Template (v1.1) for

ANALYSIS OF ALTERNATIVES

to biocidal active substances meeting the substitution criteria under the Biocidal Products Regulation

Legal name of submitter:	LKC Chem-Regs Ltd. on behalf of Mitsui Chemicals Crop & Life Solutions, Inc.
Date:	31 October 2023
Substance candidate for substitution:	dinotefuran, EC no.: 605-399-0, CAS no.: 165252-70-0

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LIST OF ABBREVIATIONS

ACE = acetamiprid

AI = artificial intelligence

BGT = a-bungarotoxin

CAGR = compound annual growth rate

CLO = clothianidin

DIN = dinotefuran

EPI = epibatidine

IMI = imidacloprid

IoT = the Internet of things

IRAC = Insect Resistance Action Committee

nAChRs = nicotinic acetylcholine receptor

NIT = nitenpyram

Sustainable Control of Harmful Organisms in the Twenty-First Century = SCOTTY

DECLARATION

The applicant is aware of the fact that evidence might be requested by ECHA or the relevant Member State Competent Authority to support information provided in this document.

Also, we request that the information redacted in the public version of the analysis of alternatives is not disclosed. We hereby declare that, to the best of our knowledge as of today (31 October 2023) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:

Date, Place:

15 November 2023
Tokyo, Japan

1. SUMMARY

This analysis of alternatives for the active substance dinotefuran and authorised dinotefuran-containing biocidal products was carried out in the timeframe of 30 August – 05 September 2023. There are four authorised dinotefuran-related biocidal products, all within product-type 18 (Insecticides, acaricides and products to control other arthropods): Dinotefuran 2% bait (gel-bait against cockroaches), Addict gel cockroach (gel-bait against cockroaches), Addict gel ants (bait station or gel drops application against ants) and SAFWS002 (window sticker against houseflies).

Dinotefuran is a neonicotinoid in the nitroguanidine class. It appears that dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides.

An attempt to identify possible alternatives to dinotefuran and dinotefuran-containing products included a data search using publicly available tools and databases, as outlined in the ECHA's *Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance from January 2023*. The public databases and tools searched were the following: ECHA biocides database, Blue Angel database, PRIO Inventory tool, SUBSPORTplus, ChemSec Marketplace, CORDIS database, SAAToolbox as well as scientific literature (PubMed database) and patent database (Espacenet). Moreover, some providers of potential alternatives that appeared in the search were contacted by the Applicant if not enough information was publicly available on the product alternative.

Firstly, the data search results were carefully reviewed considering the target organisms of the products found in the search and compared to dinotefuran-containing biocidal products: cockroaches, ants and houseflies. Secondly, the products with matching target organisms to dinotefuran-containing products were further reviewed and a conclusion was drawn if the alternative was selected or rejected for further assessment. The alternatives were reviewed regarding the application method and category of users as well as description of use in comparison to dinotefuran-containing products. Only one substance, Indoxacarb (enantiomeric reaction mass *S:R* 75:25) with CAS number: 144171-61-9 was identified as a possible alternative to Dinotefuran 2% bait and Addict gel cockroach biocidal products and the substance in question was reviewed in detail. It was concluded that Indoxacarb (enantiomeric reaction mass *S:R* 75:25) in Advion Cockroach cannot be considered as a suitable alternative to dinotefuran in Dinotefuran 2% bait or Addict gel cockroach due to more hazardous and toxic properties of Indoxacarb specified in the harmonised classification according to CLP. No other alternatives to dinotefuran and dinotefuran-containing products were found during the analysis of alternatives.

2. SCOPE OF THE ASSESSMENT AND OVERVIEW OF THE APPROACH

The scope of the assessment is to identify alternatives to dinotefuran with focus on dinotefuran-containing products: Dinotefuran 2% bait, Addict gel cockroach, Addict gel ants and SAFWS002 (window sticker against houseflies).

3. ANALYSIS OF THE SUBSTANCE FUNCTION(S), TYPES OF USES, TECHNICAL REQUIREMENTS AND MARKETS FOR THE PRODUCTS

3.1. CfS active substance identification and properties

Table 1: Substance Identity

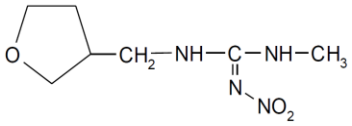
Summary table on substance identity	
ISO name	Dinotefuran
IUPAC or EC name	(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine
EC number	605-399-0
CAS number	165252-70-0
CIPAC number	749
Molecular formula	$C_7H_{14}N_4O_3$
Molecular weight or molecular weight range	202.2 g/mol
Structural formula	

Table 2: Physico-chemical properties

Physical and chemical properties of the active substance	
Physical state (appearance) at 20°C and 101.3 kPA	Solid (crystalline) (99.6%)
Colour at 20°C and 101.3 kPA	White (99.6%)
Odour at 20°C and 101.3 kPA	Odourless (99.6%)
Melting point	107.5°C (99.7%)
Boiling point	Does not boil (99.7%)
Thermal stability / Temperature of decomposition	Thermally stable (99.7%)
Vapour pressure	<1.7 x 10^{-6} Pa at 30 °C (99.7%)
Henry's law constant	Could not be determined at 20 °C. Extrapolation by linear regression was not possible due to the lack of experimentally determined data points at other temperatures.
Water solubility at 20 °C	pH 6.98 = 39.83 g/L (99.7%)
	pH 5 = 52.3 g/L pH 7 = 54.5 g/L pH 9 = 51.2 g/L Purified water: 10°C = 39.0 g/L 20°C = 54.3 g/L 30°C = 89.7 g/L (99.5%)
Partition coefficient (n-octanol/water) and its pH dependency	Log K_{OW} Mean = -0.549 at 25°C (i.e., K_{OW} = 0.283) (99.7%)

Table 3: Hazard properties

Harmonised classification according to CLP	
Classification	
Hazard Class and Category Code(s)	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement Code(s)	H400 H410
Labelling	
Pictogram, Signal Word Code(s)	GHS09, Warning
Hazard statement Code(s)	H400 H410
Specific Conc. Limits, M-factors and ATEs	Acute: M = 10 Chronic: M = 10

Table 4: Exclusion criteria

Conclusion on exclusion criteria	
Conclusion on CMR	Not a CMR
Conclusion on ED assessment	Not an ED
Conclusion on PBT and vP/vB criteria	Not PBT, Not vP/vB
Conclusion on substitution criteria	vP and T Does not contain a significant proportion of non-active isomers.
Conclusion on LRTAP/POP assessment	Not LRTAP/POP

3.2. Description of the function provided by the CfS active substance

The active substance mode of action

Dinotefuran is a neonicotinoid in the nitroguanidine class. It appears that dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides.

