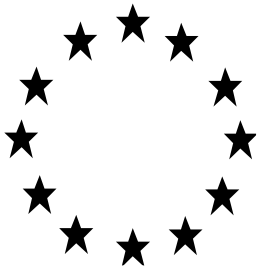
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



RAID® COCKROACH BAIT
BAYGON® COCKROACH BAIT

Product Type 18

Indoxacarb 0.5%
CAS: 173584-44-6

Case number: BC-FWO40375-20

Previous Case Number: BC-LH038320-53 (Asset Transfer)
Evaluating Competent Authority: Netherlands

Date: July 2022

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1 CONCLUSION

The CA should provide a general conclusion on the application.

APCP
The product Raid cockroach baits is a brown paste with peanut butter odour containing 0.5 %w/w pure Indoxacarb. Stored in its commercial packaging at 40 °C for 8 weeks the test item was stable with no significant changes in the content of active substance. Based on the results of the long term storage stability study and data on palatability a shelf life of 2 years is supported in commercial packaging. Considering the product is a ready for use bait and not sprayed or diluted for use, any influence of low temperatures are expected to be minor. Due to the properties of the packaging (opaque polystyrene bait station housing) the sample is not affected by neither light, temperature or humidity.

The product is not to be classified based on its physical hazards and respective characteristics.

Two HPLC-MS analytical methods were used to determine the content of active substance and are considered fully validated according to SANCO/3030/99 rev. 4.

Efficacy:

Raid cockroach bait is a ready-to-use bait which has shown efficacy against nymphs and adults of German cockroaches (*Blattella germanica*), Oriental cockroaches (*Blatta orientalis*) and American cockroaches (*Periplaneta americana*) with a recommended bait placement of one bait station every 5 linear meters or 0.5 square meter apart. As the product contains a preservative, a shelf life of 2 years can be authorised.

Human health
Raid Cockroach Bait is a ready-to-use bait station for non-professional use. There are no suitable models to estimate the exposure to bait stations, therefore the risk for human health was assessed with reverse reference calculations. For adults (non-professional user or bystanders) dermal exposure was acceptable as one would be in contact with more than half of the content of the bait station to reach the AEL. An acceptable risk for the inhalation route (infants, and older children & adults) was indicated. The reverse reference scenario for oral and dermal exposure indicated potential risks to infants, older children and companion animals. However, the applicant provided sufficient information on the robustness of the bait station (see confidential annex). It is designed in such a way that the contents of the station would not be accessible from the outside, nor can it easily be breached by a small child. Therefore, this risk is considered acceptable. The robustness of the bait station, coupled with the additional labelling (‘Keep and place away from children and pets’, 'Retain the outer carton for full use and safety instructions') decreases the likelihood of secondary exposure for children/animals mitigating risk of exposure.

The product Raid Cockroach Bait is classified as a skin sensitizer. Based on the studies performed with the product and with the active substance alone, it was concluded that the sensitization was mainly caused by the co-formulants. Therefore, a sentence was

added to section 2.1.5. General directions of use: "Contains peanuts. May produce an allergic reaction."

Environment

There is no significant concern to the environment from use of Raid® Cockroach Bait if used in line with the SPC.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1] – Trade Name	**Country (if relevant)**
Raid® Cockroach Bait	The Netherlands (eCA)
Baygon® Cockroach Bait	The Netherlands (eCA)
Raid Kakkerlakken Lokdoos	The Netherlands (eCA)

Raid® Cockroach Bait, is a ready for use semi-solid bait in a sealed bait station for the control of cockroaches (Raid JWY 0.5% w/w Indoxacarb). It is very similar (same co-formulants), to two representative products in the evaluation of the active substance (RMS UK CAR for Indoxacarb, May 2008): Raid PDQ, 1.33% w/w Indoxacarb, a ready for use semi-solid bait in a sealed bait station for the control of cockroaches; and Raid PHL, 0.13% w/w Indoxacarb, a ready for use semi-solid bait in a sealed bait station for the control of ants.

A detailed description of the identity of the product, **Raid® Cockroach Bait**, is confidential and is described in the Confidential Annex of this PAR.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SC Johnson Europe Sàrl
	Address	Z.A. la Piece 8 1180 Rolle Switzerland
Authorisation number	NL-0008421-0000	
Date of the authorisation	02.09.2022	
Expiry date of the authorisation	02.09.2032	

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

2.1.1.3 Manufacturer of the product

Name of manufacturer	SC Johnson Europe Sàrl
Address of manufacturer	Z.A. la Piece 8 1180 Rolle Switzerland
Location of manufacturing sites	Packaging Imolese S.p.A. via Filippo Turati 22, Imola 40026, Bologna, Italy

2.1.1.4 Manufacturer of the active substance

Active substance	Indoxacarb
Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Schwarzwaldallee 215, Basel, CH-4058 Zwitzerland
Location of manufacturing sites	FMC Corporation Mobile Manufacturing Center U.S. Highway 43 North, Axis Alabama 36505, USA

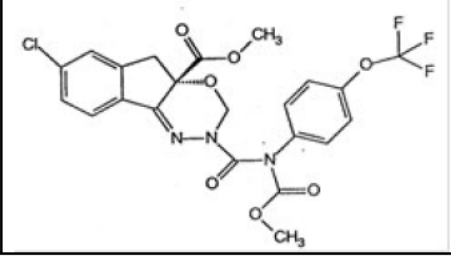
2.1.2. Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Indoxacarb
IUPAC or EC name	methyl (S)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl)carbamoyl]indeno[1,2-e][1,3,4]oxadiazine-4a-carboxylate
EC number	Not available
CAS number	173584-44-6
Index number in Annex VI of CLP	607-700-00-0
Minimum purity / content (DPX-KN128)	467 g/kg
Structural formula	

2.1.2.2 Candidate for substitution

Indoxacarb is not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Indoxacarb	methyl (S)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl)carbamoyl]indeno[1,2-	Active substance	173584-44-6	n/a	0.9620 (= 0.5% pure active)*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
	e][1,3,4]oxadiazine-4a-carboxylate				
Refer to the confidential annex 3.6 for details of the co-formulants					
*Raid® Cockroach Bait contains 0.5% w/w Indoxacarb with manufacturing tolerance range of +/- 10% Indoxacarb (0.045% - 0.055% Indoxacarb).					

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

Not applicable.

2.1.2.5 Information on technical equivalence

The active substance source for the product is a reference source, as noted on the article 95 list therefore no check for technical equivalence is necessary.

2.1.2.6 Information on the substance(s) of concern

This biocidal product contains no potential substances of concern. The non-active substances included in Raid® Cockroach Bait are listed Section 3.6.1. All of these substances meet the definition of "food" and, hence, are excluded from evaluation under BPR. Accordingly, it is not necessary to conduct a screening for Endocrine Disrupting properties for these substances.

2.1.2.7 Type of formulation

RB (Ready For Use bait)

2.1.3 Hazard and precautionary statements

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

Classification		
Hazard category	Skin Sens. 1	
Hazard statement	H317 May cause an allergic skin reaction H412 Harmful to aquatic life with long lasting effects.	
Labelling		
Hazard Pictogram		
Signal words	Warning	

Hazard statements	H317 May cause an allergic skin reaction H412 Harmful 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. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P501 Dispose of contents /container in accordance with local regulations.
Note	Indoxacarb need to be declared based on the assigned H-statements according to Art 18(3) CLP. The phrase 'P280: Wear protective gloves' will not be present on the label because dermal exposure will not occur under normal conditions of use. The phrase 'p321: Specific treatment (see … on this label).'will not be present on the label because this P-statement is only highly recommended only in exceptional cases where specific treatment is known and required.The phrases 'P261: Avoid breathing dust/fume/gas/mist/vapours/spray.', 'P272: Contaminated work clothing should not be allowed out of the workplace.', and 'P362+P364 Take off contaminated clothing.' Are not included as the procuct is a bait box against cockroaches and the active substance is not highly volatile.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Control of cockroaches (German cockroach, Oriental cockroach, American cockroach) – Indoor – General Public

Product Type (PT)	PT 18 - Insecticides, acaricides and products to control other arthropods.
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Cockroaches, including: *Blattella germanica* - German cockroach – Adults/nymphsadults *Blatta orientalis* Oriental cockroach – Adults/nymphs *Periplaneta americana* – American cockroach – Adults/nymphs
Field of use	Indoors, in residential houses
Application method(s)	Bait station (ready-to- use)
Application rate(s) and frequency	1-5 cockroaches observed, use up to 6 bait stations. 6-25 cockroaches observed, use up to 8 bait stations.

	More than 25 cockroaches observed, use up to 12 bait stations Do not use more than 12 bait stations at the same time. Recommended bait placement: Place one bait station every 5 linear meters or 0.5 square meter apart.
Category(ies) of users	General Public (non-professional)
Pack sizes and packaging material	2 or 6 polystyrene (PS) bait stations, packed in polypropylene (PP) wrapper, in a cardboard box with 2.5g of bait per station.

2.1.4.2 Use-specific instructions for use

See general directions for use.

2.1.4.3 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use. To achieve sufficient control, good hygiene is necessary, so that apart from the bait, as

little food as possible is available for the cockroaches. Place bait stations where cockroach activity is most heavy or where cockroaches may be seen congregating.

1. Use the appropriate number of stations, 1-5 cockroaches observed use up to 6 bait stations, 6-25 cockroaches observed use up to 8 bait stations and more than 25 cockroaches observed use up to 12 bait stations. Do not use more than 12 bait stations at a time. Place one bait station every 5 linear meters or 0.5 square meter apart.
2. Place bait stations in areas **inaccessible to children and pets** such as kitchen and/or bathroom cabinets, under sinks, under appliances, behind the toilet.
3. For best results, place bait stations horizontally, next to walls or in corners. Bait stations can also be placed vertically, under the rim of the kitchen sink, for example.
4. Remove dead cockroaches daily.
5. Check the bait stations weekly and if empty replace immediately with new bait stations. Continue to replace bait stations until no more cockroaches are seen.
6. You should see fewer cockroaches within days. If 3 months after the start of the treatment the infestation continues, contact a professional pest controller.

2.1.5.2 Risk mitigation measures

Use only as directed. Do not open bait station.
Retain the outer carton for full use and safety instructions
Keep and place away from children and pets.
Never let children play with the bait station.
Do not apply bait station on surfaces in places that may come into contact with food & feedstuffs.

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

If medical advice is needed, have product container or label at hand.

Likely direct or indirect effects:
Contains peanuts. May produce an allergic reaction.

Description of first aid measures:
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occurs: Get medical advice.
IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

After use, dispose of empty bait station to domestic waste (recycling). If bait remains dispose of bait station to household waste recycling centre as hazardous waste. Contact

local council for details.

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

Shelf life 2 years. Store in a cool dry environment.

2.1.6 Other information

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2.1.7. Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of packaging	Type and material of closure(s)	Intended user (e.g. Professional, non-professional)	Product Compatibility with proposed packaging materials (Yes/No)
Bait Station	2 or 6 bait stations, packed in polypropylene (PP) wrapper in cardboard box with 2.5 g of active substance per station	Polystyrene (PS)	Closure (seal method)- Heat Seal of both PS parts. Bait stations have a total of 8 openings. The four openings on the sides of the bait station measure 7.3mm high x 7mm wide, and the four openings on the ends of the bait station measure 7.3mm high x	Non-professional	Yes

			10mm wide along an arc.		
Unit Carton		Plastic coated cardboard	N/A	Non-professional	N/A

Figure 1: Photograph of Raid® Cockroach Bait (0.5% Indoxacarb) – Bait Stations

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Product
Please refer to the reference list contained in Annex 3.

Active Substance
SC Johnson as the applicant has submitted a Letter of Access and Letter of Supply (Art.95) to the data owned by Syngenta, the existing Asset Holder. In the Letter of Access, Syngenta authorises the applicant to refer to all study reports and documents originally submitted by Du Pont for the listing of Indoxacarb on the Annex I of the Biocidal Products Directive (98/8/EC).

2.1.8.2 Access to documentation

The applicant is the holder of the product data.

2.2 Assessment of the biocidal product

Intended use(s) as applied for by the applicant

The use below is the one applied for by the applicant, without any changes by the eCA. This use is assessed in the following chapters.

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

Table 2. Use # 1 – Control of cockroaches (German cockroaches, Oriental cockroaches, American cockroaches)

Product Type (PT)	PT 18 - Insecticides, acaricides and products to control other arthropods.
Where relevant, an exact description of the authorised use	This product is used for the control of large and small cockroaches for non-professional use, indoors.
Target organism (including development stage)	Cockroaches (Blattodea) among which: • German cockroach *(Blattella germanica)* • Oriental cockroach *(Blatta orientalis)* • American cockroach *(Periplaneta americana)* Adult cockroaches, large and small, gravid females including their unlaid egg capsules and the colony.
Field of use	Indoors, in residential houses
Application method(s)	Bait station (ready for use) – see section 5.1. Use instructions
Application rate(s) and frequency	1-5 cockroaches observed, use up to 6 bait stations. 6-25 cockroaches observed, use up to 8 bait stations. More than 25 cockroaches observed, use up to 12 bait stations Do not use more than 12 bait stations at the same time. Bait lasts for up to 3 months
Category(ies) of users	General Public (non-professional use)
Pack sizes and packaging material	2 or 6 polystyrene (PS) bait stations, packed in polypropylene (PP) wrapper, in a cardboard box with 2.5g of bait per station.

Physical, chemical and technical properties

The data on physical and chemical properties was extracted from the summary dossier provided by applicant SC Johnson (refer to separate document 'study summaries').

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual GLP	0.50% Indoxacarb (DPX-KN128) Batch No. 571D3	Solid (paste)	[redacted]
Colour at 20 °C and 101.3 kPa	Visual GLP	0.50% Indoxacarb (DPX-KN128) Batch No. 571D3	Brown	[redacted]
Odour at 20 °C and 101.3 kPa	Smell GLP	0.50% Indoxacarb (DPX-KN128) Batch No. 571D3	Peanut Butter	[redacted]
Acidity / alkalinity	CIPAC MT75, GLP	0.50% Indoxacarb (DPX-KN128) Batch No. 571D3	pH = 7.1 (1% dilution) Acidity not determined based on the pH.	[redacted]
Relative density / bulk density	EC Method A.3 (OECD 109). GLP	0.50% Indoxacarb (DPX-KN128) Batch No. 571D3	(D_4^R): 1.107 at 22.5 °C (+/- 0.2 °C).	[redacted]
Storage stability test - **Accelerated Storage**	CIPAC MT 46.3, ARTM-W-213491 GLP	0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D2 0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D101	Indoxacarb Content: Initial: 0.508% Final: 0.517% % Change: +2.04% Corrosion Initial: N/A Final: No evidence of corrosion or degradation Storage Stability: Initial: Beige plastic container, approximately 8.5 × 6.6 × 2.0 cm; Brown paste with dark brown specks Final: Storage container and test substance observations consistent with Day 0 Color Physical State Odor Initial: Brown, hue 10 YR, chroma 6, value 7; Solid. Nutty or peanut odor at 22.6 °C. Final: Brown, hue 10 YR, chroma 6, value 7; Solid. Nutty odor at 20.5 °C. pH/Alkalinity [aqueous 1% (w/w) dilution] Initial: pH: 6.901 at 25.0 °C acidity/alkalinity: N/A Final: pH: 6.637 at 25.0 °C acidity/alkalinity: N/A Conclusion: After eight	[redacted]

