highly conservative as they do not take into account other refinement options such as avoidance, fraction of food type in the diet or losses due to metabolism and excretion from the insect. All of these factors are expected to lead to further significant decreases in the ETE values.

Estimated theoretical exposition (ETE) of Ant Bait 1R-trans Phenothrin for selected indicator species following application

Summary table on estimated theoretical exposition (ETE)		
	ETE (Tier 1)	**ETE (Tier 2)**
	[mg/kg*d^{-1} bw d^{-1}]	**[mg/kg*d^{-1} bw d^{-1}]**
Medium insectivorous bird (Blackbird)	46.2	1.386E-2
Omnivorous bird (Magpie)	21	6.3E-2
Medium insectivorous	105	5.67E-2

mammal (Hedgehog)		
Large insectivorous mammal (Badger)	105	5.67E-2

Fish & Earthworms

Fish

Exposure of birds and mammals to residues of Ant Bait 1R-trans phenothrin that may be present in food sources such as earthworms needs to be considered.

The predicted concentration of 1R-trans phenothrin in fish is calculated as;

$PEC_{oral,predator} = PEC_{water} \times BCF_{fish} \times BMF$ (BPR Vol. IV PartB+C; Eq. 93)

BCFfish = Bioconcentration factor in fish = 2849 L/kg
BMF = Biomagnification factor in fish = 10

However it is demonstrated (in Section 3.3.2) that the proposed use of Ant Bait 1R-trans phenothrin leads to no exposure to surface water via indoor or outdoor uses. There is therefore no exposure relevant to secondary poisoning from the consumption of fish.

Earthworm

The predicted concentration of residues in earthworms is calculated as;

$PEC_{oral,predator} = C_{earthworm}$ (BPR Vol. IV PartB+C; Eq. 97)

$$= \frac{[(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})]}{[1+ (F_{gut} \times CONV_{soil})]}$$

BCFearthworm = 75, 761 L/kg for 1R-trans phenothrin

Fgut = 0.1 (BPR Vol. IV PartB+C, Default values from Equation 100b)

CONVsoil = RHOsoil ÷ (Fsolid x RHOsolid)

= 1700 ÷ (0.6 x 2500) (default values from BPR Vol. IV PartB+C,Table 3)

= 1.14

Cporewater = 1.26×10^{-4} µg/l or 0.000126 µg/L

$$PEC_{oral,\ predator} = \frac{[(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})]}{[1+ (F_{gut} \times CONV_{soil})]}$$

$$= \frac{[(75{,}761\ L/kg \times 0.000126\ \mu g/L) + (0.000279 \times 0.1 \times 1.14)]}{[1+ (0.1 \times 1.14)]}$$

= (9.545 + 0.0000318) ÷ (1+ 0.114)

= 9.55 ÷ 1.114

= 8.57 µg/L

PECoral, predator = 0.0086 mg/kg

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: 1R-trans phenothrin has a very low predicted vapour pressure (2.37E-05 Pa at 20°C). Exposure to the air compartment will be negligible.

Aquatic compartment

The proposed uses of Ant Bait 1R-trans Phenothrin are not expected to result in exposure to surface waters as outlined in the assumptions presented within the Emission Scenario Document for PT18. Zero emissions to all compartments are predicted from use of the supported products. Exposure from secondary poisoning from the consumption of fish is not predicted.

Conclusion: A risk to the aquatic compartment is not predicted.

Terrestrial compartment

No significant potential for direct exposure as a direct result of the proposed use of the Ant Bait 1R-trans Phenothrin bait product(s) is predicted. Zero emissions to all compartments are predicted from use of the supported products.

Conclusion: A risk to the terrestrial compartment is not predicted.

Groundwater

The proposed uses of Ant Bait 1R-trans Phenothrin are not expected to result in exposure to ground water as outlined in the assumptions presented within the Emission Scenario Document for PT18.

Conclusion: There is no cause for concern for groundwater.