Dinotefuran is a nitroguanidine compound included with other insect nicotinic acetylcholine receptor (nAChRs) agonists in the Insect Resistance Action Committee (IRAC) group 4A. Detailed mode of action studies suggest that dinotefuran binds to the acetylcholine receptor site in a mode that differs to the chlorinated neonicotinic molecules included in IRAC group 4A. A summary of key findings from open literature is presented in Table 5. In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted [1].

According to Arthropod Pesticide Resistance Database from Michigan State University [2], there is literature suggesting resistance towards dinotefuran for the following arthropods and locations where resistance was reported: melon and cotton aphid (South Korea, Japan), sweetpotato whitefly (Spain, India, China), bed bug, colorado potato beetle (USA), western flower thrips, green peach aphid, brown planthopper and white-backed planthopper (China). Nevertheless, the recommended uses of dinotefuran follow IRAC practices to avoid resistance development which are fully supported by the manufacturer Mitsui Chemicals Crop & Life Solutions, Inc.

Strategies to reduce the risk of resistance developing, such as recommendations to treat to levels that ensure complete kill of target pest infestations and to use dinotefuran alternately with substances with a different mode of action, can be implemented at end-use product approval. Similarly, monitoring programs to confirm that target pests remain susceptible to dinotefuran will need to be implemented in relation to product approvals as target pests will vary with product and geography.

The IRAC poster concerning resistance and management of resistance in cockroaches [3] informs that using different modes of action classes rather than insecticides from the same IRAC mode of action group should be used in a rotational

strategy. This provides more control in resistance management and can delay the development in resistance in all cockroach species.

In conclusion, resistance development against dinotefuran is possible, however, the mechanisms involved are not known. The known mechanisms for development of resistance against other neonicotinoid active substances do not seem to affect dinotefuran insecticidal activity [1].

Table 5: Summary of key findings concerning resistance from open literature

#	Methods	Materials to supply nAChRs	Findings	Main Laboratory	References
1	binding assay （[^{3}H]EPI [^{3}H]BGT）	American cockroach (nerve code)	•affinity for [^{3}H]EPI, [^{3}H]BGT binding site IMI> DIN	Shimane Univ. (Ozoe)	Pest Manag. Sci. 58:190-196 (2002)
2	electrophysio-logical method	American cockroach (nerve code)	• nerve-excitatory activity: IMI>DIN • nerve-blocking activity: IMI similar level to DIN	Osaka Pref. Univ. (Nishimura)	Pest Manag. Sci. 58:669-676 (2002)
3	electrophysio-logical method	hybrid receptor comprised of fruit fly (α)+chick (ß)	• dose-response: IMI>DIN • maximum response: DIN>IMI （DIN: full agonist, IMI: partial agonist）	Gifu Univ. (Kagabu), Kinki Univ. (Matsuda)	J. Pesticide Sci. 27:374-377 (2002)
4	binding assay （[^{3}H]IM, [^{3}H]BGT)	housefly	• affinity for [^{3}H]IMI, [^{3}H]BGT binding sites: IMI>DIN • DIN competitively inhibits [^{3}H]IMI binding	Osaka Pref. Univ. (Nishimura)	Pest Manag. Sci. 59:1093-1100 (2003)
5	binding assay ([^{3}H]DIN)	American cockroach (nerve code)	• affinity for [^{3}H]DIN binding site: DIN>IMI	Shimane Univ. (Ozoe)	Pest Manag. Sci.65:293-298 (2006)
6	electrophysio-logical method	hybrid receptor comprised of brown rice planthopper (α) +rat (ß)	• influence of the Y151S mutation in the planthopper nAChRs on agonist potency: IMI and other neonicotinoids>DIN (DIN retains potency against the mutated nAChRs)	University College London, (Millar)	J. Neurochem. 99:1273-1281 (2006)
7	binding assay ([^{3}H]IMI, [^{3}H]ACE, [^{3}H]DIN)	fruit fly & glassy-winged sharpshooter (*Homalodisca coagulata*)	• IMI and ACE interact with an identical site in the same way in both insect species. • pharmacological profile in Homalodisca: {[^{3}H]IMI ＝[^{3}H]ACE ） }≠[^{3}H] DIN	UC Berkeley, (Casida)	J. Agric. Food Chem.54:3365-3371 (2006)
8	electrophysio-logical method	American cockroach (thoracic ganglia)	• agonist efficacy (maximum inward currents): (DIN, ACE, NIT, CLO)> (IMI, nicotine, THI) (acyclic; full agonist) (cyclic; partial agonist)	Michigan State Univ. (Hollingworth)	NeuroToxicology (2007)

nAChR, nicotinic acetylcholine receptor; DIN, dinotefuran; IMI, imidacloprid; ACE, acetamiprid; EPI, epibatidine; BGT, a-bungarotoxin, NIT, nitenpyram; CLO, clothianidin

Summary of active substance efficacy towards the target organism(s)

Dinotefuran is an active substance proposed for use as an insecticide in Product Type 18 of the Biocidal Products Regulation. Insecticidal products containing dinotefuran are for use in the control of cockroaches, ants and houseflies. The biocidal formulation, Dinotefuran 2 % bait, is for professional use only and is supplied ready-to-use in a syringe style applicator tube. It is intended for indoor use only as a spot treatment to control cockroaches. It is not intended for outdoor use or for use where there is a risk of contamination of food or feedstuffs.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious [1].