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			weeks of storage in Polystyrene (PS) Bait Stations, Packaged in Polypropylene Wrappers, the average active ingredient content, indoxacarb, remained within 3% of the Day 0 value. In addition, there were no significant differences between the corrosion, color, physical state, odor, and pH measurements from Day 0 to the 8-Week sampling. Therefore, RAID JWY is considered stable for eight weeks at 40 °C.	
Storage stability test - **Long Term Storage**	BioGenius Indoxacarb Method MV010 and MV029 (analytical method used to determine content of a.s by HPLC-UV) pH testing performed according to CIPAC guideline MT 75.3 GLP	1.0% Indoxacarb Batch No. 15374E170 Nominal Purity: 1.33% DPX-MP062 (Nominally: 75% Indoxacarb (DPX-KN128) and 25% IN-KN127). Equivalent to 1.0% Indoxacarb (DPX-KN128)	Test item stored in commercial packaging for 48 months at 20 °C and 25 °C (60 % rel. humidity) Appearance (20 °C and 25 °C): Brown paste, peanut butter odour Packaging (20 °C and 25 °C): Sample in sound condition and without leakages, bait stations all impregnated with oil from the samples pH: at 20 °C: 6.6 at 25 °C: 6.4 Active substance (% w/w) at 20 °C: T0: 1.18; T48: 1.15 (-2.54 %) at 25 °C: T0: 1.18; T48: 1.12 (-5.08 %) New 4 year stability study ongoing with anticipated completion in 2025.	[redacted] Study No. 90823
eCA remark: Based on the results of the storage stability study and data on palatability a shelf life of 2 years is supported in commercial packaging.				
Storage stability test – **low temperature stability test for**			Not applicable – The product is a solid.	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
liquids				
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Visual GLP	1.0% Indoxacarb. Batch No. 15374E170 Nominal Purity: 1.33% DPX-MP062 (Nominally: 75% Indoxacarb (DPX-KN128) and 25% IN-KN127). Equivalent to 1.0% Indoxacarb (DPX-KN128) 0.50% Indoxacarb (DPX-KN128) Batch No. 571D3 0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D101	Each individual bait station is protected from light due to the commercial packaging consisting of an opaque polystyrene blister bait station, thereby protecting the active substance from light degradation. Please see also results from the stability study reports.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46.3, ARTM-W-213491, GLP	0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D2 0.50% Indoxacarb (DPX-KN128) Batch No. 571D3 0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D101	The baits were stored in the intended commercial packaging ie. blister packaging in an airtight bag made of plastic film. Indoxacarb content exhibited acceptable stability.Therefore, it can be concluded that temperature and humidity do not significantly affect indoxacarb content when stored in commercial packaging.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual CIPAC MT 46.3, ARTM-W-213491, GLP	0.50% Indoxacarb (Raid JWY formula number 15342P45-1) Batch No. 571D2 1.0% Indoxacarb. Batch No. 15374E170 Nominal Purity: 1.33% DPX-MP062 (Nominally: 75% Indoxacarb (DPX-KN128) and 25% IN-KN127). Equivalent to 1.0% Indoxacarb (DPX-KN128) 0.50% Indoxacarb (DPX-KN128) Batch No. 571D3 0.50% Indoxacarb (Raid JWY formula	The test items were stored in their commercial packaging with no significant changes observed after the study period. Please see also the results of the stability studies.	[redacted]

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		number 15342P45-1) Batch No. 571D101		
Wettability	-	-	Not applicable – the product is a solid not to be dispersed or dissolved in water.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable – the product is a solid, not to be dispersed or dissolved in water.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable – the product is a solid, not to be dispersed or dissolved in water.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable – the product is a solid, not to be dispersed or dissolved in water.	-
Disintegration time	-	-	Not applicable – the product is a solid, not to be dispersed or dissolved in water.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable - the product is not a powder or granule	-
Persistent foaming	-	-	Not applicable – the product is a solid, not to be dispersed or dissolved in water.	-
Flowability/Pourability/ Dustability	-	-	Not applicable - the product is not a granule or a suspension.	-
Burning rate — smoke generators	-	-	Not applicable - the product is not intended to be burned.	-
Burning completeness — smoke generators	-	-	Not applicable - the product is not intended to be burned and create smoke.	-
Composition of smoke — smoke generators	-	-	Not applicable - the product is not intended to be burned or create smoke.	-
Spraying pattern — aerosols	-	-	Not applicable - the product is a solid not an aerosol.	-
Physical compatibility	-	-	Not applicable - the product is self-contained within its packaging and cannot be mixed with other substances.	-
Chemical compatibility	-	-	Not applicable - the product is self-contained within its packaging and cannot be mixed with other substances.	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Degree of dissolution and dilution stability	-	-	Not applicable – the RTU product is a solid, not to be dispersed or dissolved in water.	-
Surface tension	EC Method A.5. (OECD 115), Ring Method, GLP	1.0% Indoxacarb, Batch No. 15374E170, solution of0.051 mg/l Indoxacarb in deionized water (corresponding to a concentration of 90% of the solubility in water at 20 °C, 0.057 mg/l)	50.9 mN/m at 20°C The product has surface active properties.	[redacted]
Viscosity	-	-	Not applicable - the product is a solid.	

Raid cockroach bait (Raid JWY) was developed alongside the development code Raid PDQ. The differences between the two formulae are limited to two: i) the level of Indoxacarb, which is nominal 1% in Raid PDQ and 0.5% in Raid JWY, and ii) Raid PDQ contains 0.35% of oleic acid. Other co-formulants are the same and at the same level in both formulae.

Data from the attached studies [redacted] (the long term storage stability studies) were generated using Raid PDQ Cockroach bait, batch number 15374E170, containing nominal 1.0% indoxacarb. The packaging for both products is the same, polystyrene bait station in a polypropylene wrapper. It is therefore considered acceptable to read across data from Raid PDQ to RAID JWY for the end-points addressed in the long term storage stability study.

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

The product Raid cockroach baits is a brown paste with peanut butter odour. The pH of the item is 7.1 (1% dilution) while the relative density was determined to be 1.107. Stored in its commercial packaging at 40 °C for 8 weeks and for 48 months at 20 °C and 25 °C (60 % relative humidity) the test item was stable with no appreciable changes in the active substance content. Considering the product is a ready for use bait and not sprayed or diluted for use, any influence of low temperatures are expected to be minor. Due to the properties of the packaging (opaque polystyrene bait station housing) the sample is not affected by neither light, temperature or humidity. Based on the determined surface tension of 50.9 mN/m the product has surface active properties.

Based on the above results, a 4 year shelf life is supported.

eCA remark and data gap: Based on the results of the storage studility studies a shelf life of 2 years is supported in commercial packaging. The analytical method used to determine the content of active substance in the long term storage at ambient temperature study is considered validated. Efficacy data was provided to show that aged samples were still attractive to the target organisms after six months of storage. Taking these into consideration a shelf life of 2 years is supported.

Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosive properties	EC Method A.14, GLP Guidance on the Application of the CLP Criteria, 2.1.4.2	1.0% Indoxacarb, Batch No. 15374E170	Not relevant as neither the active substance nor any of the co-formulants are classified as explosive indicating that the product will not possess explosive properties. Nor are there known chemical groups within the active substance or its co-formulants that are associated with explosive of self-reactive properties as exemplified by such groups in tables A6.1 and A6.3 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria., In addition, the application of EC Method A.14, Explosive Properties, was completed with results showing that no explosions occurred during any of the tests yielding a conclusion that the test item has no danger of explosion. **Mechanical Sensitivity (Friction):** No Explosion was observed among 6 tests **Mechanical Sensitivity (Shock):** No explosion was observed among 6 tests **Thermal Sensitivity:** No explosion was observed.	[redacted]
Flammable gases			Not relevant, not a gas.	
Flammable aerosols			Not relevant, not an aerosol.	
Oxidising gases			Not relevant, not a gas.	
Gases under pressure			Not relevant, not a gas.	
Flammable liquids			Not relevant, not a liquid.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable solids	EC Method A. 10, GLP EC Method A.9, GLP	1.0% Indoxacarb, Batch No. 15374E170	Not highly flammable Flash point 247.5 °C at 1013 hPa.	[redacted]
Self-reactive substances and mixtures	Guidance on the Application of the CLP Criteria, 2.8.2.1, Annex I: 2.8.4.2.		Not applicable, there are no known chemical groups within the active substance or its co-formulants that are associated with explosive of self-reactive properties as exemplified by such groups in tables A6.1 and A6.3 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria.	
Pyrophoric liquids			Not relevant, not a liquid.	
Pyrophoric solids	EC Method A. 13, GLP Application of the CLP Criteria, 2.10.4.2, Screening Procedures and Waiving of Testing.,	1.0% Indoxacarb, Batch No. 15374E170	No ignition observed while 1 to 2 cm^3 of the test item fell from a height of 1 meter onto a non-flammable surface or within 5 minutes of settling onto the non-flammable surface. The test was performed six times. Based on the test results from EC Method A.13 and handling of the test item during that testing, the test item is not considered pyrophoric.	[redacted]
Self-heating substances and mixtures	Guidance on the Application of the CLP Criteria, 2.8.2.1, Annex I: 2.8.4.2.		Not applicable, the product and none of its components fits the definition of Self-Heating substance as defined in section 2.11.1.1 of Annex I to CLP regulation. There are no known chemical groups within the active substance or its co-formulants that are associated with explosive of self-reactive properties as exemplified by such groups in tables A6.1 and A6.3 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The product is not solid or granular but a paste with a flash-point of 247.5 °C. The product when left open, does not react with air and will not self-heat or ignitewithout source of ignition.	
eCA note: The waiver provided by the applicant regarding the self-heating properties of the product is not considered acceptable based on the CLP requirements. The waiver refers to the self-reactive mixtures and not to the self-heating properties. In order to be able to classify the product for this hazard class a test performed in accordance with UN Test N.4 in Part III, Sub-section 33.3.1.6 of the UN-MTC is required. However, based on experience in handling and use it can be concluded that the product should not be classified in the sense of Reg. (EC) No 1272/2008.				
Substances and mixtures which in contact with water emit flammable gases	Guidance on the Application of the CLP Criteria, 2.12.4.2, Screening Procedures and Waiving of Testing., Annex I: 2.12.4.1		Not relevant as product does not contain metals or metalloids. It is also widely known based on experience in handling and use that the product does not react with water to emit flammable gases. As an example, no evidence of gas generation was observed in pH value studies where 1% (w/v) solutions of the test item in deionized water were prepared. As a result, testing is not necessary.	[redacted]
Oxidising liquids			Not relevant, not a liquid	
Oxidising solids	EC Method A. 21, GLP Guidance on the Application of the CLP Criteria, 2.14.4.1.1, Screening Procedures and Waiving of Testing.	1.0% Indoxacarb, Batch No. 15374E170	No testing or classification is required. Neither the active substance nor any of the co-formulants contain halogens and any oxygen content is bound only to carbon or hydrogen, not to any nitrogen or other oxygen atoms. In addition, the test item exhibited no oxidizing potential based on a comparison of pressure rise time (EC Method A.21) between a 1:1 mixture of 65% nitric acid and cellulose to a 1:1 mixture of the test item and cellulose. The mean pressure rise	[redacted]

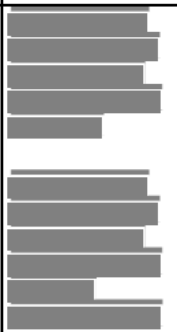
Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			time values for 5 replicate tests were 3.59 seconds and 14.97 seconds, respectively.	
Organic peroxides	EC Method A. 21, GLP	1.0% Indoxacarb, Batch No. 15374E170	Testing is not required as product does not contain organic peroxides. Additionally, no evidence of oxidizing potential was observed in testing.	[redacted]
Corrosive to metals	OECD 113, GLP Guidance on the Application of the CLP Criteria, section 2.16.4.1 and UN Test C.1 section 37.4.1.1	1.0% Indoxacarb, Batch No. 15374E170	Testing and classification is not required. No melting point was reported for the test substance up to a decomposition onset temperature of 300 °C to 470 °C (DSC Method). Therefore, the product will not become a liquid at a temperature of ≤ 55°C and testing is not required.	[redacted]
Auto-ignition temperatures of products (liquids and gases)			Not applicable, not a liquid or gas.	
Relative self-ignition temperature for solids	EC Method A .13, GLP	1.0% Indoxacarb, Batch No. 15374E170	No ignition observed, not pyrophoric. No evidence of self-ignition potential was reported from DSC data.	[redacted]
Dust explosion hazard			Not applicable - Each individual bait station is packaged in plastic film preventing the expulsion of dust. In addition, the product is a paste and is not able to produce a dust of particulate size <1mm in diameter that can ignite or explode when exposed to an ignition source when dispersed in air.	

Conclusion on the physical hazards and respective characteristics of the product

Following a review of the components of the product it can be concluded that the product is not explosive, flammable or oxidising.
The product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

Methods for detection and identification

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	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Test Substance *Roach Bait Raid JWY.* *Active Substance* *Indoxacarb 0.5% (nominal)*	**MV029** HPLC with Chiracel OD-H column, isocratic elution with 70:30 hexane:2-propanol mobile phase and 310 nm UV detection.	3 levels from 0.06295 mg/mL to 0.2518 mg/mL (50% to 200% of nominal); 3 replicates at each level, n = 9. Note: Preparation of the test substance according to the procedure in MV029 leads to a diluted nominal concentration of 0.125 mg/mL.	y = 23243.38x – 29.2; r = 0.9999 over 9 levels from 0.005055 mg/mL to 0.3033 mg/mL; 3 replicates at each level.	No interferences occurred at the retention time of indoxacarb (DPX-KN128) in the placebo (blank formula).	0.06295 mg/mL to 0.2518 mg/mL (50% to 200% of nominal) Level 1: 0.252 mg/mL Level 2: 0.126 mg/mL Level 3: 0.063 mg/mL	99.9 % 100.9 % 100.1	0.4 % 1.4 % 1.3 % Precision: n=6 RSD = 0.59 % RSD_{Hr} = 2.97 % H_r = 0.2	Limit of the limit of quantitation for this method is considered to be the lowest fortified surrogate concentration of 0.06295 mg/mL.	
Test Substance *Roach Bait SOF#34319 (Raid PDQ)* *Active*	**MV010** HPLC with LiChrospher 60 RP-select B (5µm) in LiChroCART 125-4 column, isocratic elution with 80:12	4 levels from 0.0187 mg/mL to 0.4061 mg/mL (6% to 130% of nominal); 3 replicates at each level, n = 12.	y = 9953.1738x - 4.9734 r^2 = 0.9998 over 6 levels from 0.187 mg/mL to	No interferences occurred at the retention time of indoxacarb in the placebo (blank	0.0187 mg/mL to 0.5005mg/mL (6% to 130% of nominal) Level 1: 0.0187			Limit of the limit of quantitation for this method is considered to be the lowest fortified surrogate concentration of	

Substance *Indoxacarb 1.0% (nominal)*	methanol:water mobile phase and 310 nm UV detection.	Note: Preparation of the test substance according to the procedure in MV010 leads to a diluted nominal concentration of 0.3125 mg/mL.	0.5005 mg/mL; 3 replicates at each level.	formula).	mg/ml Level 2: 0.22 mg/ml Level 3: 0.31 mg/ml Level 4: 0.41 mg/ml	98 % 97 % 97 % 97 %	1.02 % 0.59 % 0.59 % 1.03 % Precision: n=6 RSD = 0.18 RSD_{Hr} = 2.68 % H_r = 0.07	0.0187 mg/mL.	[redacted]

N/A = Not Applicable

Analytical Method Summary – MV029

Approximately 2.5 g of the test substance (Raid JWY, 0.05% w/w Indoxacarb) is weighed into a 100 mL volumetric flask and diluted to volume with a 70:30 hexane:2-propanol solvent mixture and stirred until dispersed, creating a nominal indoxacarb concentration of 0.125 mg/mL. After filtering, the sample is placed into a vial and injected onto an HPLC fitted with a Chiracel OD-H column and eluted isocratically with a 70:30 hexane:2-propanol (v/v) mobile phase with UV detection at 310 nm.

Method MV029 exhibited linear response over nine levels ranging from 0.00505 to 0.3033 mg/mL with a correlation coefficient (r) of 0.9999. Method precision was evaluated through measurement of repeatability, one test sample analysed six times, and reproducibility, six individually prepared samples taken through the sample preparation and analysis methodology. Method repeatability and reproducibility measurements yielded % RSD values of 0.15% and 0.59%, respectively, demonstrating acceptable reproducibility compared to the modified Horwitz equation value of 2.97% for an analyte at 0.5% w/w. Method specificity was confirmed by the lack of interference and response of a blank formulation (placebo) at the retention time of the analyte. Accuracy was addressed by analysing three fortified blank formulas at each of 3 fortification levels, 0.06295 mg/mL, 0.1259 mg/mL and 0.2518 mg/mL. Recoveries ranged from 99.9% to 100.9% with an average value of 100.3% and an % RSD of 1.1% (n=9).