Primary and secondary poisoning

Primary poisoning
It is considered that the possibility of primary poisoning is negligible due to the nature and intended positioning of the baits. The bait boxes are designed to be tamper resistant to minimise environmental release and accidental poisoning. Bait boxes are placed/applied in and around the home in inaccessible places. It is not considered that the supported products are in a form that could be sufficiently accessible or appetent to bird or mammals to be a risk. In conclusion, the possibility of primary poisoning is considered negligible.

Secondary poisoning
According to the ESD for type 18 products, Secondary poisoning relates to toxic effects occurring in higher levels of food chains, either in the aquatic or terrestrial environment, which result from ingestion of organisms from lower trophic levels that contain accumulated substances. It relates to the potential exposure of vertebrates (*i.e.* birds or mammals) consuming contaminated insects or taking their food.

The main routes of secondary poisoning for birds and mammals are the consumption of food items containing residues such as insects that may have eaten the bait, fish that may have been exposed to residues in surface water, and earthworms that may have been exposed to residues in soil. These scenarios are considered in detail below. PNEC values for 1R-trans Phenothrin were established during the Annex I inclusion evaluation (2013).

Birds: The risk to fish-eating organisms (birds) was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator,}$) and the no-effect-concentration for oral intake ($PNEC_{oral,\ predator\ bird}$). In this case, the $PNEC_{oral}$ was derived from the LC_{50} of 5620 ppm and the appropriate assessment factor of 3000 was then applied to this value resulting in a **$PNEC_{oral,\ predator}$ of 1.87 mg/kg food (0.225 mg/kg bw/d)**

Mammals: The risk to fish-eating organisms (mammals) was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). From the CAR, the 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives: **$PNEC_{oral,\ predator}$ of 10.0 mg/kg food (1 mg/kg bw/d)**

Insectivorous birds and mammals

The Tier 1 ETE for indicator species of birds and mammals was calculated to be 18.9 – 46.2 mg/kg bw/day, which is above the PNEC for both birds and mammals. Therefore a refined ETE was calculated, taking into consideration the fraction of time wild birds and mammals might spend feeding in the treated area. Nevertheless this is still considered to represent a conservative estimate, as it does not take into consideration the significant effect of avoidance, the fraction of diet represented by ants that have consumed bait, and losses of the active substance due to metabolism and excretion.

- Medium insectivorous bird (Blackbird); ETE = 0.01386 mg/kg bw/day
- Omnivorous bird (Magpie); ETE = 0.0632 mg/kg bw/day

– The PEC/PNEC ratio is 0.062 (0.01386/0.225) and 0.28 (0.0632/0.225) for the 2 bird indicator species; therefore the risk to birds from the proposed use is acceptable.

- Medium insectivorous mammal (Hedgehog); ETE = 0.0567 mg/kg bw/day
- Large insectivorous mammal (Badger); ETE = 0.0567 mg/kg bw/day

– The PEC/PNEC ratio is 0.058 (0.0567/1) for both of the mammal indicator species; therefore the risk to wild mammals from the proposed use is acceptable.

Earthworm-eating birds and mammals

The risk to earthworm-eating mammals was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). From the ACR, the 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives: **$PNEC_{oral,\ predator}$ of 10.0 mg/kg food.**

The maximum concentration of residues in earthworms was calculated to be 0.077 mg/kg, based on the worst-case bioconcentration factor for 1R-trans Phenothrin.

- The PEC/PNEC ratio for birds is (0.0086/1.87) = 0.0046 and <1
- The PEC/PNEC ratio for mammals is (0.0086/10) = 0.00086 and <1

Fish-eating birds and mammals
In terms of secondary poisoning from the consumption of fish, no assessment is required in line with the current PT18 ESD (no obvious emissions pathway to surface waters is predicted from indoor and outdoor use of bait stations). No exposure to surface water is predicted from the indoor and outdoor uses Ant Bait 1R-trans Phenothrin, therefore there is no exposure to fish. As there is no exposure, the risk to birds and mammals from the consumption of fish is considered acceptable.