3.3. Intended uses and products

Dinotefuran has been evaluated for its intended use as an insecticide (PT 18). As of 31 August 2023, there are four dinotefuran-containing biocidal products with market areas, target organisms and application method outlined in Table 6.

Table 6: Authorised trade names and market areas of all dinotefuran-containing biocidal products as of 31 August 2023

Trade name	Member States in which product is authorised	Target organisms	Application method
Dinotefuran 2% bait	CY, FR, GR, IT, PL, PT, ES	German cockroach and Oriental cockroach (adults and nymphs)	Ready-to-use gel bait
Addict gel cockroach	AT, BE, HR, CZ, FI, DE, HU, IT, LT, LU, NL, PL, SI, CH	German cockroach and Oriental cockroach (adults and nymphs)	Ready-to-use gel bait
Addict gel ants	HR, FR, DE, IT, SI, SE	Black garden ant, Pharaoh ant and Argentine ant (all developmental stages)	Bait station or gel drops
SAFWS002	BE, FR, DE, GR, ES	Houseflies (adults)	Window sticker

Table 7: Overview of the intended uses of Dinotefuran 2% bait

1	Product Type	PT-18 (insecticides, acaricides and products to control other arthropods
2	Product name	**Dinotefuran 2% bait**
3	Target organisms (including development stage)	Adult and nymph cockroaches (i.e., *B. germanica* and *B. orientalis*).
4	Description of use(s)	Gel-bait product for indoor use only as a spot or crevice and crack treatment at / near locations where target pests gather
5	Application rate(s)	Apply in 0.1 g spots (with each spot containing 0.002 g of dinotefuran) - Apply 0.2 g of product per m² for small cockroach species - Apply 0.4 – 0.6 g of product per m² for large cockroach species - Apply a maximum of 0.8 g per m² of product per m² for heavy infestations
6	Frequency of application	Minimum of one application. Every 7 days in the event of heavy infestation
7	Field of use (indoors/outdoors)	Indoor use only To be used in/at: • Industrial/commercial premises • Households/private areas. • Public area (e.g., Hospitals, Nursing Homes)
8	Category(ies) of user(s)	Professionals
9	Instruction for use	Applied as a spot treatment via syringe (ready-to-use). To apply the gel, remove the cap from the nozzle, touch the tip of the nozzle to the surface to be treated and depress plunger slightly. Re-apply

		according to remaining level of infestation and when bait is no longer visibly present. Replace cap for storage of the product. Use only as a spot treatment in areas that will not be accessible, will not be submerged in water and where bait would not be removed by routine cleaning. To maintain product palatability, apply away from sources of heat. Spot treatment method of application: Remove cap from tip of applicator tube. Place tip at spot where gel is to be applied. Depress plunger until appropriate amount is dispensed. Replace cap when finished dispensing gel. Cracks and crevices method of application: Gel bait should be applied directly into cracks and crevices where insects hide. Place the applicator tip directly into cracks and crevices and deposit gel. Bait should be in the void area and not on open or exposed surfaces.

Table 8: Overview of the intended uses of Addict gel cockroach

1	Product Type	PT-18 (insecticides, acaricides and products to control other arthropods
2	Product name	**Addict gel cockroach**
3	Target organisms (including development stage)	Adult and nymph cockroaches (i.e., *B. germanica* and *B. orientalis*)
4	Description of use(s)	Gel-bait product for indoor use only as a spot or crevice and crack treatment at / near locations where target pests gather
5	Application rate(s)	Applied dose: 2-4 drops of gel placed on the surface of 1 m^2 (0.2 - 0.4 g/m^2), • 4-8 drops of gel placed on the surface of 1 m^2 (0.4 - 0.8 g/m^2). Dilution (%): 0 When fighting the German cockroach: • 2-4 drops of gel placed on the surface of 1 m^2 (0.2 - 0.4 g/m^2). With heavy insect infestation, very dirty conditions or cockroach dominance, a higher number of gel drops/m^2 is recommended: In the case of eastern cockroach control: • 4-8 drops of gel placed on the surface of 1 m^2 (0.4 - 0.8 g/m^2). Apply a maximum (one time) of 0.8 g/m^2 in case of heavy infestation: • up to 16 drops when used in a residential home; • up to 72 drops when used in a public building.
6	Frequency of application	A single application of the product to cracks and crevices allows for the destruction of the whole population. If necessary, the treatment can be repeated after 7 days.
7	Field of use (indoors/outdoors)	Indoors
8	Category(ies) of user(s)	Professionals
9	Instruction for use	To apply the gel, remove the cap from the nozzle, cover the area to be treated with the tip of the nozzle touch and gently press the plunger. Reapply if infestation persists or if the bait is no longer available or visible. Replace the cap to store the product. Spot treatment is allowed only in areas that are inaccessible, not flooded by water and where the bait will not be removed by routine cleaning. To maintain product compatibility, do not use near heat sources.

Table 9: Overview of the intended uses of Addict gel ants

1	Product Type	PT-18 (insecticides, acaricides and products to control other arthropods
2	Product name	**Addict gel ants**
3	Target organisms (including development stage)	Black garden ant, Pharaoh ant and Argentine ant (all developmental stages)
4	Description of use(s)	Bait station or gel drops application for indoor and outdoor uses
5	Application rate(s)	Application Rate: 0.2 g/m² Dilution (%): 0
6	Frequency of application	-
7	Field of use (indoors/outdoors)	Indoor: industrial, commercial or public premises and private area Outdoor: around houses, buildings and on terraces
8	Category(ies) of user(s)	Trained professionals, professionals and general public (non-professionals)
9	Instruction for use	Treatment with the syringe or bottle: Apply gel drops as spot or directly in cracks and crevices where insects hide, on the ants trail or near to the nest. Apply 2 drops of 0.1 g (0.5 cm diameter) per square or linear meter. Treatment with the pre-baited station: Apply the pre-baited station adapted to the area of treatment respecting the dose of 0.2 g/m². For example, one pre-baited station of 2 g to treat 10 m² or one pre-baited station of 5 g to treat 25 m². Place the bait station along the ant trail or close to the nest if possible.