Analytical Method Summary – MV010

The test substance (Roach Bait SOF#34319, Raid PDQ nominal 1% w/w Indoxacarb) is weighed (approximately 2500 mg) into a 100 mL Erlenmeyer flask to which 20 mL of n-heptane is added, stirred for 30 minutes followed by the addition of 20 mL of 2-propanol and 40 mL of methanol and stirred once again for 30 minutes. The nominal indoxacarb concentration after sample preparation is 0.3125 mg/mL. After filtering, the sample is placed into a vial and injected onto an HPLC fitted with a LiChrospher 60 RP-select B (5µm) in LiChroCART 125-4 column and eluted isocratically with a 80:12 methanol:water mobile phase with UV detection at 310 nm.

Method MV010 exhibited linear response over six levels ranging from 0.1877 to 0.5005 mg/mL with a correlation coefficient (r) of 0.9999. Method precision was evaluated through measurement of repeatability, one test sample analysed six times, and reproducibility, six individually prepared samples taken through the sample preparation and analysis methodology. Method repeatability and reproducibility measurements yielded % RSD values of 0.18% and 1.12%, respectively, demonstrating acceptable reproducibility compared to the modified Horwitz equation value of 2.68% for an analyte at 1% w/w. Method specificity was confirmed by the lack of interference and response of a blank formulation (placebo) at the retention time of the analyte. Accuracy was addressed by analysing three fortified blank formulas at each of 4 fortification levels, 0.0187 mg/mL, 0.2187 mg/mL, 0.3124 mg/mL, and 0.4061 mg/mL. Recoveries ranged from 97% to 98% with an average value of 97% and an %RSD of 0.81% (n=12).

Conclusion on the methods for detection and identification of the product
Analytical methods MV029 and MV010 for the determination of Indoxacarb (DPX-KN128) in Raid® Cockroach Bait (0.5% Indoxacarb) products were fully validated in accordance with the criteria and guidance in SANCO/3030/99 rev. 4 11/7/00 for test method linearity, precision, accuracy and specificity. Therefore, method MV029 is suitable for use to quantitatively measure indoxacarb in Raid® Cockroach Bait (0.5% Indoxacarb) products.

Efficacy against target organisms

2.2.5.1 Function and field of use

Raid® Cockroach Bait is a ready-to-use bait station with 2.5 g bait containing 0.5% w/w indoxacarb (PT18) for control of cockroaches indoors.

The bait station consists of a base with a well to contain the bait and a domed top with entry holes for the cockroaches to gain access to the bait. The bait stations should be placed indoors in the paths/tracks of cockroaches along base boards, in corners, under sinks, in cabinets and neat plumbing fixtures, preferably on horizontal surfaces touching corner walls.

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

The organisms to be controlled are the following cockroach (Blattodea) species: -

- German cockroach *(Blattella germanica)* - nymphs and adults
- Oriental cockroach *(Blatta orientalis)* - nymphs and adults
- American cockroach *(Periplaneta americana)* - nymphs and adults

2.2.5.3 Effects on target organisms, including unacceptable suffering

Ingestion of this product leads to the death of the target organisms.
As the target organisms are invertebrate animals, animal welfare is not assessed.

2.2.5.4 Mode of action, including time delay

Indoxacarb is a pro-insecticide – it is not toxic to insects until it goes through an activation process. Upon ingestion by the insect, the indoxacarb is rapidly converted to DPX-JT333 by enzymatic cleavage of the N-carbomethoxy group in the insect mid-gut. DPX-JT333 binds to the sodium channels within the insect, thus blocking sodium movement into the cell, resulting in mild convulsions, paralysis and ultimately death. There is a time delay which permits the insect to return to the nest, thus potentially infecting more insects as other cockroaches feed on the dead insect and excrement, i.e. secondary kill ('chain-kill') effect. This also means that insects are likely to die in their harbourages, rather than be knocked-down at the site of application.
This time delay is due to the time taken for the insect to ingest the indoxacarb and then to metabolise it into DPX-JT333, which is toxic and can bind to the sodium channels. The delay varies slightly across species and is also influenced somewhat by the formulation and manner in which the insect is exposed/dosed. Generally, the conversion process begins shortly after ingestion with mortality beginning within hours after ingestion.

2.2.5.5 Efficacy data

Laboratory tests have been conducted with product 15342P45-1, which is identical to Raid Cockroach Baits (0,5% w/w Indoxacarb) (see the composition of Raid Cockroach Baits in the confidential Annex).

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and Field of use envisaged	**Test substance**	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

Insecticide *Bait product*	0.5% w/w Indoxacarb Cockroach Bait Fresh and aged bait (6 months old) (OPPTS 810.3500) Test sub: 15342P 45-1	German cockroach (*Blattella germanica*) American cockroach (*Periplaneta americana*) Oriental cockroach (*Blatta orientalis*)	Free-choice laboratory test 5 treatment arenas and 3 control arenas per species (100x100x11.4 cm) 50 cockroaches per arena (10 adults males, 10 adult females, 10 large nymphs and 20 small nymphs) Water and lab chow available ad libitum mortality was recorded on day 1-4 and 7 for German cockroaches. Day 1-4, 11 and 18 for American cockroaches. Day 1-4, 11 and 14 for oriental cockroaches. environmental conditions: Temperature: 27C ± 4C Humidity: 50% ± 20% RH	See tables below B. germanica - Fresh Bait – dying from day 1, after 7 days 98% mortality. B. germanica - Aged Bait - dying from day 1, after 7 days 90% mortality. P. americana – Fresh Bait – dying from day 2, after 18 days 92% mortality. P. americana – Aged Bait – dying from day 2, after 18 days 96% mortality. B. orientalis – Fresh Bait – dying from day 2 days, after 14 days 97% mortality. B. orientalis – Aged Bait – dying from day 2, after 14 days 98% mortality.	Study 1

German Cockroach Percent Mortality At:

	Day 1	Day 2	Day 3	Day 4	Day 7
Control	0	0	0	0	1
Fresh	51	57	66	90	98
6 Month Aged	27	34	35	68	90

American Cockroach Percent Mortality At:

	Day 1	Day 2	Day 3	Day 4	Day 11	Day 18
Control	0	0	0	0	1	1
Fresh	0	2	9	32	81	92
6 Month Aged	0	3	15	46	95	96

Oriental Cockroach Percent Mortality At:

	Day 1	Day 2	Day 3	Day 4	Day 11	Day 14
Control	0	0	1	3	7	11
Fresh	0	6	23	60	94	97
6 Month Aged	0	13	47	75	98	98

Insectide *Bait product*	0.5% w/w Indoxacarb Cockroach Bait Test sub: 15342P 45-1 Fresh bait	American cockroach (*Periplaneta americana*)	Laboratory test 5 treatment and 2 control arenas. (31.75 cm by 25.4 cm by 10.16 cm). environmental conditions: Temperature: 27C ± 4C Humidity: 50% ± 20% RH Primary kill test: Bait was offered to either 5 adult male cockroaches or 40, 4- week old nymphs. Secondary kill test: After 5 days, the harborages from the adult males and the harborages and 15 corpses from the 4-week old nymphs were transferred to secondary kill arenas containing 30 2-week old nymphs. Mortality was recorded over time.	Table 1. Mean percent primary kill of males or 4-week old nymphs feeding on the test substance 15342P45-1.	Study 2

	Mean Percent Mortality at Day:				Mean Bait Consumption (mg):
Life Stage	**D4**	**D5**	**D6**	**D7**	
Males	70	100	-	-	300
Controls	0	0	-	-	-
4-week Nymphs	27	49	69	83	35
Controls	2	-*	-	-	-

*controls were frozen for the secondary kill portion of the test.

Table 2. Mean percent secondary kill of 2-week old nymphs from male arenas. Note: only the harbourage insert was transferred to the nymphs.

	Mean Percent Mortality at Day Post Transfer								
Arena	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**
Treatment	33	47	53	65	72	77	78	81	82
Controls	3	6	6	6	6	6	6	7	8

Table 3. Mean percent secondary kill of 2-week old nymphs from the 4-week old nymph arenas. NOTE: The harbourage insert plus 15 corpses were transferred to the 2-week old nymph arenas.

	Mean Percent Mortality at Day Post Transfer								
Arena	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**
Treatment	11	27	37	43	53	62	71	77	84
Controls	1	2	3	3	3	6	6	6	7

<table>
<tr>
<td>Insectide

Bait product</td>
<td>0.5% w/w Indoxacarb Cockroach Bait

Test sub: 15342P 45-1</td>
<td>American cockroach (Periplaneta americana)</td>
<td>Laboratory test: 10 treatment and 10 control arenas. (31.75cm by 25.4 cm by 10.16 cm).

Environmental Conditions: Temperature: 27C ± 4C Humidity: 50% ± 20% RH

Single gravid female cockroaches in individual arenas with standard laboratory chow.

First egg capsule removed and destroyed, and the chow removed and replaced with a bait station. Mortality was recorded and the second and third egg capsules were collected and incubated. Egg hatch and subsequent mortality was recorded over time. (OPPTS 810.3500)</td>
<td>Adults were observed to die after 3 days, by 5 days 100% of the cockroaches were dead. Hatch of first egg capsules following test substance application was reduced with 76%. No hatch was observed from the second egg capsule (100% reduction).

Table 1: Cumulative percent female mortality resulting from Test Substance 15342P45-1
<table>
<tr><th>Treatment</th><th>D2</th><th>D3</th><th>D4</th><th>D5*</th></tr>
<tr><td>15342P45-1</td><td>0</td><td>30</td><td>90</td><td>100</td></tr>
<tr><td>Control</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
</table>
*No mortality was observed in the female group over the entire observation period (25 days).

Table 2: Percent of females that produced a second or third viable egg capsule.
<table>
<tr><th>Treatment</th><th>Second Capsule*</th><th>Third Capsule</th></tr>
<tr><td>15342P45-1</td><td>22</td><td>0</td></tr>
<tr><td>Control</td><td>80</td><td>60</td></tr>
</table>
*One treatment female was excluded from the analysis because she ate her first capsule before it could be recovered and held for observation.

Table 3: Total number of nymphs produced from viable second or third egg capsules.
<table>
<tr><th>Treatment</th><th>Second Capsule</th><th>Third Capsule</th></tr>
<tr><td>15342P45-1</td><td>26</td><td>0</td></tr>
<tr><td>Control</td><td>108</td><td>83</td></tr>
<tr><td>Percent Reduction</td><td>76%</td><td>100%</td></tr>
</table>
</td>
<td>Study 3
  </td>
</tr>
</table>

<table>
<tr>
<td>Insectide

Bait product</td>
<td>0.5% w/w Indoxacarb Cockroach Bait

Fresh and aged bait (3 months old)

Test sub: 15342P 45-1</td>
<td>American cockroach (Periplaneta americana)</td>
<td>Free-choice laboratory test
5 treatment and 2 control arenas
50 cockroaches per arena (10 adults males, 10 adult females, 10 large nymphs, 10 medium nymphs and 10 small nymphs)

Arena Dimensions: Plexiglas walled arenas (100 cm x 100 cm x 11.4 cm).

Water and lab chow available ad libitum.

Environmental Conditions:
Temperature: 27C ± 4C
Humidity: 50% ± 20% RH.</td>
<td>Table 1. Mean Cumulative Percent Mortality of Fresh Test substance through 17DAT.
<table>
<tr><th>Time (DAT)</th><th>Control*</th><th>Treatment*</th></tr>
<tr><td>0</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>1</td><td>1 (1)</td><td>0 (0)</td></tr>
<tr><td>2</td><td>1 (1)</td><td>4 (0.6)</td></tr>
<tr><td>3</td><td>1 (1)</td><td>14 (0.9)</td></tr>
<tr><td>4</td><td>5.1 (1.1)</td><td>40.8 (4.1)</td></tr>
<tr><td>7</td><td>2 (0)</td><td>78.8 (4.2)</td></tr>
<tr><td>10</td><td>6.1 (0.1)</td><td>92 (1.8)</td></tr>
<tr><td>14</td><td>6.1 (0.1)</td><td>97.6 (1.0)</td></tr>
<tr><td>17</td><td>4.1 (1)</td><td>98.8 (1.2)</td></tr>
</table>
*n=2 and 5 for Control and Treatment, respectively. Numbers in parentheses are standard errors. Note: control arenas were apparently miscounted at 4DAT-14DAT because a very careful count and search for live insects was conducted at 17DAT. At 17DAT, 12% of the insects in the treatment and 3% in the control arenas were cannibalized.

Table 2. Mean cumulative Percent Mortality of Aged Test Substance through 21DAT.
<table>
<tr><th>Time (DAT)</th><th>Control*</th><th>Treatment*</th></tr>
<tr><td>0</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>1</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>2</td><td>0 (0)</td><td>2.8 (0.8)</td></tr>
<tr><td>3</td><td>0 (0)</td><td>12.4 (4.5)</td></tr>
<tr><td>4</td><td>3 (1)</td><td>44.0 (2)</td></tr>
<tr><td>7</td><td>1 (1)</td><td>79.2 (3.3)</td></tr>
<tr><td>10</td><td>3 (1)</td><td>86.4 (5)</td></tr>
<tr><td>14</td><td>0 (0)</td><td>91.6 (5)</td></tr>
<tr><td>17</td><td>1 (1)</td><td>92.0 (5)</td></tr>
<tr><td>21</td><td>0 (0)</td><td>93.2 (5.3)</td></tr>
</table>
*n=2 and 5 for Control and Treatment, respectively. Numbers in parentheses are standard errors. Note: control arenas were apparently miscounted at 4DAT-17DAT because a very careful count and search for live insects was conducted at 21DAT. At 21DAT, 4% of the insects in the treatment and 0% in the control arenas were cannibalized.</td>
<td>Study 4
  </td>
</tr>
</table>

<table>
<tr>
<td>Insecticide

Bait product</td>
<td>0.5% w/w Indoxacarb Cockroach Bait

Fresh and aged bait (3 months old)

Test sub: 15342P 45-1</td>
<td>Oriental cockroach (Blatta orientalis)</td>
<td>Free-choice laboratory test

5 treatment arenas and 2 control arenas per species (100x100x11.4 cm)

Environmental Conditions: Temperature: 27C ± 4C Humidity: 50% ± 20% RH

50 cockroaches per arena (10 adults males, 10 adult females, 10 large nymphs and 20 small nymphs)

Water and lab chow available ad libitum

mortality was recorded on 0-4 and 7, 10 and 14 days after treatment for Fresh bait and 0-4, 7 and 10 days after treatment for aged bait.</td>
<td>Table 1. Mean Cumulative Percent Mortality of Fresh Test Substance through 14DAT.
<table>
<tr><th>Time (DAT)</th><th>Control*</th><th>Treatment*</th></tr>
<tr><td>0</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>1</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>2</td><td>0 (0)</td><td>19.2 (3.3)</td></tr>
<tr><td>3</td><td>0 (0)</td><td>49.2 (2.0)</td></tr>
<tr><td>4</td><td>0 (0)</td><td>79.2 (3.7)</td></tr>
<tr><td>7</td><td>0 (0)</td><td>93.2 (1.5)</td></tr>
<tr><td>10</td><td>0 (0)</td><td>99.6 (0.4)</td></tr>
<tr><td>14</td><td>0 (0)</td><td>100 (0)</td></tr>
</table>
*n=2 and 5 for Control and Treatment, respectively. Numbers in parentheses are standard errors. NOTE: at 14DAT, 2.0% of the insects in the Treatment and 0% Control arenas were cannibalized.