Summary table on secondary poisoning							
Scenario	**Species**		**$PEC_{oral\ predator}$ mg/kg bw/day**		**PEC/PNEC birds**	**PEC/PNEC mammals**	**PEC/PNEC fish**
1	Med. insectivorous bird (Blackbird)	Med. insectivorous mammal (Hedgehog)	0.01386	0.0567	0.062	0.058	-
	Omnivorous bird (Magpie)	Large insectivorous mammal (Badger)	0.0632	0.0567	0.28	0.058	
1	Earthworm-eating birds & mammals		0.0349 $mg.kg^{-1}$		4.6E-03	8.6E-04	-

Conclusion:
1R-trans Phenothrin was determined to have a very high bioconcentration factor (BCF) (2506-3192 l/kg) suggesting the potential for bioconcentration in the aquatic environment and/or bioaccumulation in the food chain leading to secondary poisoning. However, the $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating mammals (0.058 for both indicator species) and birds (0.062 and 0.28 respectively) was below the risk quotient of 1, suggesting there is no risk of secondary poisoning for fish-eating mammals and birds. Equally, no risk of secondary poisoning following the appropriate use of Ant Bait 1R-trans Phenothrin BPF is predicted for earthworm eating mammals and birds (0.00086 and 0.0046 respectively) as the risk quotient is less than one.

Mixture toxicity

The Biocidal Family Products contain only one active substance. It is not necessary to perform a "multiple active" assessment. The Applicant has identified a non-active preservative component of the formulation, Parmetol D11 (BIT), which is classified as H400 'Very toxic to aquatic life' and a substance of concern in the frame of the Directive 91/414/EEC on the basis of its environmental toxicity. The concentration of BIT does not trigger a classification in the biocidal product(s).

The concentration of this agent used in the Ant Bait 1R-trans Phenothrin Biocidal Family Products does not contribute to the environmental classification of the Ant Bait 1R-trans phenothrin BPF. There is no other substance of concern in the Ant Bait 1R-trans phenothrin BPF. The effects of Ant Bait 1R-trans phenothrin Biocidal Product Family are considered to outweigh those of the non-active components of the product and that the effects assessment for the Ant Bait 1R-trans phenothrin Biocidal Product Family can be extrapolated from the effects assessment of the active substance 1R-trans phenothrin.

Aggregated exposure (combined for relevant emmission sources)

An aggregated exposure has not been performed for Ant Bait 1R-trans phenothrin BPF.