Table 10: Overview of the intended uses of SAFWS002

1	Product Type	PT-18 (insecticides, acaricides and products to control other arthropods
2	Product name	**SAFWS002**
3	Target organisms (including development stage)	Houseflies (adults)
4	Description of use(s)	Window sticker
5	Application rate(s)	Place sticker on window on the inside of the windowpane. Use one sticker per room of 30 m³; for larger room use one sticker per 30m³ without exceeding 8 stickers per house. Application once or twice per year, with efficacy lasting for 6 months.
6	Frequency of application	Use one sticker per 30 m³ room
7	Field of use (indoors/outdoors)	Indoors
8	Category(ies) of user(s)	General public (non-professionals)
9	Instruction for use	Open the outer packaging and take a paper card out of the folding cardboard. Remove white silicon paper cover. Peel off the sticker from the backing layer. Place sticker on window on the inside of the windowpane out of the reach of children and pets. Protect remaining stickers again with the white silicon paper cover and return to folding cardboard. Replace/remove stickers after 6 months.

Market and supply chains

There has been a trend in consumers shifting towards hiring professional pest control services rather than treatments available for non-professionals for home use, especially in urban areas. The general public, as pest control product users, begin to shift their perception that professional pest control services offer more effective and long-term solutions [5].

Moreover, artificial intelligence (AI) and the Internet of Things (IoT) technologies are being rapidly adopted in the pest control industry resulting in advanced monitoring technologies, apps for tracking infestations or digital platforms for

service providers to interact with customers [6]. The development of pest control technology aims to enhance product's efficiency and effectiveness.

Global market trends

Business Research Insights [6] suggest that the global cockroach killer market size was USD 537.8 million in 2021 and is projected to increase to USD 749.6 million by 2028. The predicted compound annual growth rate (CAGR) amounts to 4.8 % during the forecast period. The authors of the report claim that due to the global COVID-19 pandemic, the cockroach killer substances experienced a higher than anticipated demand across all regions when compared with the pre-pandemic levels. The list of global largest manufacturers of cockroach control services according to the report lists the following companies: Bayer, Syngenta, Henkel, PF Harris, S.C. Johnson & Son, Rockwell Labs, BASF, Sumitomo Chemical and others.

Fortune Business Insights [7] expects considerable growth in global ant control market, especially spray and bait formulations in their forecast for 2023-2030. The prominent companies operating in the global ant control market are Syngenta, BASF, Sumitomo Chemical, Bayer CropScience, Ensystex, United Phosphorous Limited, FMC Corporation and more, based on the Fortune Business Insights report.

A report on houseflies by Fortune Business Insights [8] assesses that housefly control is expected to hold a significant share in the global market in years 2023-2030. The high availability and rapid action of such products is expected to positively impact the growth of product demand. Nevertheless, there is an increase in consumer awareness regarding the adverse health effects of synthetic products as well as increasing houseflies' resistance to many synthetic products. Thus, there is an expectation that the demand for natural housefly control products will be increased in forthcoming years. The report identifies the largest global manufacturers in housefly control market as: SC Johnson & Son, Inc., FMC Global Specialty Solutions, Relaxo Domeswear LLP, Jyothy Laboratories Ltd., and more.

3.4. Description of the technical requirements that must be achieved by the product(s)

The active substance dinotefuran does not meet any criteria for physical or chemical hazard.

Both dinotefuran-containing biocidal formulations against cockroaches, Dinotefuran 2% bait and Addict gel cockroach, are ready for use gel-bait. Both products are for professional use only and are supplied ready-to-use in a syringe style applicator tube. They are intended for indoor use only as a spot treatment to cracks and crevices to control cockroaches. They are not intended for outdoor use or for use where there is a risk of contamination of food or feed stuffs.

The dinotefuran-containing biocidal formulation against ants, Addict gel ants, is a bait station or gel drops application formulation. The product is for trained professionals and general public (non-professional) use indoors and outdoors around houses, buildings and on terraces. The product should not be applied to vegetable gardens.

The dinotefuran-containing biocidal formulation against houseflies, SAFWS002, is a ready-to-use window sticker against houseflies for indoor use by non-professionals. Window stickers act as carriers for insecticidal paste. The stickers should not be applied on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious [1].

4. ANNUAL TONNAGE

Dinotefuran 2% bait: 1-10 tonnes per year

5. IDENTIFICATION OF POTENTIAL ALTERNATIVES

5.1. Description of efforts made to identify possible alternatives

5.1.1. Stakeholders' involvement

Manufacturers *APC AG* and *IHD Schädlingsbekämpfung und Taubenabwehr* appeared in the Blue Angel products and services database as potential alternatives to chemical pest control (for details of the search refer to Section "Data searches"). The manufacturers offer thermal pest control, however based on their website, cockroaches and flies are not the target organisms of the offered pest control products. Nevertheless, the manufacturers were contacted by the Applicant by email to inquire if their product portfolios cover efficacy against cockroaches or flies.

Based on the manufacturer website, *IHD Schädlingsbekämpfung und Taubenabwehr* offer solutions for ant infestations but only after detailed discussion of the extent of infestation will they disclose the means and measures used to eliminate and relocate the ants. The Applicant contacted the manufacturer by email to inquire about more details of treatments involved in ant control.

The Applicant did not receive a response from any of the manufacturers (true as of 03 November 2023).

The email addresses used to contact the manufacturers are outlined below.

APC AG: apc@apc-ag.de
IHD Schädlingsbekämpfung und Taubenabwehr: info@ihd-deutschland.de

Additionally, other stakeholders within the supply chain involved in manufacturing and distribution of dinotefuran-containing products were contacted by the Applicant. Two stakeholders shared their input with the Applicant.