Table 2. Mean Cumulative Percent Mortality of Aged Test Substance through 10DAT.
<table>
<tr><th>Time (DAT)</th><th>Control*</th><th>Treatment*</th></tr>
<tr><td>0</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>1</td><td>0 (0)</td><td>0.4 (0.4)</td></tr>
<tr><td>2</td><td>0 (0)</td><td>0.4 (0.4)</td></tr>
<tr><td>3</td><td>0 (0)</td><td>42.0 (2.7)</td></tr>
<tr><td>4</td><td>0 (0)</td><td>88.4 (1.5)</td></tr>
<tr><td>7</td><td>0 (0)</td><td>99.6 (0.4)</td></tr>
<tr><td>10</td><td>0 (0)</td><td>100 (0.0)</td></tr>
</table>
*n=2 and 5 for Control and Treatment, respectively. Numbers in parentheses are standard errors. NOTE: at 10DAT, 0% of the insects in the Treatment and in the Control, arenas were cannibalized.</td>
<td>Study 5
  </td>
</tr>
</table>

Insecticide *Baitproduct*	0.5% w/w Indoxacarb Cockroach Bait Test sub: Raid JWY, 15342P 45-1 Fresh bait	German cockroach (*Blattella germanica*)	Free-choice Laboratory test 5 treatment and 2 control arenas (31. 75 cm by 25.4 cm by 10.16 cm) **Primary Kill Test Design:** 1. Five treatment arenas and two untreated controls arenas. 2. Treatment arenas receive bait, alternative food, water, and harborage. Control arenas receive lab chow, water, and harborage only. 3. 30 four-week-old nymphs in each of the seven arenas using light CO2. Acclimate for 24hrs. **Secondary Kill Test Design**: 1. Five treatment arenas and two untreated controls arenas. 2. Treatment and control arenas contain water and harborage only. 3. 300 two-week-old nymphs in each container 4. Add five nymphs from primary kill arenas to each Secondary Kill arena Environmental Conditions: Temperature: 79-81°F Humidity: 42-49% RH Photo period: 14hr light, 10hr dark	Primary Kill – Mean Percent Reduction of Four-week-old nymphs after 24-hour exposure to 0.5 Indoxacarb Bait. **Treatment** / **24 Hour Percent Mortality** **Raid JWY** 91.3 **Control** 1.7 Secondary Kill - Mean Percent mortality of two-week-old nymphs following transfer of five primary kill corpses (treatment) or five corpses (control). **Treatment** / **Day 3** / **Day 4** / **Day 7** / **Day 9** **Raid JWY** 42.7 / 56.2 / 58.9 / 99.7 **Control** 0 / 0.3 / 0.3 / 11.0 **Net Effect** 42.7 / 55.9 / 58.6 / **88.7** Final humidity Corrected Mean Primary Kill Consumption of Bait (g) from four-week-old nymphs using Raid JWY 0.5% Indoxacarb Bait. **Four Week Nymph Consumption (g)** Raid JWY- **0.015**	Study 6 

Insecticide

Baitproduct

0.5% w/Indoxacarb Cockroach Bait

Aged bait (3months old). (OPPTS 810.3500)

Test sub: 15342P 45-1

German cockroach (*Blattella germanica*)

American cockroach (*Periplaneta americana*)

Oriental cockroach (*Blatta orientalis*)

Free-choice laboratory test

5 treatment and 5 control arenas (75 cm by 25.4 cm by 10.16 cm) per species

1. German cockroach: 10 replicates of 10 adult males, 10 adult females, 10 five-week nymphs, and 20 three-week nymphs.

2. American cockroach: 10 replicates of 10 adult males, 10 adult females, 30 five-week nymphs.

3. Oriental cockroach: 10 replicates of 10 adult males, 10 adult females, and 30 four-week nymphs.

Environmental Conditions:
Temperature: 27C ± 4C
Humidity: 50% ± 20% RH
Photo period: 14hr light, 10hr dark

Mean Percent Mortality of mixed populations of German cockroaches exposed to 3-month aged bait.

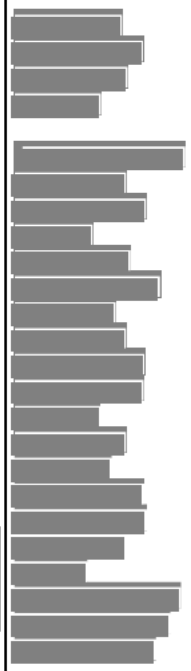
German Cockroach Mean Percent Mortality														
	D1	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**D11**	**D12**	**D13**	**D14**
RaidJWY	88	92.4	94.4	99.2	100	100	100	100	100	100	100	100	100	100
Control	0	0	0	0	0	0	0	0.8	0.8	0.8	0.8	0.8	0.8	0.8

Mean Percent Mortality of mixed populations of American cockroaches exposed to 3-month aged bait.

American Cockroach Mean Percent Mortality														
	D1	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**D11**	**D12**	**D13**	**D14**
Raid JWY	5.2	20	22.4	34.8	49.2	52.4	52.4	54	54	54	54	54	54	100 *
Control	0.4	0.4	0.4	0.4	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	25.6 *

*Day 14 mortality results were corrected for cannibalism by using the final total cockroaches to calculate mean percent mortality. Data prior to day 14, used the initial 50 total cockroaches for calculating mean percent mortality Live insects were not counted directly untill day 14 because that would disturb the insects and lead to skewed consumption of bait
Control arenas - Cannibalism was assumed since no discernable American cockroach corpses were present at the end of the day 14 study.

Study 7.



Mean Percent Mortality of mixed populations of Oriental cockroaches exposed to 3-month aged bait.

Oriental Cockroach Mean Percent Mortality														
	D1	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**D11**	**D12**	**D13**	**D14**
Raid JWY	30.1	71.1	80.3	87.1	99.6	99.6	100	100	100	100	100	100	100	100
Control	0	0	0.8	0.8	0.8	0.8	0.8	0.8	1.2	1.2	1.2	1.2	1.6	1.6

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

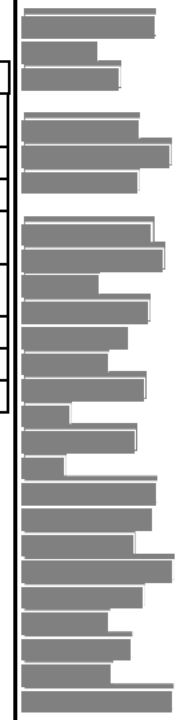
Function and Field of use envisaged	Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Insecticide *Baitproduct*	0.5% w/w Indoxacarb Cockroach Bait Test sub: Raid Cockroach Bait (Indoxacarb 0.50%)	German cockroach (*Blattella germanica*)	Field study in seven rental Apartments infested with German cockroaches in a large apartment block in the Netherlands The apartments were of two different types having a living surface areas of approximately 80m² and 100m². Each apartment received 12 bait stations. The typical temperature range was expected to range between 15-25C and 40-50% relative humidity. Study was performed in September, October and November 2011. Glue traps were placed and cockroaches were counted on day 0, 28 and 56. Visual inspections were done on day 0,3,14,28,42,and 56	Efficacy after 8 wks: one apartment 100%, four apartments efficacy 87 – 95%, two apartments 36% and 61%. The latter two apartments were classified beforehand as having a very low level of hygiene.	Study 8.

Total number of cockroaches counted during visual inpsections

Apartment	Hygiene	Day 0	Day 3	Day 14	Day 28	Day 42	Day 56	Reduction (%) Day 56
1	Medium	7	5	11	3	6	0	100
2	Low	25	35	42	10	14	11	56
3	Very Low	19	9	4	4	3	0	100
4	Very Low	8	8	6	4	4	4	50
5	High	26	35	21	9	6	3	80
6	Medium	10	5	3	3	0	0	100
7	High	21	25	4	0	1	0	100

Total number of cockroaches on glue traps

Apartment	Hygiene	Day 0	Day 28	Day 56	Reduction (%) Day 56
1	Medium	106	36	14	87
2	Low	45	4	3	93
3	Very Low	112	25	44	61
4	Very Low	45	89	29	36
5	High	120	9	6	95
6	Medium	51	44	3	94
7	High	68	5	0	100



Insecticide

Baitproduct

0.5% w/w Indoxacarb Cockroach Bait

Test sub: Raid Cockroach Bait (Indoxacarb 0.50%)

German cockroach (*Blattella germanica*)

Field trial on eight test sites infested with German cockroaches in Czech Republic.

Environmental conditions: 20-25C and 30-40% relative humidity.

Glue traps were placed and cockroaches were monitored on 0, 5, 8, 14, 15, 18, 20, 22, 24, 28, 29, 42, 43, 46, 54, 56, 57. Depending on site.

Test conditions: Experiment start date: 22.08.2011 Experiment end date: 09.11.2011

The treatment resulted in significant efficacy ranging from 93.7 % to 100 % compared with the pretreatment assessment at all test sites.

Site	Apartment size	Number of baits
1	21 m^2	6
2	21 m^2	8
3	21 m^2	12
4	21 m^2	14
5	21 m^2	6
6	21 m^2	12
7	80 m^2	7
8	21 m^2	14

Table 1. Total number of cockroaches found at each site (1-8).

Number of Cockroaches	No. of cockroaches at day #						
	0	**8**	**15**	**20**	**28**	**42**	**56**
Site 1	16	13	3	6	6	9	2
Site 2	4	2	7	3	0	0	0
Site 3	9	4	9	5	6	3	4
Site 4	54	62	41	17	18	9	3
Site 5	15	15	6	9	8	9	3
Site 6	330	448	84	37	103	n/a	111

Number of Cockroaches	No. of cockroaches at day #							
	0	**5**	**10**	**18**	**24**	**32**	**46**	**54**
Site 7	14	15	12	29	14	8	3	0

Number of Cockroaches	No. of cockroaches at day #						
	0	**8**	**14**	**22**	**29**	**43**	**57**
Site 8	105	206	54	28	13	11	3

Study 9

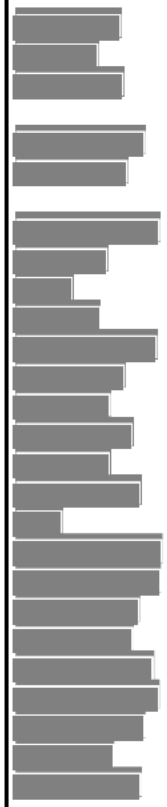


Table 2. Average percentage reduction in cockroach numbers post treatment after about two months:

Site	After 54, 56 or 57 days
Site 1	87.5
Site 2	100.0
Site 3	55.6
Site 4	94.4
Site 5	80.0
Site 6	66.4
Site 7	100.0
Site 8	97.1
Average	**85.1**

<table>
<tr>
<td>Insecticide

Baitproduct</td>
<td>0.5% w/w Indoxacarb Cockroach Bait

Test sub: Raid Cockroach Bait (Indoxacarb 0.50%)</td>
<td>· American cockroach (Periplaneta americana)</td>
<td>Field trial on three test sites infested with American cockroaches in Spain.

A pre-monitoring assessment was conducted to establish infestation levels at test sites using monitoring traps.

Monitoring of cockroach numbers were performed at weekly intervals, up to 8 weeks post bait station placement.

Test conditions Expected Approximate site conditions:
20-30C
40-60 relative humidity
Trial period:
October-September.</td>
<td>The treatment resulted in significant efficacy ranging from 99.0 % to 100 % by week 8 compared with the pretreatment assessment at all test sites.

Table 1. Site area and bait placement
<table>
<tr><th>Site</th><th>Area (m²)</th><th>Baits Placed</th></tr>
<tr><td>1</td><td>110</td><td>10</td></tr>
<tr><td>2</td><td>30</td><td>9</td></tr>
<tr><td>3</td><td>20</td><td>6</td></tr>
</table>
Table 2. Percentage population reduction of Periplaneta americana exposed to 0.5% Indoxacarb baits over 8 weeks.
<table>
<tr><th>Treatment</th><th>Week 1</th><th>Week 2</th><th>Week 3</th><th>Week 4</th><th>Week 5</th><th>Week 6</th><th>Week 7</th><th>Week 8</th></tr>
<tr><td>Site 1</td><td>80.6</td><td>93.5</td><td>92.7</td><td>98.2</td><td>99.1</td><td>99.5</td><td>100</td><td>100</td></tr>
<tr><td>Site 2</td><td>83.3</td><td>N/A</td><td>93.1</td><td>96.4</td><td>95.2</td><td>97.9</td><td>99</td><td>100</td></tr>
<tr><td>Site 3</td><td>57.2</td><td>87.3</td><td>95.4</td><td>96.5</td><td>96.5</td><td>100</td><td>99</td><td>99</td></tr>
<tr><td>Mean</td><td>73.7</td><td>90.4</td><td>93.7</td><td>97.0</td><td>96.9</td><td>99.2</td><td>99.3</td><td>99.7</td></tr>
</table>
N/A* assessment was not taken because traps were removed due to owner misinterpretation.</td>
<td>Study 10</td>
</tr>
</table>

<table>
<tr>
<td>Insecticide

Baitproduct</td>
<td>0.5% w/w Indoxacarb Cockroach Bait

Test sub: Raid Cockroach Bait (Indoxacarb 0.50%)</td>
<td>Oriental cockroach (Blatta orientalis)</td>
<td>Field trial on four test sites infested withOriental cockroaches in Spain.

A pre-monitoring assessment was conducted to establish infestation levels at test sites using monitoring traps.

Monitoring of cockroach numbers were performed at weekly intervals, up to 8 weeks post bait station placement.

Test conditions Expected Approximate site conditions:
20-30C
40-60 relative humidity
Trial period: September-November.</td>
<td>The treatment resulted in significant efficacy ranging from 96.5 % to 100 % by week 8 compared with the pretreatment assessment at all test sites.

Table 1. Area and Bait placement
<table>
<tr><th>Site</th><th>Area (m^2)</th><th>Baits placed</th></tr>
<tr><td>1</td><td>120</td><td>12</td></tr>
<tr><td>2</td><td>71</td><td>6</td></tr>
<tr><td>3</td><td>68</td><td>6</td></tr>
<tr><td>4</td><td>22</td><td>6</td></tr>
</table>
Table 2. Percentage population reduction of Blatta orientalis exposed to 0.5% Indoxacarb baits over 8 weeks.
<table>
<tr><th>Treatment</th><th>Week 1</th><th>Week 2</th><th>Week 3</th><th>Week 4</th><th>Week 5</th><th>Week 6</th><th>Week 7</th><th>Week 8</th></tr>
<tr><td>Site 1</td><td>77.3</td><td>63.3</td><td>86</td><td>96.5</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>Site 2</td><td>95.8</td><td>82</td><td>71.4</td><td>97.9</td><td>96.8</td><td>98.9</td><td>96.5</td><td>100</td></tr>
<tr><td>Site 3</td><td>45.5</td><td>45.5</td><td>67.5</td><td>83.1</td><td>97</td><td>100</td><td>100</td><td>98.3</td></tr>
<tr><td>Site 4</td><td>96.6</td><td>95.4</td><td>88.6</td><td>95.4</td><td>97.3</td><td>98</td><td>98.3</td><td>96.5</td></tr>
<tr><td>Mean</td><td>78.8</td><td>83.2</td><td>78.4</td><td>93.2</td><td>97.8</td><td>99.2</td><td>98.7</td><td>98.7</td></tr>
</table>
</td>
<td>Study 11</td>
</tr>
</table>

Conclusion on the efficacy of the product
Based on the provided efficacy data authorization can be granted for use against the German cockroach (*Blatella germanica*), the American cockroach (*Periplaneta americana*) and the Oriental cockroach (*Blatta orientalis*). For a full evaluation of the label claims, please refer to section 2.2.5.8.

2.2.5.6 Occurrence of resistance and resistance management

To date, field strains of cockroaches collected in the USA displayed moderate to high levels of resistance to indoxacarb, fipronil, acetamiprid, and all pyrethroids tested (beta-cyfluthrin, bifenthrin, and lambda-cyhalothrin) [redacted]). The development of resistance to insecticides in cockroaches is increasing. To date, only *B. germanica* have developed a degree of resistance that presents control problems in the USA ([redacted] Resistance to all the major groups of insecticide (pyrethroids, organochlorines, organophosphates and carbamates) have been reported in the USA. However, www.pesticideresistance.org reports no known resistance/cross resistance to indoxacarb

Resistance management strategies should be used considering the reports on german cockroaches developing resistance to indoxacarb. In areas where the presence of resistant strains is confirmed, alternation or combination with other insecticides having a different mode of action is recommended.

Raid® Cockroach Baits (0.5% Indoxacarb) is meant for non-professional use only. If 3 months after the start of the treatment the infestation is not controlled, the user should seek help of a professional pest controller. Subsequently, the label includes the following phrase, 'When the product is not used according to the label, resistance of insects might occur. When the infestation persists contact a professional pest controller.'

2.2.5.7 Known limitations

This product can have a time delay (for up to several days) before the first efficacy results will become evident.

2.2.5.8 Evaluation of the (bio-efficacy) label claims

The product consists of a solid (paste) insecticide formulation in a bait station. The formulation is consumed by the cockroach causing mortality in German cockroaches, Oriental cockroaches and American cockroaches.

Due to the specificity of baits, only efficacy against species of cockroach that have been tested in the field can be claimed on the product label.