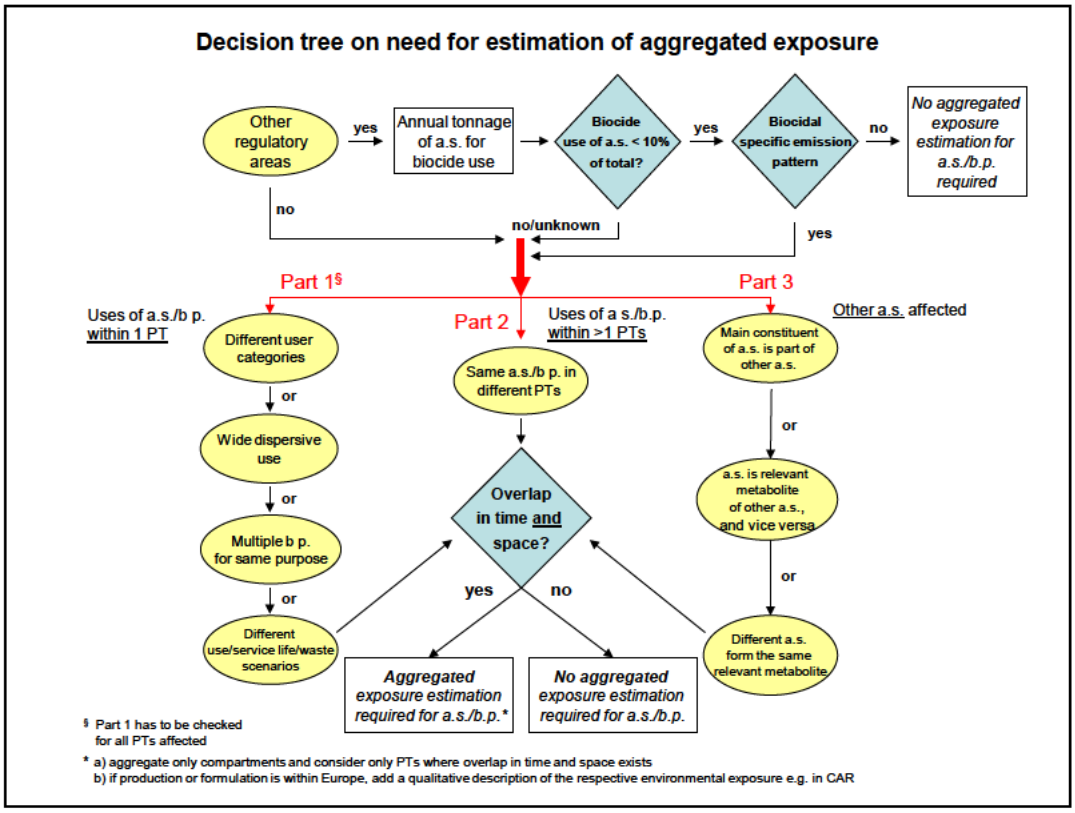

Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
The applicant did not provide ecotoxicological data for the Ant Bait 1R-trans Phenothrin Biocidal Family Products. The environmental risk assessment is based on the data obtained from the active substance 1R-trans Phenothrin (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, 1R-trans phenothrin CAS 188023-86-1, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Ireland, March 2013. A preservative. Parmetol D11 (BIT), is present in some of the proposed formulations. This substance is classified as H400 'Very toxic to aquatic life' in the frame of the Directive 91/414/EEC. This substance is classified as H412 "Toxic to aquatic organisms, may cause

long-term adverse effects in the aquatic environment" in the frame of the Directive 91/414/EEC. The concentration of this agent used in the Ant Bait 1R-trans Phenothrin Biocidal Family Products does not contribute to the environmental classification of the Ant Bait 1R-trans phenothrin BPF. There is no other substance of concern in the Ant Bait 1R-trans phenothrin BPF. The effects of Ant Bait 1R-trans phenothrin Biocidal Product Family are considered to outweigh those of the non-active components of the product and that the effects assessment for the Ant Bait 1R-trans phenothrin Biocidal Product Family can be extrapolated from the effects assessment of the active substance 1R-trans phenothrin.

The proposed uses of Ant Bait 1R-trans Phenothrin pre-filled bait products are not expected to result in exposure to surface waters as outlined in the assumptions presented within the Emission Scenario Document for PT18. Zero emissions to all compartments are predicted from use of the supported products. Therefore no primary environmental risk assessment was performed.

The Emission Scenario Document, Page 149, indicates "It is not believed that powder, gels or any other insecticides are in the form that could be sufficiently appetent to birds or mammals so they would be at risk." In conclusion, the areas of application and the nature of the supported products are such that the possibility of primary poisoning is considered negligible and a primary poisoning risk assessment was not required.

A secondary poisoning risk assessment was performed for the intended use(s) of the Ant Bait 1R-trans Phenothrin BPF. An unacceptable risk was not identified.

2.2.9 Measures to protect man, animals and the environment

Products Meta SPC 1 – 1a (TP-050-C1), Meta SPC 2 – 2a (TP-050-C2), 2b (J-70021) & 2c (IIRD-08002), Meta SPC 3 – 3 (TP-050-C1b & TP-050-C2).

Methods and precautions concerning placing on the market	The bait stations are specifically designed to prevent users and non-target organisms coming into contact with the bait.
Methods and precautions concerning production, handling and use of the active substance and its formulations	The bait is a ready to use formulation. The product is specifically designed to prevent users and non-target organisms coming into contact with the bait.
Methods and precautions concerning storage of the active substance and its formulations	Keep the product in clearly labelled containers. Store the containers sealed, in a well ventilated place, away from direct sunlight.