Information shared by Stakeholder 1 was in accordance with the Applicant's findings from public database searches covered in this report, hence no new information emerged from the dialogue with Stakeholder 1.

Stakeholder 2 informed the Applicant that they are not aware of any chemical alternatives to dinotefuran, but that non-chemical alternatives are common among their customers. Input from Stakeholder 2 initiated detailed review of non-chemical alternatives of fly, ant, and cockroach control products for non-professional use available for purchase online by general public (for details of the search refer to Section "Data searches").

5.1.2. Research and development

The Applicant is not aware of any past or planned research and development activities to develop an alternative to dinotefuran.

5.1.3. Data searches

ECHA biocides database

ECHA biocides database was searched on 30 August 2023; considering approved active substances that are not candidates for substitution and fall under category of product type 18. The active substances and authorised biocidal products were reviewed in terms of biocidal efficacy against target organisms to identify biocidal products efficacious against cockroaches, ants and houseflies that could be a potential alternative to dinotefuran-containing products. The outcomes of the ECHA biocides database search are summarised in Table 11.

Table 11: Approved active substances that are not CfS with PT 18 uses from ECHA biocides database

Active substance (a.s.)	Number of related authorised PT 18 biocidal products	Biocidal efficacy against target organisms	A.s. selected for further assessment in Section 5.2 due to matching target organisms
Bacillus sphaericus 2362, strain ABTS-1743	1	Mosquitoes	No
Bacillus thuringiensis subsp. israelensis, strain SA3A	0	Mosquitoes and black fly larvae	No
Bacillus thuringiensis subsp. kurstaki, strain ABTS-351	1	Moths and caterpillars	No
Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	11	Mosquitoes	No
N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine)	0	Fly larvae	No
(*RS*)-α-cyano-3phenoxybenzyl-(1*RS*)-*cis, trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	55	Cockroaches and ants	Yes
epsilon-Momfluorothrin	0	Cockroaches, ants, flies or mosquitoes	Yes
[2,4-Dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1*R*)-*cis*-chrysanthemate; [2,4- Dioxo-(2-propyn-1-yl)imidazolidin-3-yl] methyl(1*R*)-*trans*-chrysanthemate (Imiprothrin)	1	Flying and crawling insects (adults)	Yes
Transfluthrin	76	Mosquitoes, flies, beetles, cockroaches, ants and moths	Yes
deltamethrin	98	Cockroaches, ants, bedbugs, fleas, beetles, flies and mosquitoes	Yes
Silicium dioxide (Silicium dioxide/Kieselguhr)	44	Cockroaches, fleas, ants, silverfishes and mites	Yes
Magnesium phosphide releasing phosphine	4	Moths and beetles	No
Aluminium phosphide releasing phosphine	3	Moths and beetles	No
2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)	21	Mosquitoes and houseflies	No
α-cyano-4-fluoro-3-phenoxybenzyl3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cyfluthrin)	17	Flies, beetles, fleas, mites, ants and cockroaches	Yes
Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	1	Mites	No
sulfuryl fluoride	2	Moths and beetles	No
Indoxacarb (enantiomeric reaction mass *S:R* 75:25) or	4	Cockroaches, ants and houseflies	Yes

Active substance (a.s.)	Number of related authorised PT 18 biocidal products	Biocidal efficacy against target organisms	A.s. selected for further assessment in Section 5.2 due to matching target organisms
Indoxacarb			
[1.alpha.(*S**),3.alpha.]-(.alpha.)-cyano-(3-phenoxyphenyl)methyl3-(2,2-dichlor-oethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate (alpha-Cypermethrin); [1α(*S**),3α]-(α)-cyano-(3-phenoxyphenyl)methyl3-(2,2-dichlor-oethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate αCypermethrin)	15	Cockroaches and fleas	Yes

Blue Angel products and services database

German Blue Angel products and services database, a database for environmentally friendly products and services, has been searched on 30 August 2023. In the search, "services/municipality" as category and "pest control (thermal, indoor) (DE-UZ 57b)" as subcategory were selected. Three manufacturers appeared in the search: *APC AG, IHD Schädlingsbekämpfung und Taubenabwehr and THERMOkill GmbH*.

Manufacturer *APC AG* did not provide detailed product information and only limited information was available regarding their thermal pest control products. From the manufacturer's website, the target organisms for available thermal pest control products do not include cockroaches, ants or flies (Figure 1), thus the products of manufacturer *APC AG* have been rejected for further assessment as an alternative to dinotefuran. Nevertheless, the manufacturer was contacted by email by the Applicant in order to confirm that none of the manufacturer's products can be an alternative to dinotefuran (details in Section Stakeholders' involvement).

Manufacturer *IHD Schädlingsbekämpfung und Taubenabwehr* provided details on thermal product for indoor pest control. The product is a double-wall fan heater with high-performance fan for high temperatures up to 60 °C, for use in rooms with high ambient temperatures. However, based on the information on the Blue Angel and manufacturer's websites, neither cockroaches nor flies are the target organism for the manufacturer's products. However, the manufacturer offers solutions for ant control but the process on how the ant control is carried out is described only in a general way. The manufacturer was contacted by email by the Applicant in order to inquire what solutions the manufacturer offers for ant control (details in Section Stakeholders' involvement).

Manufacturer *THERMOkill GmbH* did not provide detailed product information and only limited information was available regarding their thermal pest control products. According to the manufacturer's website, the target organisms for available thermal pest control products include bed bugs only, thus the products of manufacturer *THERMOkill GmbH* have been rejected for further assessment as an alternative to dinotefuran.