ECHA Guidance on the Biocidal Products Regulation Volume II Efficacy – Assessment and Evaluation (Parts B+C) Version 3.0 April 2018 for PT18 products states that for products intended for use as baits the following test are needed:

- a laboratory test showing palatability, of fresh product and product at the end of the claimed maximum storage period;

- a simulated-use test showing mortality according to the claim;

- a field trial according to the directions for use and with the claimed cockroach species. Simulated-use tests can be waived if a robust field trial is submitted.

Required results in laboratory palatability choice test (bait and alternative food):
- at least 95% of the test insects have been killed at a given time point;

Required results in field tests:
- after a period of 2-10 weeks, the population reduction exceeds 80% relative to either untreated sites or pre-treatment levels.

In total 11 efficacy studies were provided; seven laboratory tests and four field tests. Although no simulated-use tests were provided, the eCA considers the laboratory and field test sufficient to show efficacy of the product, in line with the requirements of the guidance.

Laboratory tests (German cockroaches, Oriental cockroaches & American cockroaches):

Four free-choice laboratory tests (B5.10(1), B5.10(4), B5.10(5) and B5.10(7)) were provided with product 15342P45-1, which is identical to Raid Cockroach Baits (0,5% w/w Indoxacarb). In these free choice laboratory studies the palatability and efficacy of both fresh and aged product (3 and 6 months old) against German cockroaches (*Blatella germanica*), American cockroaches (*Periplaneta americana*), and Oriental cockroaches (*Blatta orientalis*) was tested.

-B5.10 (1): For fresh product, 98% mortality for German cockroaches was found after 7 days, 92% for American cockroaches after 18 days and 97% for Oriental cockroaches after 14 days. For aged product (6 months old) 90% mortality for German cockroaches was found after 7 days, 96% for American cockroaches after 18 days and 98% for Oriental cockroaches after 14 days. However, as this study contained no raw data, the results of this study were not used for the evaluation of the label claims.

-B5.10 (4): For fresh product, 99% mortality for American cockroaches after 14 days and 93.2% after 21 days for aged product (3 months old)

-B5.10 (5): For fresh product, 100% mortality for Oriental cockroaches was found for both fresh product after 14 days and for aged product (3 months old) after 10 days.

-B5.10 (7): For 3 months aged product, 100% mortality was found for German cockroaches, American coackroaches and Oriental cockroaches within 14 days.

-Besides these free choice studies, three laboratory studies with 15342P45-1 were provided in which the secondary kill resulting from coprophagy, necrophagy or contact with oral/anal secretions (study B5.10(2) on *P. americana* and B5.10(6) on *B. germanica*) and killing of eggs in formation (study B5.10(3) on *P. americana*) were tested. Results showed that mortality among 2-week old nymphs of *P. americana* due to secondary kill was 82-84% (control group 7-8%) and 99.7%% among 2-week old nymphs of *B. germanica* (control group 11%, net mortality 88.7%). A 76-100% reduction in the number of nymphs hatching from second and third egg capsules was shown. These results are due to the mode of action of indoxacarb. However, as secondary kill and killing of eggs in formation is not specifically claimed these parts of the studies are considered as supporting information only.

It is therefore concluded that under laboratory conditions the palatability and mortality of Raid cockroach bait (=15342P45-1) in standard bait stations is shown to be sufficient for up to 3 months for all three species of cockroaches. As the product contains a preservative, a shelf life of 2 years can be authorized.

Field studies (German cockroaches, Oriental cockroaches & American cockroaches):

Four field studies (B5.10(8), B5.10(9), B5.10(10) and B5.10(11) were provided in which Raid Cockroach Baits was applied. In these field studies the efficacy of Raid Cockroach Bait against German cockroaches (*Blatella germanica*), American cockroaches (*Periplaneta americana*), and Oriental cockroaches (*Blatta orientalis*) was tested.

-B5.10 (8): In a field trial with German cockroaches in the Netherlands efficacy was shown in seven apartments with low up to high hygiene levels. In the five apartments with normal to high hygiene efficacy was shown to be 87-100%. In the two apartments with a very low hygiene level, efficacy was much lower (36% and 61%) compared to the other apartments. In this study efficacy was shown to be sufficient (>80%) provided that a sufficient level of hygiene is reached during treatment.

-B5.10 (9): In a field trial with German cockroaches in Czech Republic efficacy resulted in an average of 85% reduction in pre-treatment German cockroach numbers. The efficacy in this study is sufficient against *B. germanica (above 80%)*.

-B5.10 (10): In a field trial with American cockroaches in Spain efficacy ranged from 99.0% to 100% by week 8 compared with the pretreatment assessment at all three test sites.

-B5.10 (11): In a field trial with Oriental cockroaches in Spain, efficacy ranged from 96.5% to 100% by week 8 compared with the pretreatment assessment at all four test sites.

It is therefore concluded that the efficacy of Raid Cockroach Baits (Indoxacarb 0.50%) is sufficient against all three species under field conditions, provided that the bait is applied in premises with a sufficient level of hygiene.

These results make authorization possible against nymphs and adults of German cockroaches (*Blatella germanica*), American cockroaches (*Periplaneta americana*), and Oriental cockroaches (*Blatta orientalis*) when used with a sufficient level of hygiene and with a shelf life of2 years (24 months).

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

Not applicable as Raid Cockroach Bait is not recommended for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The toxicology studies submitted previously for Raid® Cockroach Bait are described below. These studies were conducted on a very similar product, Raid PDQ, which was the representative product in the Indoxacarb CAR (Indoxacarb CAR, 2008). This was considered a conservative approach as Raid PDQ contains 1.0% (w/w) Indoxacarb, whereas Raid® Cockroach Bait contains half the amount of active substance, at 0.5% w/w Indoxacarb. Indoxacarb is considered the only formulant relevant in regard to human health as all other co-formulants are not classified for toxicological properties and are food ingredients, therefore using the toxicology studies from Raid PDQ which contains a higher level of Indoxacarb (1.0% (w/w)) is considered an appropriate read-across.

Additionally, the following text was included in the original PAR for authorisation;
Raid PDQ contains 1.9 % (w/w) DPX-MP062-MUP which is equivalent to 1.33 % (w/w) DPX-MP062 (which is equivalent to 1.0% w/w indoxacarb), for use as an insecticide. From a toxicological view, Raid PDQ differs from Raid Cockroach Bait only in concentration indoxacarb, 0.5% in Raid Cockroach Bait vs. 1% in Raid PDQ, all other co-formulants are not classified for toxicological properties. As the concentration of indoxacarb in Raid Cockroach Bait is lower, the results for Raid PDQ are considered worst-case for Raid Cockroach Bait and therefore the no new data/information is required.

No new studies were conducted on the current biocidal product.

Skin corrosion and irritation

A primary skin irritation study in rabbits was conducted with the paste in Raid PDQ as described in the CAR of indoxacarb (Indoxacarb CAR, 2008). The results from this study are considered to be valid for the assessment of the current product, Raid® Cockroach Bait (for more information see text included in section 2.2.6.1).

Summary table of *in vivo* studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 404	Rabbit, New Zealand White, 3 males	0.5 ml Raid PDQ, 4 h exposure, Semi-occlusive binding	Average scores of 1 or less for erythema at 24, 48 and 72 hours and completely resolved by day 7.	None	[redacted]

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product does not require classification for skin irritation according to Regulation (EC) No. 1272/2008 Classification, Labelling and Packaging Regulation (CLP).
Justification for the value/conclusion	The mean erythema score in at least 2 of the 3 animals was NOT ≥ 2.3 over the three observation periods (the threshold for classification under CLP). Additionally, any inflammation was resolved by the 7th day post exposure. Therefore, the product does not require classification for skin irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Eye irritation

An eye irritation study in rabbits was conducted with the paste in Raid PDQ as described in the CAR of indoxacarb (Indoxacarb CAR, 2008). The results from this study are considered to be valid for the assessment the current product, Raid® Cockroach Bait (for more information see text included in section 2.2.6.1).

Summary table of *in vivo* studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 405	0.1 ml Raid PDQ	4 New Zealand White rabbits, 3 male, 1 female. Single dose administered into the conjunctival sac of the right eye.	Mean scores were 0 at 24h, 48h and 72h for corneal opacity and iritis. Conjunctival redness and chemosis scored 2 or less at 24 and 48h, but was resolved by 72h. Not irritating to eyes	One male animal was replaced due to no documentation of the fluorescein procedure. The data for this animal was considered additional information and was presented in a separate appendix.	[redacted]

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product does not require classification for eye irritation according to Regulation (EC) No 1272/2008.
Justification for the value/conclusion	The results of the study did not meet or exceed the thresholds for classification under CLP. Therefore, the product does not require classification for eye irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Currently, there are no standard tests for respiratory tract irritation and testing is not required under BPR. As RAID Indoxacarb products are not classified for corrosion or irritation, respiratory tract irritation is unlikely to occur; therefore, no additional consideration is needed.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	8.7.1. Other endpoints
Justification	As RAID Indoxacarb products are not classified for corrosion or irritation, respiratory tract irritation is unlikely to occur. Therefore, the product does not require classification for respiratory irritation according to Regulation (EC) No 1272/2008.

Skin sensitization

A Modified Buehler Design Sensitisation Study was performed. The study was conducted with the paste in Raid PDQ but the results from this study are considered to be valid for the assessment of the current product, Raid® Cockroach Bait. The study below is included in the CAR for Indoxacarb and additional information on applicablility of read across is included in section 2.2.6.1.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Modified Buehler Design, OECD Guideline 406	Guinea pig; Hartley-derived albino. Test animals: 10 ♀ and 10 ♂. Challenge control animals: 5 ♀ and 5 ♂.	Dose: 0.3 ml of 100% test article for induction. Test article is Raid PDQ. Challenge (test and control groups): exposure *ca* 6h, dermal exposure using an occlusive patch.	Responses in 19/20 test animals at 24h. Responses in 20/20 test animals at 48h. 0 (No reaction) to ± (Slight patchy erythema) observed in challenge control animals. Sensitising	None	[redacted]

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The product requires classification for skin sensitisation according to Regulation (EC) No 1272/2008.
Justification for the value/conclusion	Skin sensitisation testing with neat indoxacarb results in 33% of animals becoming sensitized, whereas, the sensitising study conducted with Raid PDQ (1% Indoxacarb) resulted to 100% sensitised animals. Therefore, it can be concluded that the sensitising potential is partly due to the co-formulants and not solely the active substance. As the co-formulants are comparable between Raid PDQ and Raid® Cockroach Bait, read across is considered applicable as the major difference between the two products is a decrease in the level of indoxacarb. While bridging to a formulation with a higher level of active substance could result in an over-classification, the test data for sensitisation indicated that the co-formulants contribute in a greater proportion to sensitisation potential and must be considered. Therefore, this bridge from Raid PDQ (1% Indoxacarb) to Raid Cockroach Bait (0.5% Indoxacarb) is deemed appropriate due to comparable co-formulants. The results (summarised above) indicate that the formula needs to be classified as sensitizing to skin (Skin Sens. 1B, H317) based on Regulation 1272/2008/EC. This is because ≥15% of animals responded to >20% of the topical induction dose, thus meeting the CLP criteria for classification.
Classification of the product according to CLP	Skin Sens. 1B, H317

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	These products do not require classification for respiratory sensitisation according to Regulation (EC) no. 1272/2008.
Justification for the value/conclusion	Under Regulation (EC) No. 1272/2008, in the absence of data, preparations may be classified for respiratory sensitisation by calculation. Section 3.4.3 of the regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a respiratory sensitiser and is present at or above the appropriate generic concentration limit shown in table 3.4.5 or is present at or above the concentration limit for sensitised individuals presented in table 3.4.6. Details of the product compositions are presented in the Confidential Annex. These products do not contain any substances which are classified for respiratory sensitisation; therefore, these products do not require classification for respiratory sensitisation.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	8.4 Respiratory sensitisation
Justification	These products do not contain any substances which are classified for respiratory sensitisation. Therefore, the product does not require classification for eye irritation according to Regulation (EC) No 1272/2008.

Acute toxicity

Acute toxicity by oral route

An acute oral toxicity study in rats was conducted with the paste in Raid PDQ as included in the CAR of Indoxacarb (Indoxacarb CAR, 2008). The results from this study are considered to be valid for the assessment of the current product, Raid® Cockroach Bait (for more information see text included in section 2.2.6.1).

Summary table of animal studies on acute oral toxicity

Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)	Rat; Sprague Dawley; 3 ♀	5000 mg/kg bw Raid PDQ, single exposure	No mortality observed. Clinical abnormalities included transient incidences of decreased defecation and faeces small in size. Bodyweight gain observed for all animals and no significant gross internal findings at necropsy.	> 5000 mg/kg bw	None	[redacted]

Value used in the Risk Assessment – Acute oral toxicity	
Value	> 5000 mg/kg bw According to Regulation (EC) No 1272/2008 the product does not require classification for acute oral toxicity.
Justification for the selected value	No mortality was observed at doses of 5000 mg/kg bw. Therefore, the product does not require classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

An acute inhalation toxicity study was not conducted for this product or Raid PDQ. However, within the Indoxacarb CAR (Indoxacarb CAR, 2008) it was indicated that low inhalation toxicity was observed for the active substance (used in the current product) following acute inhalation exposure in rats.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product does not require classification for acute inhalation toxicity using the calculation method according to Regulation (EC) No 1272/2008.
Justification for the selected value	Under Regulation (EC) No 1272/2008, section 1.1.3, where the mixture itself has not been tested to determine its hazardous properties, but there are sufficient data on similar tested mixtures and individual hazardous ingredient substances to adequately characterise the hazards of the mixture. Therefore, since the co-formulants in Raid PDQ were not classified for acute inhalation toxicity (and as the co-formulants have been deemed as comparable to Raid Cockroach Bait) and the active substance also demonstrated low acute inhalation toxicity(>5.5mg/l), it was likely the product would have low acute toxicity following inhalation exposure. Comparable argumentation is included in Indoxacarb CAR (Indoxacarb CAR, 2008) for the formulation toxicity section included for Raid PDQ.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

An acute dermal toxicity study in rabbits was conducted with the paste in Raid PDQ as described in the Indoxacarb CAR (Indoxacarb CAR, 2008). The results from this study are considered to be valid for the assessment of the current product, Raid® Cockroach Bait (for more information see text included in section 2.2.6.1).

Summary table of animal studies on acute dermal toxicity

Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 402 (Acute Dermal toxicity)	New Zealand White Rabbits; 5 ♀ and 5 ♂	5000 mg/kg bw Raid PDQ, single exposure	No mortality observed. Clinical abnormalities observed were soft stools, faecal stain and dermal irritation at site of test material. Bodyweight gain observed for all animals and no gross internal findings at necropsy.	> 5000 mg/kg bw	None	[redacted]

Value used in the Risk Assessment – Acute dermal toxicity	
Value	> 5000 mg/kg bw According to Regulation (EC) No 1272/2008 the product does not require classification for acute dermal toxicity.
Justification for the selected value	No mortality was observed at doses of 5000 mg/kg bw. Therefore, the product does not require classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Information on dermal absorption

A conservative default dermal absorption value of 100% was used in the current document. This value was used previously in the Indoxacarb CAR (Indoxacarb CAR, 2008)..

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Indoxacarb	
Value(s)*	100%	
Justification for the selected value(s)	Please refer to section above.	

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

According to the Human Health Guidance on the Biocidal Products Regulation ECHA (2017), a chemical is defined as a Substance of Concern (SoC) if it (a) drives the product classification, (b) is another registered active substance present in the formula, (c) enhances the effects of the active substances in the product, (d) is on the REACh candidate list at ≥ 0.1%, or (e) has a community workplace exposure limits (CWELs).

As per (a) the product is classified for dermal sensitisation (H317) on the basis of a positive Buehler sensitization test (see acute toxicity summary above). It was noted in the Indoxacarb CAR (Indoxacarb CAR, 2008) that as the study performed with Raid PDQ gave as stronger sensitising response compared to the study performed with the active ingredient only, the sensitisation reaction observed was due in part to the co-formulants (i.e. food ingredients). In line with CLP classification, it is not possible to identify one of the component as adding to the sensitising potential, none of of the co-formulants are considered a SoC.
That said, under normal conditions of use, dermal exposure to the bait formula will not occur as this is securely housed within the bait station. In addition, the co-formulant food ingredients are consumed in significant quantities by the general public via normal dietary intake. Therefore, the risk of inducing allergic contact dermatitis from using the biocidal product is considered minimal and this endpoint was not evaluated further.However, although none of the co-formulants (i.e. food ingredients) could be identified as adding to the sensitising potential and exposure is considered minimal as it is included in a bait box, peanut allergies are well known and considering the severe effects of allergic people, the following sentence is included in the first aid section of the SPC: Contains peanuts. May produce an allergic reaction.