Methods and precautions concerning transport of the active substance and its formulations	These goods must be transported by vehicles authorized to the carriage of dangerous goods according to the provisions set out in the current edition of the Code of International Carriage of Dangerous Goods by Road (ADR) and in all the applicable national regulations. These goods must be packed in their original packagings or in packagings made of materials resistant to their content and not reacting dangerously with it. People loading and unloading dangerous goods must be trained on all the risks deriving from these substances and on all actions that must be taken in case of emergency situations. Road and rail transport: ADR/RID Class: 9 UN: 3082 Packing Group: III Label: 9 Nr. Kemler: 90 Limited Quantity. 5 L Tunnel restriction code. (E) Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Carriage by sea (shipping): IMO Class: 9 UN: 3082 Packing Group: III Label: 9 EMS: F-A, S-F Marine Pollutant. YES Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Transport by air: IATA: 9 UN: 3082 Packing Group: III Label: 9 Cargo: Packaging instructions: 964 Maximum quantity: 450 L Pass.: Packaging instructions: 964 Maximum quantity: 450 L Special Instructions: A97, A158 Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS

	SUBSTANCE, LIQUID, N.O.S.
Methods and precautions concerning fire of the active substance and its formulations	Extinguishing media. SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT None in particular. Special hazards arising from the substance or mixture. HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products. Advice for firefighters. GENERAL INFORMATION Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations. SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).
In case of fire, nature of reaction products, combustion gases, etc.	There are no combustion products of concern listed.
Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	Inhalation: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention. Ingestion: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person. Eyes: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention. Skin: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.
Emergency measures to protect the environment	The product is mostly composed of food ingredients. The product is specifically designed to prevent spillage and release into the environment. Environmental precautions: P revent product from entering

	drains. D o not flush into surface water or sanitary sewer system. If the product contaminates rivers and lakes or drains inform respective authorities. Use appropriate containment to avoid environmental contamination.
Possibility of destruction or decontamination following release in the air	The ingredients of the bait station are non-volatile and therefore the risk to the atmospheric environment is negligible.
Possibility of destruction or decontamination following release in water, including drinking water	There are no measures to decontaminate water. When used acccording to label instructions the bait will not come into contact with drinking water.
Possibility of destruction or decontamination following release in or on soil	There are no measures to decontaminate soil. When used according to label instructions the potential contamination of soil is negligible.
Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration	Not applicable
Possibility of re-use or recycling	The test substance and empty packaging cannot be recycled.
Possibility of neutralisation of effects	The test substance cannot be neutralised.
Conditions for controlled discharge including leachate qualities on disposal	Waste treatment methods. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Avoid littering. Do not contaminate soil, sewers and

	waterways. Waste transportation may be subject to ADR restrictions. CONTAMINATED PACKAGING Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
Conditions for controlled incineration	There are no special conditions for controlled incineration. Disposal should be in accordance with local, state or national legislation.
Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	The recommended conditions of use and the physical design will prevent beneficial insects (bees) or other organisms ingesting the bait.
Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances	There are no substances present that are contained in these lists.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

Ant Bait 1R-trans phenothrin BPF products are not intended for use with other biocidal products.

2.2.11 Comparative assessment

A comparative assessment is not required for the active substance 1R-trans phenothrin.

3 ANNEXES[10]

3.1 List of studies for the biocidal product (family)

[redacted]

3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

There is no new information on 1R-trans phenothrin that has been submitted in the Ant Bait 1R-trans phenothrin BPF dossier.

3.4 Residue behaviour

Residue behaviour is not applicable for Ant Bait 1R-trans phenothrin BPF products.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[11]

Summaries of the efficacy studies have been presented in the IUCLID dossier.

Three additional laboratory studies were performed using aged baits and summaries of these studies are presented below.

[redacted]

3.6 Confidential annex

[redacted]

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

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