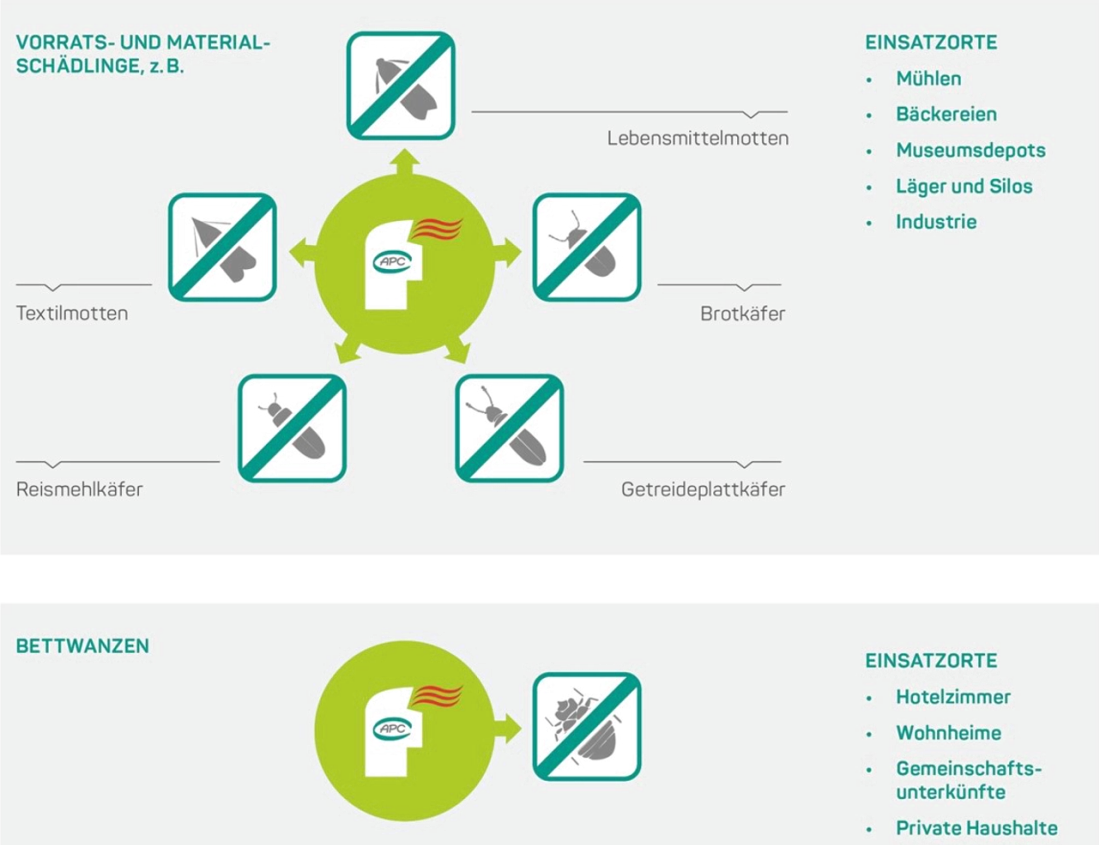


Figure 1: Target organisms for thermal pest control products from manufacturer APC AG [9]

Online retailer

A popular online retailer was searched for non-chemical alternatives to dinotefuran-containing products. Searches using the terms fly, ant, and cockroach control were carried out and the most popular search results are listed below.

Fly control: fly trap sticker for potted plants, fly catcher adhesive or ribbon, bag fly trap, door/window net, ultrasonic repellent or UV insect killer lamp.

Ant control: insect strip, sticky band for trees.

Cockroach control: low temperature (-45°C) insect killer spray.

The presented alternatives did not undergo peer-reviewed scientific studies to demonstrate their effectiveness against the target organisms, thus in the absence of reliable evidence, the non-chemical alternatives cannot be directly compared to dinotefuran or dinotefuran-containing products. Nevertheless, the non-chemical alternatives do provide an alternative to insecticide-containing products for non-professional users.

Adhesive tapes for catching insects are a simple and cheap solution with limited efficacy against insects. Some users find that the appearance of such adhesive tapes in a household setting is unsightly. The odour, appearance, or tendency of the product to stick to hands and other surfaces might discouraging for its repeated use. Such a product is not long-lasting and therefore needs to be replaced regularly.

UV or ultrasonic lamps or repellents might have similar disadvantages as insect adhesive tapes regarding limited efficacy and unappealing appearance for domestic use due to the design of the product as well as visibility of the dead insects.

Low temperature insect killer spray provides a potential alternative but requires a lot of effort from the user to efficiently deal with the infestation by spraying the insects one-by-one, thus providing limited efficacy.

In conclusion, the Applicant does not believe that the non-chemical alternatives can be reasonably compared to biocidal products with proven efficacy and thus does not consider them for further assessment.

PRIO Inventory tool

PRIO Inventory tool is a web-based tool for substitution of chemicals. The search was carried out on 30 August 2023 with search terms "dinotefuran", CAS number "165252-70-0" and EC number "605-399-0". The search showed 0 results for all search terms.

SUBSPORTplus

SUBSPORTplus is a substitution portal with lists of assessed alternatives, tools and guidance for substance evaluation and substitution management.

The search was carried out on 30 August 2023 with search terms "dinotefuran", CAS number "165252-70-0" and EC number "605-399-0". The search yielded two lists of substances: *Bluesign System Substances List* and *OEKO-TEX Standard 100*. The categories available in both lists did not cover insecticides, thus none of the lists were considered for further assessment as an alternative to dinotefuran.

ChemSec Marketplace

ChemSec Marketplace is an online platform with alternatives to substances of concern, enabling buyers and sellers of alternatives to hazardous chemicals to interact. The platform was searched on 30 August 2023 with search terms "dinotefuran", CAS number "165252-70-0" and EC number "605-399-0" with applied filter to look for evaluated alternatives and alternatives only (requests box was unticked). "Dinotefuran" term resulted in 0 search results, whereas searching by CAS and EC numbers yielded 21 and 53 results, respectively. None of the obtained hits were insecticide products, thus no alternatives to dinotefuran were found.

CORDIS database

CORDIS database is a database of projects under the EU Research and Innovation funding programs: information on all EU-supported R&D activities, projects, results, and publications. The database was searched on 30 August 2023 with the search term "dinotefuran", but no results were found. When CAS number was used, an unmanageable amount of 77 724 results were obtained that were not connected to dinotefuran (conclusion drawn based on the first page of the search results).