There are no other chemicals present in the formula that fulfil SoC criteria (b) (c)or (d). For the last criteria (e), none of the chemicals in the product had CWELs listed in COMMISSION DIRECTIVE (EU) 2017/164. Therefore, it was concluded that no chemicals were identified as substances of concern.

Screening non-active substance(s) for endocrine disrupting potential

Article 2 Point 5 (a) of the BPR notes that the Regulation shall not apply to food or feed used as repellents or attractants. In this case, the definition of "food" is taken from Regulation (EC) No 178/2002 whereby "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

"Food" shall not include:
(a) feed;
(b) live animals unless they are prepared for placing on the market for human consumption;
(c) plants prior to harvesting;
(d) medicinal products within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22);

(e) cosmetics within the meaning of Council Directive 76/768/EEC(23);
(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24);
(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
(h) residues and contaminants.

The non-active substances included in Raid® Cockroach Bait are listed Section 3.6.1. All of these substances meet the definition of "food" and, hence, are excluded from evaluation under BPR. Accordingly, it is not necessary to conduct screening for Endocrine Disrupting properties for these substances.

Available toxicological data relating to a mixture
Refer to Section 2.2.6.1 for data on the product.

Other
No data are required for the following endpoints because:

- *Food and feedstuffs*: the biocidal product will not be in contact with food and feedstuffs because the product label states: "Do not apply in places that may come into contact with food and feedstuffs".
- *The effects of Industrial processing or domestic preparation*: Not relevant as the product is 'Ready to Use'.

2.2.6.2 Exposure assessment

Raid® Cockroach Bait is sufficiently similar in composition to Raid PDQ as outlined in Section 2.2.6.1. As these products serve similar functions, potential exposure would be consistent between both. As such, the exposure assessment outlined in the Indoxacarb CAR (Indoxacarb CAR, 2008) is sufficient to determine the exposure to Raid® Cockroach Bait. Calculations were also adjusted to latest guidance considering biological parameters outlined in HEAdHoc Opinion 14 and to represent the level of active in Raid® Cockroach Bait (0.5% w/w Indoxacarb) rather than Raid PDQ (nominal 1% w/w Indoxacarb), where appropriate.

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	Yes*	No
Dermal	No	No	Yes*	No	No	Yes*	No
Oral	No	No	No	No	No	Yes*	No

**Accidental exposure*

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Primary Exposure Application	To apply the product, the non-professional user separates the conjoined bait stations and places the stations. Such interaction with the bait station can result in dermal contact. . .	Non-Professionals
2a.	Secondary t exposure dermal	Following application of the bait station, an infant, child, or adult could potentially come into contact with the bait and is dermally exposed.	General Public

2.b.	Secondary exposure: Oral	Following application of the bait station, an infant may come into contact with the bait and try to ingest its contents.	General Public
2.c.	Secondary exposure: Inhalation	Following application of the bait station, vapours of indoxacarb may volatilise from the bait becoming available for inhalation exposure.	General Public

Industrial exposure

Not applicable, as industrial-scale use of the product is not proposed.

Professional exposure

Not applicable, as this product is intended for non-professional (consumer households) use only.

Non-professional exposure

Scenario 1

Description of Scenario [1] Exposure of non-professional		
During application of Raid® Cockroach Bait, the consumer is directed to separate the conjoined bait stations and place the stations where cockroach activity is most heavy or where cockroaches may be seen congregating. During handling of the bait station, dermal contact may occur.		
	Parameters	Value
Tier 1	NOAEL from the rat acute neurotoxicity study, the basis of the AEL short-term	12.5 mg/kg (Indoxacarb CAR, 2008)
	Raid® Cockroach Bait station bait weight	2.6g
	% Indoxacarb in Bait	0.5%
	Weight of total Indoxacarb in Raid® Cockroach Bait station	13 mg
	Adult body weight	60 kg (HEAdHoc, 2017)
	% dermal absorption	100%

Calculations for Scenario [1]

Reverse reference calculation to achieve NOAEL for Indoxacarb:

As described in the Indoxacarb CAR (Indoxacarb CAR, 2008), the amount of Indoxacarb in Raid PDQ required to contact the skin in order to achieve the hazard threshold was calculated. Given the short-term nature of this potential dermal exposure, the value of 12.5 mg/kg from the rat acute neurotoxicity study, i.e. the basis of the $AEL_{short\text{-}term}$, was

considered for the hazard endpoints with the assessment factor of 100 applied, resulting in an AELshort-term of 0.125 mg/kg bw/day.

Applying an assessment factor of 100, a 60kg adult would need to be in dermal contact with:
(Note: this calculation assumes 100% dermal absorption rather than 0.3% derived from human skin noted in the Indoxacarb CAR (Indoxacarb CAR, 2008))

NOAEL (mg/kg/d) ÷ Assessment factors x adult bodyweight (kg) x dermal absorption (100%)
= 12.5 mg/kg/d ÷ 100 x 60kg x 100% = 7.5mg Indoxacarb/day

Each Raid® Cockroach Bait station contains 2.6g bait, which contains 0.5% (w/w) Indoxacarb. Therefore, one bait station contains 2.6g x 0.5% = 0.013g Indoxacarb= 13.0mg Indoxacarb

If one Raid® Cockroach Bait station contains 13.0mg of Indoxacarb, then to achieve systemic exposure of 7.5 mg Indoxacarb, the adult would need to be dermally exposed to:

(7.5mg/13mg) x 100 = 57.7% of a bait station

Summary table: systemic exposure from non-professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**	**Estimated oral exposure**
Scenario [1] Application, adult	Tier 1 (No PPE)	N/A	Contact with 57.7% of the bait is needed to reach Short-term AEL.	N/A

Combined scenarios

As only one scenario is considered, i.e. applying the product, and dermal exposure is the only relevant exposure pathway, no combination of scenarios is necessary for estimating exposure for non-professional use.

Exposure of the general public

Scenario 2a

Description of Scenario [2a] Post-application dermal exposure of the general public:		
Following application of the bait station, an infant, child, or adult could potentially come into contact with the bait and is dermally exposed. It should be noted that the instructions for use indicate, "Place the bait stations in areas inaccessible to children and pets…". As such, this scenario is considered a potential worst case.		
	Parameters	Value

Tier 1	NOAEL of 2.1 mg/kg from the 90-day dietary rat study, the basis of the AELmedium-term	2.1 mg/kg (Indoxacarb CAR, 2008)
	Raid® Cockroach Bait station bait weight	2.6g
	% Indoxacarb in Bait	0.5%
	Weight of total Indoxacarb in Raid® Cockroach Bait station	13 mg
	Infant body weight	8 kg (HEAdHoc, 2017)
	Child body weight	23.9 kg (HEAdHoc, 2017)
	Adult body weight	60 kg (HEAdHoc, 2017)
	Dermal absorption	100%

Calculations for Scenario 2a- *Post-application dermal exposure*

The amount of Indoxacarb required to be in contact with skin to achieve the NOAEL of 2.1 mg/kg/d (from the 90-day dietary rat study), the basis of the AELmedium-term was calculated. Dermal absorption was conservatively assumed to be 100%. Exposure was determined for an infant, child and adult, and bodyweight data were taken from HEAdHoc Recommendation no. 14.

(i) reverse reference scenario to achieve NOAEL for Indoxacarb :

Infant:

Applying a 100-fold assessment factor, a 8kg infant would need to be in dermal contact with:

NOAEL (mg/kg/d) ÷ assessment factor x infant bodyweight (kg) x dermal absorption = 2.1 mg/kg/d ÷ 100 x 8kg x 100% = 0.168 mg Indoxacarb/infant/d.

Each Raid® Cockroach Bait station contains 2.6g bait, which contains0.5% (w/w) Indoxacarb . Therefore, one bait station contains 2.6g x 0.5% = 0.013 g Indoxacarb= 13.0 mg Indoxacarb

If one Raid® Cockroach Bait station contains13.0 mg of Indoxacarb , then to achieve systemic exposure of 0.168mg Indoxacarb the infant would need to be dermally exposed to:

(0.168mg/13mg) x 100 = 1.3% of a bait station

Child:

Applying a 100-fold assessment factor, a 23.9kg child would need to be in dermal contact with:

NOAEL (mg/kg/d) ÷ assessment factor x child bodyweight (kg) x dermal absorption = 2.1 mg/kg/d ÷ 100 x 23.9kg x 100% = 0.502 mg Indoxacarb/child/d.

Each Raid® Cockroach Bait station contains 2.6g bait, which contains0.5% (w/w) Indoxacarb . Therefore, one bait station contains 2.6g x 0.5% = 0.013 g Indoxacarb= 13.0 mg Indoxacarb

If one Raid® Cockroach Bait station contains 13.0 mg of Indoxacarb , then to achieve systemic exposure of 0.502mg Indoxacarb , the child would need to be dermally exposed to:

(0.502 mg/13 mg) x 100 = 3.9% of a bait station

Adult:
Applying a 100-fold assessment factor, a 60kg adult would need to be in dermal contact with:

NOAEL (mg/kg/d) ÷ assessment factor x adult bodyweight (kg) x dermal absorption = 2.1 mg/kg/d ÷ 100 x 60kg x 100% = 1.26 mg Indoxacarb /d.

Each Raid® Cockroach Bait station contains 2.6g bait, which contains 0.5% (w/w) Indoxacarb . Therefore, one bait station contains 2.6g x 0.5% = 0.013 g Indoxacarb= 13.0 mg Indoxacarb

If one Raid® Cockroach Bait station contains 13.0 mg of Indoxacarb , then to achieve systemic exposure of 1.26mg Indoxacarb, the adult would need to be dermally exposed to:

(1.26 mg/13 mg) x 100 = 9.7% of a bait station

Summary table: Exposure for general public			
Exposure scenario 2a	**Exposure required to achieve $AEL_{medium-term}$**		
	infant	**child**	**adult**
Dermal contact with bait	1.3%of a bait station	3.9% of a bait station	9.7% of a bait station

Description of Scenarios 2b: Post-application oral exposure of the general public:		
Following application of the bait station, an infant may come into contact with the bait and try to ingest its contents. It should be noted that the instructions for use indicate, "Place the bait stations in areas inaccessible to children and pets…". As such, this scenario is considered a potential worst case.		
	Parameters	Value

Tier 1	NOAEL of 2.1 mg/kg from the 90-day dietary rat study, the basis of the AELmedium-term	2.1 mg/kg (Indoxacarb CAR, 2008)
	Raid® Cockroach Bait station bait weight	2.6 g
	% Indoxacarb in Bait	0.5%
	Weight of total Indoxacarb in Raid® Cockroach Bait station	13 mg
	Infant body weight	8 kg (HEAdHoc, 2017)
	Oral absorption	100%

Calculations for Scenario 2b- Post application*S oral exposure*

The amount of Indoxacarb required to be ingested to achieve the NOAEL of 2.1 mg/kg/d (from the 90-day rat study), the basis of the AELmedium-term, was calculated. This was done for infants only as this is considered worst case, and body weight data were taken from HEAdHoc Recommendation no. 14.

(i) reverse reference scenario to achieve NOAEL for Indoxacarb:

Applying a 100-fold assessment factor, a 8kg infant would need to consume:

NOAEL (mg/kg/d) x infant bodyweight (kg) ÷ assessment factor x dermal absorption = 2.1 mg/kg/d x 8kg ÷ 100 x 100% = 0.17 mg Indoxacarb /infant/d.

Each Raid® Cockroach Bait station contains 2.6g bait, which contains 0.5% (w/w) Indoxacarb . Therefore, one bait station contains 2.6g x 0.5% = 0.013 g Indoxacarb= 13.0 mg Indoxacarb

If one Raid® Cockroach Bait station contains 13.0 mg of Indoxacarb, then to ingest 0.17mg Indoxacarb , the infant would need to consume:

(0.17 mg/13 mg) x 100 = 1.3% of a bait station

Summary table: Exposure for general public			
Exposure scenario 2b	**Exposure required to achieve $AEL_{medium-term}$**		
	infant	**child**	**adult**
Oral ingestion of bait	1.3% of a bait station	Not calculated	Not calculated

Description of Scenarios 2c: Post-application inhalation exposure of the general public:

Following application of the bait station, vapours of indoxacarb may volatilise from the bait becoming available for inhalation exposure.		
	Parameters	Value
Tier 1	Indoxacarb vapor pressure (Pa)	2.5 x 10^{-8} Pa (Indoxacarb CAR, 2008)
	Indoxacarb molecular weight	527.84 (Indoxacarb CAR, 2008)
	Exposure time (h)	24 hours (Indoxacarb CAR, 2008)
	Infant body weight	8 kg (HEAdHoc, 2017)
	Infant daily inhalation rate (m^3/d)	5.4 m^3/day (HEAdHoc, 2017)
	Child body weight	23.9 kg (HEAdHoc, 2017)
	Child daily inhalation rate (m^3/d)	12 m^3/day (HEAdHoc, 2017)
	Adult body weight	60 kg (HEAdHoc, 2017)
	Adult daily inhalation rate (m3/d)	16 m^3/day (HEAdHoc, 2017)
	Inhalation absorption	100%

Calculations for Scenario 2c- *Long term inhalation exposure*

The saturated vapour concentration for the active substance was used to determine worst-case consumer exposure via the inhalation route. This was done for infants, children and adults. Please note that Raid® Cockroach Bait contains DPX-MP062 (Indoxacarb) and not DPX-JW062 and therefore the assessment below was based on the former material only.

The DPX-MP062 in Raid PDQ Bait and Raid® Cockroach Bait (Raid JWY 0.5% Indoxacarb) contains 52.7% w/w DPX-KN128 (the insecticidally active S-enantiomer of indoxacarb). DPX-KN128 has a higher vapour pressure as referenced In the Indoxacarb CAR, 2008; DPX-KN128: 2.5 × 10^{-8} Pa at 25 °C as compared to DPX-JW062: 4.0 x 10^{-10} Pa at 25 °C. Therefore, DPX-KN128 will be used for risk assessment purposes.

The vapour pressure of DPX-KN128 is 2.5 x 10^{-8} Pa at 25°C and its molecular weight is 527.84 (Indoxacarb CAR). Therefore, the saturated vapour concentration (SVC) of DPX-KN128 is 532.58 x 10^{-8} mg/m^3 at 25°C (Appendix 1, Indoxacarb CAR, 2008).

Infant, child and adult bodyweights and long-term breathing rates were taken from HEAdHoc Recommendation no. 14. Exposure calculations using HEEG opinion 13, 2011 for this scenario are summarised below:-

Revolatiliazed Inhalation Exposure = SVC X Inhalation Rate X Exposure Period X Inhalation Absorption / Body Weight

Infant:
Considering the saturated vapor concentration and the exposure duration, an 8kg infant would be exposed as calculated:

5.33×10^{-6} mg/m³ at 25°C X 5.4 m³/day X 1-day X 100% / 8 kg = 3.6×10^{-6} mg/kg/d

Child:
Considering the saturated vapor concentration and the exposure duration, a 23.9kg child would be exposed as calculated:
5.33×10^{-6} mg/m³ at 25°C X 12 m³/day X 1-day X 100% / 23.9 kg =2.7×10^{-6} mg/kg/d

Adult:
Considering the saturated vapor concentration and the exposure duration, a 60kg adult would be exposed as calculated:
5.33×10^{-6} mg/m³ at 25°C X 16 m³/day X 1-day X 100% / 60 kg = 1.4×10^{-6} mg/kg/d

Summary table: systemic exposure for general population					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Scenario 2c Post Application, infant	Tier 1 (No PPE)	3.6×10^{-6} mg/kg/d	NA	NA	3.6×10^{-6} mg/kg/d
Scenario 2c Post Application, child	Tier 1 (No PPE)	2.7×10^{-6} mg/kg/d	NA	NA	2.7×10^{-6} mg/kg/d
Scenario 2c Post Application, adult	Tier 1 (No PPE)	1.4×10^{-6} mg/kg/d	NA	NA	1.4×10^{-6} mg/kg/d

Further information and considerations on scenarios
None

Combined scenarios
Not applicable due to nature of calculations, reverse calculations are not appropriate for combined scenarios. Any combined scenario is an acceptable risk due to the extreme worst-case nature of the exposure calculations used in each scenario. The exposure scenarios are highly unlikely to occur, because the formula is contained within the bait station. Product parameters which limit dermal contact are explained with detail in the confidential annex section 3.6.2

Monitoring data
Not applicable

Dietary exposure
No dietary exposure is expected during directed usage of this bait product due to the applied RMM in section 2.1.5.2- "Do not apply bait station on surfaces in places that may come into contact with food & feedstuffs". Worst case scenario of oral ingestion of the bait has been calculated within section 2.6.2 scenario 1. However, the formula is contained within the bait station so dermal contact is highly unlikely, product parameters which limit dermal contact are explained with detail in the confidential annex section 3.6.2

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

In general, the manufacturing of products is subject to EU and national worker protection legislation, such as the EU Chemical Agents Directive, (Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work) and has residual risk controlled through control measures and the use of Personal Protective Equipment (PPE).

During disposal, the bait will either have been consumed therefore not present or remain in the station as per section 2.1.5.4 in an inaccessible state (see confidential annex section 3.6.2). Consequently, consumer contact during disposal is negligible.

2.2.6.3 Risk characterisation for human health

Maximum residue limits or equivalent

Maximum residue limits (MRL) were determined for indoxacarb under Reg. (EU) 2015/845.

MRLs under Reg. (EU) 2015/845

MRLs or other relevant reference values	Reference	Relevant commodities	Value (range)
MRL (permethrin)	Reg. (EC) No 839/2008	all	0.02* to 30 mg/kg

* MRL set at LOQ

Indoxacarb reference values to be used in Risk Characterisation

The following information has been adapted from the summary section for non-professional users of Indoxacarb CAR, 2008 (Pg.49).

$AEL_{short\text{-}term}$: In a rat acute neurotoxicity study, a NOAEL of 12.5mg/kg was found. The pathogenesis of the brain lesions is unknown, however, the study authors suggested that the brain lesion might have occurred secondary to seizures. An overall assessment factor of 100 was proposed resulting in a short term AEL of 0.125 mg/kg.

$AEL_{medium\text{-}term}$: In a 90-day dietary rat study, a NOAEL of 2.13mg/kg/day was found based on haematotoxicity. An overall assessment factor of 100 was proposed resulting in a medium term AEL of 0.21mg/kg/day.

$AEL_{long\text{-}term}$: In a 2-year rat study, a NOAEL of 0.55mg/kg/day was found based on mild haematological effects observed in females at 1.04 mg/kg/d. An overall assessment factor of 100 was proposed resulting in a long term AEL of 0.006mg/kg/day.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption (%)	Value
$AEL_{short\text{-}term}$	rat acute neurotoxicity study	12.5 mg/kg	100	100%	0.125 mg/kg
$AEL_{medium\text{-}term}$	90-day rat study	2.1 mg/kg/day	100	100%	0.021 mg/kg
$AEL_{long\text{-}term}$	2-year rat study	0.55 mg/kg/day	100	100%	0.006 mg/kg/day
ARfD	Rat acute neurotoxicity study	12.5mg/kg bw	100	100%	0.125 mg/kg
ADI					Not relevant

[1] As noted in the Indoxacarb CAR, a safety factor of 100 was applied to account for inter- and intraspecies differences (10 x 10 = 100)

Risk for industrial users

Not applicable, as industrial-scale use of the product is not proposed.

Risk for professional users

Not applicable, as this product is intended for non-professional (consumer households) use only.

Risk for non-professional users

Summary table: exposure from non-professional uses						
Exposure scenario	**Tier/PPE**	**NOAEL**	**AEL (mg/bw/day)**	**Amount of active (Indoxacarb) to reach AEL (mg)**	**% Contact with the bait needed to reach Short-term AEL.**	**Acceptable (yes/no)**
Scenario 1 Application, adult	Tier 1 (No PPE)	12.5 mg/kg	0.125mg/bw/day	7.5mg Indoxacarb	57.7%	yes

Conclusion

The reverse reference calculations above demonstrate that an unrealistic amount of bait (57.7%) would need to be dermally absorbed (assuming 100% dermal absorption). The resulting amounts are considered unrealistic because the product matrix (formula) is contained within a child-resistant bait station (see confidential annex section 3.6.2), which the adult user would likely not attempt to open.

Risk for the general public
Dermal Route

Summary table: exposure from non-professional uses						
Exposure scenario	**Tier/PPE**	**NOAEL**	**AEL (mg/bw/day)**	**Amount of active (Indoxacarb) to reach AEL (mg)**	**% of bait contact needed to reach Short-term AEL.**	**Acceptable (yes/no)**
Scenario 2a Application, Infant	Tier 1 (No PPE)	2.1 mg/kg	0.021mg/bw/day	0.17	1.3	Yes

Scenario 2a Application, Child	Tier 1 (No PPE)	2.1 mg/kg	0.021mg/bw/day	0.5	3.9	Yes
Scenario 2a Application, Adult	Tier 1 (No PPE)	2.1 mg/kg	0.021mg/bw/day	1.26	9.7	Yes

Oral Route

Summary table: exposure from non-professional uses						
Exposure scenario	**Tier/PPE**	**NOAEL**	**AEL (mg/bw/day)**	**Amount of active (Indoxacarb) to reach AEL (mg)**	**% of bait contact needed to reach Short-term AEL.**	**Acceptable (yes/no)**
Scenario 2b Application, Infant	Tier 1 (No PPE)	2.1 mg/kg	0.021	0.17	1.3	Yes

Inhalation route

Summary table: systemic exposure for general population						
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg/day)	**NOAEL** (mg/kg/day)	**AEL** (mg/kg/day)	**Estimated inhalation uptake % of AEL**	**Acceptable (yes/no)**
Scenario 2c Post Application, infant	Tier 1 (No PPE)	3.6×10^{-6} mg/kg/d	0.55 mg/kg/d	0.006 mg/kg/d	<1%	Yes
Scenario 2c Post Application, child	Tier 1 (No PPE)	2.7×10^{-6} mg/kg/d	0.55 mg/kg/d	0.006 mg/kg/d	<1%	Yes
Scenario 2c Post Application, adult	Tier 1 (No PPE)	1.4×10^{-6} mg/kg/d	0.55 mg/kg/d	0.006 mg/kg/d	<1%	Yes

Conclusion

For adults (non-professional user or bystanders) dermal exposure was acceptable as one would be in contact with more than half of the content of the bait station to reach the AEL. An acceptable risk for the inhalation route (infants, and older children & adults) was indicated. The reverse reference scenario for oral and dermal exposure indicated potential risks to infants, older children and companion animals. However, the applicant provided sufficient information on the robustness of the bait station (see confidential annex 3.6.2.). It is designed in such a way that the contents of the station would not be

accessible from the outside, nor can it easily be breached by a small child. Therefore, this risk is considered acceptable. The robustness of the bait station, coupled with the additional labelling ('Keep and place away from children and pets', 'Retain the outer carton for full use and safety instructions') decreases the likelihood of secondary exposure for children/animals mitigating risk of exposure.

Combined scenarios
Not applicable due to the nature of calculations, reverse calculations are not appropriate for combined scenarios as those exposures are meant to achieve the worst-case NOAEL and do not represent typical interaction or exposure to the consumer.

Local effects
The Indoxacarb CAR, 2008 noted the following, with regard to the sensitisation study on Raid PDQ: "A positive skin sensitisation response was observed in guinea pigs exposed to DPX-MP062", meeting the EU criteria for classification. Similarly, Raid PDQ demonstrated skin sensitisation potential in a well-reported guinea pig maximisation test. It is noted that Raid PDQ produced a stronger sensitisation response of animals (i.e. 100%) compared to the results observed in animals challenged with 33.3% DPX-MP062 (approximately 25% DPX-KN128 w/w), therefore it is concluded that the sensitisation reaction observed with Raid PDQ is due in part to the co-formulants.

Dermal sensitisation is a potential local effect from dermal exposure to the formula in Raid® Cockroach Bait. However, dermal exposure is required for sensitisation to occur and the formula is contained within the bait station so dermal contact is anticipated to be low to negligible. Product parameters which limit dermal contact are explained with detail in the confidential annex section 3.6.2.

2.2.7 Risk assessment for animal health

Indoxacarb CAR, 2008 provides two reverse reference calculations for short-term oral exposure of a companion animal (page 20). In this scenario, a kitten or puppy comes into contact with the bait and consumes it. Raid PDQ contains 1.3% Indoxacarb, therefore these calculations will be included as a worst-case representation taken directly from the Indoxacarb CAR, 2008.

For Raid PDQ, as a worst-case, only 0.08 g of bait (equivalent to 3 % of the contents of one bait station) needs to be consumed by a companion animal to achieve a body burden equivalent to the systemic NOAEL for short-term exposure. The worst-case exposure required to achieve the highest dose tested in the acute oral toxicity study for companion animals is 2.5 g of bait (equivalent to 96 % of the contents of one bait station- same amount of amount of bait used in this PAR).

However, the risks to companion animals via the oral route are of acceptable risk. The robustness of the bait station (see confidential annex section 3.6.2), coupled with the additional labelling ('Keep and place away from children and pets', 'Retain the outer

carton for full use and safety instructions') decreases the likelihood of secondary exposure for pets mitigating risk of exposure.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The effects assessment is consistent with UK's Indoxacarb's Competent Assessment Report (CAR) Product-Type 18 dated May, 2008. No new data are available. Accordingly, only the PNEC values taken from the CAR are reproduced in this assessment.
As indicated in the Indoxacarb CAR (2008), test have been performed on DPX-MP062 containing 2 enantiomers; indoxacarb (DPX-KN128) and IN-KN127 in a 75:25 ratio unless otherwise stated. In addition, some ecotoxicity tests have been submitted for 2 of the major metabolites of DPX-MP062; IN-JT333 (N-decarbomethoxylated DPX-KN128) (formed only in soil and sediment) and IN-KT413 (formed in soil, water and sediment). DPX-KN128 is the insecticidally active or S enantiomer. IN-KN127 is the insecticidally inactive or R enantiomer and does not have a common name. IN-KN127 is a constituent of the DPX-MP062 mixture.
In laboratory investigations using both artificial and natural soils, DPX-MP062 was shown to be strongly adsorbed to soils and underwent degradation to form 3 major metabolites; IN- JT333 and IN-KT413 and IN-KG433, with mineralisation over time to CO2. However, a higher tier field study indicated that no major metabolites were formed in the field, with a mean DT50 of 7 d for DPX-MP062, under field conditions. Although metabolites did occur in the field study, these were not considered significant (all < 10 % applied parent), with the data indicating that they have low potential for mobility and were less persistent than the parent compound. The UK CA has concluded that these data sets are consistent with one another and demonstrate that under laboratory conditions the degradation is artificially inhibited.Consequently, the UK CA concluded that the identified metabolites that had been of concern in the laboratory studies, provided no area of concern in soil when DPX-MP062 is used under field conditions. This was also the conclusion of the review under the Plant Protection Products Directive (PPPD, 91/4144-/EC).
Therefore, the UK CA considers that there are no metabolites of concern in soil and no consideration of metabolites has been made in the risk assessment for the soil compartment.

Conclusion used in Risk Assessment – STP Microorganisms	
Value/conclusion	$PNEC_{STP}$ for indoxacarb: 10 mg/L
Justification for the value/ conclusion	Indoxacarb CAR (UK, 2008)

Conclusion used in Risk Assessment – Aquatic Toxicity	
Value/conclusion	$PNEC_{aquatic}$ for indoxacarb: 0.009 mg/L $PNEC_{aquatic}$ for IN-JT333: 0.029 µg/L $PNEC_{aquatic}$ for IN-KT413: 0.039 mg/L
Justification for the value/ conclusion	Indoxacarb CAR (UK, 2008)

Conclusion used in Risk Assessment - Sediment Toxicity	
Value/conclusion	$PNEC_{sediment}$ for indoxacarb: 1.01 mg/kg wwt (4.6 mg/kg dwt) sediment $PNEC_{sediment}$ for IN-JT333: 0.00022 mg/kg wwt (0.001 mg/kg dwt) sediment $PNEC_{sediment}$ for IN-KT413: 0.322 mg/kg wwt (1.48 mg/kg dwt) sediment
Justification for the value/ conclusion	Indoxacarb CAR (UK, 2008)

Conclusion used in Risk Assessment – Terrestrial Toxicity Data	
Value/conclusion	$PNEC_{soil}$ for indoxacarb: 0.0056 mg/kg dw soil
Justification for the value/ conclusion	Indoxacarb CAR (UK, 2008)

Conclusion used in Risk Assessment – Secondary Poisoning *via* the Food Chain	
Value/conclusion	$PNEC_{oral}$ for indoxacarb: 4.8 mg/kg feed
Justification for the value/ conclusion	Indoxacarb CAR (UK, 2008)

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

In accordance with the Guidance on the BPR: Volume IV. Part A Chapter II: - Requirements for Active Substances Version 1.1 November 2014 as there are valid data available on each of the components in the mixture and synergistic effects between the components are not expected, classification of the mixture has been made per the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Details of the product composition are presented in the confidential Annex 3.6. In the case of the active substance Indoxacarb, the lowest acute aquatic toxicity endpoint is an EC_{50} of 0.6 mg/L for the invertebrate *Daphnia*. The lowest chronic aquatic toxicity endpoint is a NOEC of 90 µg/L also reported for the invertebrate *Daphnia*. In accordance with the guidance on application of the CLP criteria, the classification of indoxacarb is therefore Aquatic Acute 1 (M-factor 1) H400, Aquatic Chronic 1 (M-factor 1) H410.

Taking account of the concentration of Indoxacarb in the biocidal product, the minimum environmental classification of the product can be calculated as follows:-

Acute Environmental Classification of Product:

Acute 1: Acute 1 x M ≥25% = Acute 1

(0.5 x 1) = 0.5

Chronic Environmental Classification of Product:

Chronic 1: (Chronic 1 * M) >= 25%

0.5 x 1 = 0.5

Chronic 2: (Chronic 1 * M * 10) + Chronic 2 >= 25%

0.5 x 1 x 10 = 5

Chronic 3: (Chronic 1 * M * 100) + (Chronic 2 * 10) + Chronic 3 >= 25%

0.5 x 1 x 100 = 50

Therefore, the environmental classification per CLP-Regulation (EC) No 1272/2008 is Aquatic Chronic 3 (H412). Co-formulants in the product do not result in classfication of the product for environmental hazards and therefore are not considered SoCs.

As the use of **Indoxacarb** will be indoors only for small scale, localised use as a domestic insecticide (non-professional, ready-to-use household product), no significant direct exposure of outdoor environmental compartments will occur.

It is considered that the ecotoxicological information on the active substance, Indoxacarb (presented in detail in the active substance dossier) and the data provided on the components of the product are sufficient to assess any potential risk to the environment from use of the product. A study using the formulated product is therefore not considered necessary.

Information relating to the environmental fate of the active substance

Information relating to the environmental fate of the active substance was previously reviewed and summarised in the UK Competent Assessment Report (CAR) for Indoxacarb Product-Type 18 dated May, 2008. No new data are available.

Further Ecotoxicological studies

No data are available.

Data waiving	
Information requirement	-
Justification	All information on the ecotoxicology of the product can be extrapolated from the information on the active substance and co-formulants. Ecotoxicity data for the active substance are summarised in the Indoxacarb CAR. No additional testing with the product is therefore considered necessary.

Screening non-active substance(s) for endocrine disrupting potential

Article 2 Point 5 (a) of the BPR notes that the Regulation shall not apply to food or feed used as repellents or attractants. In this case, the definition of "food" is taken from Regulation (EC) No 178/2002 whereby "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

"Food" shall not include:
(a) feed;
(b) live animals unless they are prepared for placing on the market for human consumption;
(c) plants prior to harvesting;
(d) medicinal products within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22);
(e) cosmetics within the meaning of Council Directive 76/768/EEC(23);
(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24);
(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
(h) residues and contaminants.