OECD Substitution and Alternatives Toolbox (SAAToolbox)

SAAToolbox compiles resources relevant to chemical substitution, selection and alternatives assessment. The platform has been searched on 30 August 2023 with search terms "dinotefuran", CAS number "165252-70-0" and EC number "605-399-0" in both sections: "Tools, Guides, Frameworks and more" and "Case Studies". No search results were found.

PubMed

PubMed comprises more than 36 million citations for biomedical literature from MEDLINE, life science journals, and online books. The platform was searched on 30 August 2023 with search terms "dinotefuran" AND "alternative" with no restriction on the publication year. The search resulted in 9 hits that are listed in Table 12. No relevant results were found for dinotefuran use against cockroaches, ants or flies after review of the publication abstracts.

Table 12: PubMed search results

Authors	Publication year	Publication title	Publication relevance based on the abstract
Zhu, G., Ding, W., Zhao, Y., Xue, M., Zhao, H., Liu, S.	2023	Biological and physiological responses of two Bradysia pests, *Bradysia odoriphaga* and *Bradysia difformis*, to Dinotefuran and Lufenuron	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Zhang, Q., Fu, L., Cang, T., Tang, T., Guo, M., Zhou, B., Zhu, G., Zhao, M.	2022	Toxicological Effect and Molecular Mechanism of the Chiral Neonicotinoid Dinotefuran in Honeybees	Not relevant to dinotefuran biocidal use against

Authors	Publication year	Publication title	Publication relevance based on the abstract
			cockroaches, ants or houseflies
Xiao, Z., Yang, Y., Li, Y., Fan, X., Ding, S.	2013	Determination of neonicotinoid insecticides residues in eels using subcritical water extraction and ultra-performance liquid chromatography-tandem mass spectrometry	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Snyder, D., Cernicchiaro, N., Allan, S. A., Cohnstaedt, L. W.	2016	Insecticidal sugar baits for adult biting midges	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Peck, D.C., Olmstead, D., Morales, A.	2008	Application timing and efficacy of alternatives for the insecticidal control of *Tipula paludosa Meigen (Diptera: Tipulidae*), a new invasive pest of turf in the northeastern United States	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Mace, K., Rudder, J., Goodhue, R., Tolhurst, T., Tregeagle, D., Wei, H., Grafton-Cardwell, B., Grettenberger, I., Wilson, H., Van Steenwyk, R., Zalom, F., Steggall, J.	2022	Balancing Bees and Pest Management: Projected Costs of Proposed Bee-Protective Neonicotinoid Regulation in California	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Kanne, D. B., Dick, R. A., Tomizawa, M., Casida, J. E.	2005	Neonicotinoid nitroguanidine insecticide metabolites: synthesis and nicotinic receptor potency of guanidines, aminoguanidines, and their derivatives	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Corbel, V., Duchon, S., Zaim, M., Hougard, J. M.	2004	Dinotefuran: a potential neonicotinoid insecticide against resistant mosquitoes	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies
Barbee, G. C., Stout, M. J.	2009	Comparative acute toxicity of neonicotinoid and pyrethroid insecticides to non-target crayfish (*Procambarus clarkii*) associated with rice-crayfish crop rotations	Not relevant to dinotefuran biocidal use against cockroaches, ants or houseflies

Espacenet patent search by European Patent Office

Espacenet is a platform with free access to over 140 million patent documents. The platform was searched on 31 August 2023 with advanced search containing search terms “dinotefuran” AND “alternative”. The search resulted in 5 hits that are listed in Table 13. The relevance of the search results was evaluated based on the abstracts. None of the patents were found relevant to dinotefuran use against cockroaches, ants or flies.

Table 13: Espacenet search results

Applicants	Publication year	Title	Patent relevance based on the abstract
BAYER CROPSCIENCE AG	2009	Safeguarding seed safety of treated seeds	Not relevant to dinotefuran biocidal uses
E. I. DU PONT DE NEMOURS AND COMPANY	2018	Bicyclic pyrazole pesticide	Not relevant to dinotefuran biocidal uses
SYNGENTA LTD *et al.*	2007	Pesticidal mixtures	Not relevant to dinotefuran biocidal uses
PFIZER	2013	Isoxazoline derivatives as antiparasitic agents	Not relevant to dinotefuran biocidal uses
NIPPON KAYAKU KK	2018	Pyrazine compound	Dinotefuran is mentioned only as a partner of the “Pyrazine compound” insecticide

5.2. Identification of alternatives

5.2.1. Screened alternatives and selection for further assessment

Table 14: Initial list of chemical and non-chemical alternatives and outcome of the selection for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment
PT 18	1	(*RS*)-α-cyano-3phenoxybenzyl-(1*RS*)-*cis, trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	CAS number: 52315-07-8 EC number: 257-842-9	The authorised product is for indoor use by professionals and trained professionals with spraying as the application method against cockroaches and ants.	The alternative is **rejected** due to differing application method: the alternative is applied by spraying and dinotefuran-containing products are baits.
PT 18	2	epsilon-Momfluorothrin	CAS number: 1065124-65-3	No authorised products available.	The alternative is **rejected** due to no authorised products available.
PT 18	3	[2,4-Dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1*R*)-cis-chrysanthemate; [2,4- Dioxo-(2-propyn-1-yl)imidazolidin-3-yl] methyl(1*R*)-*trans*-chrysanthemate (Imiprothrin)	CAS number: 72963-72-5 EC number: 428-790-6	The authorised product is a pre-pressurised handheld aerosol spray for indoor use only by non-professionals against cockroaches, flies, ants and other target species.	The alternative is **rejected** due to differing application method and category of users: the alternative is applied by spraying by non-professionals and dinotefuran-containing products are baits and window stickers for professional and non-professional use.