The non-active substances included in Raid® Cockroach Bait are listed Section 3.6.1. All of these substances meet the definition of "food" and, hence, are excluded from evaluation under BPR. Accordingly, it is not necessary to conduct a screening for Endocrine Disrupting properties for these substances.

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

No data are available.

Data waiving	
Information requirement	-
Justification	This is not a core data requirement. Information concerning the potential for the product to cause adverse effects on non-target organisms can be extrapolated from information on the active substance.

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

No data are available.

Data waiving	
Information requirement	-

Justification	The product is used indoor only in a bait station and therefore this data requirement does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The product is used indoor only in bait stations this data requirement does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The biocidal product is intended to be used indoors and will not, therefore, influence a large proportion of a specific habitat. No further scientific investigation is therefore considered necessary.

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

Please refer to section 2.2.8.2 Environmental Exposure Assessment.

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

Data waiving	
Information requirement	-
Justification	No further studies are considered necessary to assess the fate and behaviour in the environment for the product. The exposure and risk assessment have demonstrated a safe use without further refinements necessary.

Leaching behaviour (ADS)

Data waiving	
Information requirement	-
Justification	A leaching test is not required for this type of product.

Testing for distribution and dissipation in soil (ADS)

No further data are required.

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

No further data are required.

Testing for distribution and dissipation in air (ADS)

No further data are 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)

The biocidal product will not be sprayed. Not relevant.

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)

The biocidal product will not be sprayed. Not relevant.

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

Data waiving	
Information requirement	-
Justification	This is not a core data requirement. Information concerning the potential for the product to cause adverse effects on non-target organisms can be extrapolated from information on the active substance.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Consumer use of insecticide bait product
ESD(s) used	OECD Series on Emission Scenario Documents No. 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users. OECD, Paris. 17th July 2008.
Approach	Quantitative assessment not required, since emission during use and service life of the product is expected to be negligible
Distribution in the environment	Not relevant
Groundwater simulation	Not relevant
Confidential Annexes	YES: In the confidential Annex 3.6 business confidential information concerning composition of the product is included

Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	The product is sold in a ready to use form; therefore, the mixing/loading step identified in the Emission Scenario Document (OECD, 2008) is not relevant for this product. There is no differentiation between use and service life, so separate assessments are not required for these steps.

Emission estimation

Raid® BCockroach Bait is intended for use indoors only, in private houses. The dosage defined on the product label is as follows:

- 1-5 cockroaches observed, use up to 6 bait stations
- 6-25 cockroaches observed, use up to 8 bait stations
- More than 25 cockroaches observed, use up to 12 bait stations

The label also includes the following restrictions:

- Do not use more than 12 bait stations at the same time, bait lasts for up to 3 months

Bait stations should be placed where cockroach activity is most heavy or where cockroaches may be seen congregating. Bait stations should be placed in areas inaccessible to children and pets such as kitchens and/or bathroom cabinets, under sinks, under appliances and behind the toilet. It is recommended for best results to place bait stations horizontally, next to walls or in corners. Bait stations can be placed vertically also, under the rim of the kitchen sink, for example.

In accordance with the ESD (OECD, 2008 page 64) it is assumed that no release will occur during the service life (cleaning) stage for baits deployed in bait stations, and hence, quantitative environmental assessment is not required for this product.

Emission to air

The vapour pressure for the insecticidally active S enantiomer DPX-KN128 is 9.8 x 10-9 Pa at 20°C and the technical material DPX-JW062 is 1.3 x 10-10 Pa @ 20°C which suggests that DPX-MP062 is not volatile. It is therefore expected that exposure to the air compartment will be negligible.

Emission to Floor

According to the ESD (OECD, 2008) it is assumed that no release will occur during the service life stage of a bait station. Therefore, emission to floor can be assumed to be negligible.

Emission to Wastewater

According to the ESD it is assumed that no release will occur during the service life stage of a bait station. Therefore, emission to waste water and subsequent emission to the aquatic and terrestrial compartments can be assumed to be negligible.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Groundwater
No	No	No	No	No	No	No	No

Calculated PEC values

PEC values not calculated since emissions to the environment are no expected for this product type.

Primary and secondary poisoning

Primary poisoning

It is considered that the possibility of primary poisoning of birds and mammals is very unlikely as the bait is placed indoors in inaccessible places. Even if a wild bird or mammal did gain access to the bait the exposure would only be localised and would not result in widespread (population level) exposure.

Secondary poisoning

The physico-chemical properties of the active substance suggest that it may theoretically be subject to bio-accumulative processes. The results of a fish bioaccumulation study [redacted] initially support this conclusion (BCF for whole fish averaged 1053 L/kg and 847 L/kg at Day 21 and Day 28 of the exposure phase, respectively). However, given a depuration rate of 90% after 21 days during the post-exposure phase of this study, coupled with the fact that the pattern of use and design of Raid® Cockroach Bait is such that the potential for secondary poisoning is negligible. When used as instructed on the label, there is essentially no potential for contamination of the aquatic or terrestrial compartment to occur. Even in the rare event that accidental contamination does occur, the infrequent nature of such emissions, will not give rise to a realistic possibility of significant bioconcentration in exposed organisms. Accordingly, it is not necessary to calculate risk characterisation ratios for secondary poisoning.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:

The vapour pressures for the insecticidally active S enantiomer DPX-KN128 and the technical material DPX-JW062 are 9.8 x 10-9 Pa at 20°C and 1.3 x 10-10 Pa at 20°C respectively which suggests that DPX-MP062 (indoxacarb) is not volatile. It is therefore expected that risks to the air compartment will be negligible.

Sewage treatment plant (STP)

No emission to wastewater is foreseen. Therefore, exposure to sewage treatment plant (STP) microorganisms can be assumed to be negligible. Accordingly, it is not necessary to calculate risk characterisation ratios for this compartment.

Conclusion:
No unacceptable risk the aquatic compartment is expected since exposure is not foreseen.

Aquatic compartment

No emission to wastewater is foreseen. Therefore, exposure to aquatic organisms can be assumed to be negligible. Accordingly, it is not necessary to calculate risk characterisation ratios for the surface water and sediment compartments.

Conclusion:
No unacceptable risk the aquatic compartment is expected since exposure is not foreseen.

Terrestrial compartment

No emission to wastewater is foreseen. Therefore, terrestrial exposure *via* spreading of sewage sludge can be assumed to be negligible. Further, no direct emission pathway to soil exists. Accordingly, it is not necessary to calculate risk characterisation ratios for this compartment.

Conclusion:
No unacceptable risk the terrestrial compartment is expected since exposure is not foreseen.

Groundwater

No emission to soil is foreseen. Therefore, potential for exposure to groundwater can be assumed to be negligible. Accordingly, it is not necessary to calculate risk characterisation ratios for this compartment.

Conclusion:

No unacceptable risk the groundwater is expected since exposure to soil is not foreseen.

Primary and secondary poisoning

Primary poisoning
It is considered that the possibility of primary poisoning of birds and mammals is very unlikely as the bait is placed indoors in inaccessible places. Even if a wild bird or mammal did gain access to the bait the exposure would only be localised and would not result in widespread (population level) exposure.

Secondary poisoning
The physico-chemical properties of the active substance suggest that it may theoretically be subject to bio-accumulative processes. The results of a fish bioaccumulation study [redacted] initially support this conclusion (BCF for whole fish averaged 1053 L/kg and 847 L/kg at Day-21 and Day-28 of the exposure phase, respectively). However, given a depuration rate of 90% after 21 days during the post-exposure phase of this study, coupled with the fact that the pattern of use and design of Raid® Cockroach Bait is such that the potential for secondary poisoning is negligible. When used as instructed on the label, there is essentially no potential for contamination of the aquatic or terrestrial compartment to occur. Even in the rare event that accidental contamination does occur, the infrequent nature of such emissions, will not give rise to a realistic possibility of significant bioconcentration in exposed organisms.

Mixture toxicity

Screening Step 1: Identification of the concerned environmental compartments

The formula will not be released directly to the environment.

Screening Step 2: Identification of relevant substances

Other than the active substance, there are no environmentally classified ingredients or substances of concern in the product.

Screening Step 3: Screen on synergistic interactions
Not required as previous steps indicate further mixture toxicity assessment is not neccessary.

Screening step	
	Significant exposure of environmental compartments? (Y/N) No
	Number of relevant substances >1? (Y/N) None
	Indication for synergistic effects for the product or its constituents in the literature? (Y/N) No

Aggregated exposure (combined for relevant emmission sources)

The emission of the active substance to the environment through the service life of this product is considered negligible. Therefore, an aggregated exposure assessment is not required.

Overall conclusion on the risk assessment for the environment of the product
Overall it is considered that there is no significant concern to the environment from use of Raid® Cockroach Bait.

2.2.9 Measures to protect man, animals and the environment

Use only as directed. Do not open bait.
Contains peanuts. May produce an allergic reaction.
Retain the outer carton for full use and safety instructions
Keep and place away from children and pets.
Never let children play with the bait station.
Do not apply in places that may come into contact with food.
After use, dispose of empty bait station to domestic waster (recycling). If bait remains dispose of bait station to household waste recycling centre as hazardous waste. Contact local council for details.

Likely direct or indirect effects:
No adverse effects expected when used as directed.

Description of first aid measures:
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/ attention.
Ingestion: If swallowed, do not induce vomiting, seek medical advice immediately and show the container or label. Rinse mouth with water.

2.2.10 Assessment of a combination of biocidal products

Not relevant.

2.2.11 Comparative assessment

Not relevant as Indoxacarb is not included on the list of substances requiring comparative assessment.

3. Annexes

3.1.1 Annex: List of studies reviewed

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
Phys-chem	Mo3808	[redacted]	2010	[redacted]	S C Johnson & Son, Inc.	X	
Storage Stability	Mo3012	[redacted]	2010	[redacted]	S C Johnson & Son, Inc.	X	
Validation of analytical method for the active substance.	Mo3807	[redacted]	2010	[redacted]	S C Johnson & Son, Inc.	X	
Validation of analytical method for the active substance.	Mo3807	[redacted]	2010	[redacted]	S C Johnson & Son, Inc.	X	
Accelerated storage stability of the active substance.	571A3	[redacted]	2007	[redacted]	S C Johnson & Son, Inc.	X	
Relative Density	20091154.01	[redacted]	2010	[redacted]	S C Johnson & Son, Inc.	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
Summary or physico-chemical properties; • Relative Density • Surface Tension • Flash Point • Flammability • Pyrophoric Properties • Explosive Properties • Oxidizing Properties			2006		S C Johnson & Son, Inc.	X	
Water Solubility and pH			2006		S C Johnson & Son, Inc.	X	
Validation of analytical method for the active substance			2006		S C Johnson & Son, Inc.	X	
B. germanica - Fresh Bait – dying from day 1, after 7 days 98% mortality. B. germanica - Aged Bait - dying from day 1, after 7 days 90%			2007	**Study 1.**	S C Johnson & Son, Inc	X	
mortality. P. americana – Fresh Bait – dying from day 2, after 18 days 92% mortality. P. americana – Aged Bait – dying from day 2, after 18 days 96% mortality. B. orientalis – Fresh Bait – dying from day 2 days, after 14 days 97% mortality. B. orientalis – Aged Bait – dying from day 2, after 14 days 98% mortality.			2007		S C Johnson & Son, Inc	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
Primary kill : Adult Males dying after 4 days, by 5 days 100% mortality. Primary kill : Nymphs dying after 4 days, by 7 days 83% mortality. Secondary Kill : 2-wk old nymphs matched to adult males dying after 2 days and by day 10, 82% mortality (8% mortality at matched controls). Secondary Kill : 2-wk old nymphs matched to 4 week old nymphs dying after 2 days and by day 10, 84% mortality (7% mortality at the matched controls).	[redacted]	[redacted]	2007	**Study 2.** [redacted]	S C Johnson & Son, Inc	X	
Adults were observed to die after 3 days, by 5 days 100% of the cockroaches were dead. Hatch of first egg capsules following test substance application was reduced with 76%. No hatch was observed from the second egg capsule (100% reduction).	[redacted]	[redacted]	2008	**Study 3.** [redacted]	S C Johnson & Son, Inc	X	
Fresh Bait - Cockroaches were dying after 2 days, by 14 days 99% mortality. Aged Bait - Cockroaches dying after 2 days, by 21 days 93.2% mortality.	[redacted]	[redacted]	2008	**Study 4.** [redacted]	S C Johnson & Son, Inc	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
Fresh Bait - Cockroaches dying after 2 days and by 14 days 100% mortality. Aged Bait - Cockroaches were dying after 2 days, by 10 days 100% mortality.			2008	**Study 5.**	S C Johnson & Son, Inc	X	
Primary kill: 4-week old nymphs were dying after 1 day (91.3%). Secondary kill: 2-week old nymphs after 9 days 88.7% mortality			2021	**Study 6.**	S C Johnson & Son, Inc	X	
			2021	**Study 7.**	S C Johnson & Son, Inc	X	
Efficacy after 8 weeks: one apartment 100%, four apartments efficacy 87 – 95%, two apartments 36% and 61%. The latter two apartments were classified beforehand as having a very low level of hygiene.			2011	**Study 8.**	S C Johnson & Son, Inc	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
The treatment resulted in significant efficacy ranging from 93.7 % to 100 % compared with the pretreatment assessment at all test sites.	[redacted]	[redacted]	2012	**Study 9.** [redacted]	S C Johnson & Son, Inc	X	
		[redacted]	2018	**Study 10.** [redacted]	S C Johnson & Son, Inc	X	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
			2018	**Study 11.** [redacted]	S C Johnson & Son, Inc	X	

3.1.2 References

Efficacy:

Study 1 : Conclusion - Guidance on the BPR: Volume II Efficacy, Assessment and Evaluation (Parts B and C) Version 3, April 2018.

2.2.5.6. Resistance

1 [redacted]

2 [redacted]

3 [redacted]

[redacted]

Human Health:

eCA Ctgb's Product Assessment Report (PAR) for Raid Cockroach Bait (0.5% w/w Indoxacarb, Authorisation No: 13674 N, dated 2012).

eCA Ctgb's Product Assessment Report (PAR) for Raid Baits (0.05% w/w Abamectin, Authorisation No: NL-000-9322-0000, dated 2014).

ECHA Technical Notes for Guidance (TNsG) Human exposure 2002 Final, Part 2, Section 6.1 Exposure.

European Food Safety Authority (EFSA) Guidance Document on Dermal Absorption, EFSA Journal 2017;15(6):4873

HEAdHoc. Recommendation no. 14 of the Biocidal Products Committee (BPC) Ad hoc Working Group on Human Exposure. Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017).

HEEG opinion 13. opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance , EUROPEAN COMMISSION, 2011

RMS UK's Competent Authority Report (CAR) for Indoxacarb, Product-type 18 (Insecticides, acaricides and products to control other arthropods), May 2008.

Raid PDQ (1.33% w/w Indoxacarb) Doc II-B. Effects and Exposure Assessment for Biocidal Products. Competent Authority Report: UK. Indoxacarb, 2008.

[redacted]

[redacted]

[redacted]

Environment:

RMS UK's Competent Authority Report (CAR) for Indoxacarb, Product-type 18 (Insecticides, acaricides and products to control other arthropods), May 2008.

[redacted]

3.2 Output tables from exposure assessment tools

Not applicable.

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies

Please refer to IUCLID Section 6.7 and section 2.2.5.5. of the PAR.

3.6 Confidential annex

3.6.1 Confidential Product Composition and formulation

Please refer to the separate document

3.7 Other

Abbreviations

eCA	Evaluating Competant Authority
Raid JWY	S.C.Johnson's Cockroach Bait Station with 0.5% w/w Indoxacarb
Raid PDQ	S.C.Johnson's Cockroach Bait station with 1.33% w/w Indoxacarb
Raid PHL	S.C.Johnson's Ant Bait Station with 0.13% w/w Indoxacarb
RMS UK	Rappateur Member State UK Competent Authority
CAR	Competent Authority Report for an active substance authorised under BPR
SCJ	S.C. Johnson
PAR	Product Assessment Report for a biocidal product
CIPAC Methods	Collaborative International Pesticides Analytical Council Methods
RB	Ready For Use Bait
Regulation (EC) No. 528/2012	The Biocidal Products Regulation (BPR)
Regulation (EC) No. 1272/2008	The Classification, Labelling and Packaging Regulation (CLP)
TMIV17	Technical Meeting (IV), 2017