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment
PT 18	4	Transfluthrin	CAS number: 118712-89-3 EC number: 405-060-5	The authorised product is for indoor use in cracks and crevices by non-professionals with spraying as the application method against cockroaches, ants and flies.	The alternative is **rejected** due to differing application method and category of users: the alternative is applied by spraying by non-professionals and dinotefuran-containing products are baits and window stickers for professional and non-professional use.
PT 18	5	deltamethrin	CAS number: 52918-63-5 EC number: 258-256-6	The authorised product is for indoor use as dusting powder by non-professionals or spray non-professionals and professionals to be used indoors or outdoors against cockroaches, ants and flies.	The alternative is **rejected** due to differing application method and category of users: the alternatives are applied by spraying or dusting powder application by non-professionals or professionals and dinotefuran-containing products are baits and window stickers for professional and non-professional use.
PT 18	6	Silicium dioxide (Silicium dioxide/Kieselguhr)	CAS number: 61790-53-2 EC number: 612-383-7	The authorised product is for indoor use by professionals and non-professionals with dusting by spraying as the application method against cockroaches and ants.	The alternative is **rejected** due to differing application method and category of users: the alternatives are applied by dusting by spraying by non-professionals or professionals and dinotefuran-containing products are baits for professional use.

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment
PT 18	7	α-cyano-4-fluoro-3-phenoxybenzyl3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate (Cyfluthrin)	CAS number: 68359-37-5 EC number: 269-855-7	The authorised product is for indoor and outdoor use as ready-for-use household foam spray by non-professionals or perimeter strip for all user categories against cockroaches or fogging (cold and thermal) by professionals against houseflies.	The alternative is **rejected** due to differing application method and category of users: the alternative is applied as foam spray by non-professionals or fogging by professionals or perimeter strip and dinotefuran-containing products are baits and window stickers for professional and non-professional use.
PT 18	8	Indoxacarb (enantiomeric reaction mass *S:R* 75:25)	CAS number: 144171-61-9 EC number: 604-398-2	One of the products is for indoor and outdoor use for selective treatment (surfaces, cracks and crevices) as gel-bait by professionals against cockroaches.	The alternative is **selected** for further assessment due to similar application method and category of users as dinotefuran-containing products.
				One of the products is for indoor and outdoor use as crack, crevice and spot treatment gel-bait by professionals only against ants.	The alternative is **rejected** due to differing category of users: the alternative is for professional use only and dinotefuran-containing product can be used by trained professionals, professionals and general public (non-professionals).
PT 18	9	Indoxacarb	CAS number: 173584-44-6 EC number: 605-683-4	One of the products is for indoor use in residential houses as ready-to-use bait station by non-professionals against cockroaches.	The alternative is **rejected** due to differing application method and category of users: the alternative is applied as bait station by non-professionals and dinotefuran-containing product are gel-baits for professional use.

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment
				One of the authorised products is the granulated product used as a bait treatment using only bait stations designed for use with granular fly control baits in agricultural, livestock (except broilers), residential and commercial buildings/structures used by professionals against houseflies.	The alternative is **rejected** due to differing application method and category of users: the alternative is applied as bait station by professionals and dinotefuran-containing product are window stickers for non-professional use.
PT 18	10	[1.alpha.(*S**),3.alpha.]-(.alpha.)-cyano-(3-phenoxyphenyl)methyl3-(2,2-dichlor-oethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate (alpha-Cypermethrin); [1α(*S**),3α]-(α)-cyano-(3-phenoxyphenyl)methyl3-(2,2-dichlor-oethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate αCypermethrin)	CAS number: 67375-30-8 EC number: 614-054-3	The authorised product is for indoor use for cracks and crevices treatment as spray by professionals against cockroaches.	The alternative is **rejected** due to differing application method: the alternative is applied by spraying and Dinotefuran 2% bait is a gel-bait.

Table 15: Shortlisted chemical and non-chemical alternatives for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of alternative
PT 18	1	Indoxacarb (enantiomeric reaction mass *S:R* 75:25)	CAS number: 144171-61-9 EC number: 604-398-2	The authorised product is for indoor and outdoor use for selective treatment (surfaces, cracks and crevices) as gel-bait by professionals only.

6. SUITABILITY AND AVAILABILITY OF POTENTIAL ALTERNATIVES

6.1. INTENTED USE PT18

6.1.1. Chemical alternatives

6.1.1.1 Alternative substance 1

6.1.1.1.1 Indoxacarb (enantiomeric reaction mass *S:R* 75:25)

According to ECHA's website, there are 4 related authorised biocidal products assigned to Indoxacarb (enantiomeric reaction mass *S:R* 75:25), namely: Advion Cockroach Gel, ADVION ANT GEL, ADVION FLY GRANULAR BAIT, Baygon® Cockroach Bait (other name: Raid® Cockroach Bait). Only two out of four authorised biocidal products have an assessment report available on ECHA's website: ADVION FLY GRANULAR BAIT and Baygon® Cockroach Bait.

In the available assessment reports, the active substance has different CAS number(s) than the active substance that was obtained from ECHA biocides database search as a PT18 non-CfS (Table 11). The active substance for ADVION FLY GRANULAR BAIT has CAS numbers: (*S*)-enantiomer: 173584-44-6 and (*R*)-enantiomer: 185608-75-7, whereas the active substance for Baygon® Cockroach Bait has CAS number: 173584-44-6. The name of the active substance with CAS number 173584-44-6 is Indoxacarb. The name of the active substance with CAS number 185608-75-7 is Indoxacarb *R* enantiomer.

ADVION FLY GRANULAR BAIT is efficacious against houseflies, however it has differing application method and category of users than SAFWS002, dinotefuran-containing window sticker against houseflies. Hence ADVION FLY GRANULAR BAIT is disregarded as a technically feasible alternative.

Baygon® Cockroach Bait was reviewed and the alternative was rejected due to differing application method and category of users than for Dinotefuran 2% bait and Addict gel cockroach (see Table 14).

Table 16: Alternative substance 1 identity [10]

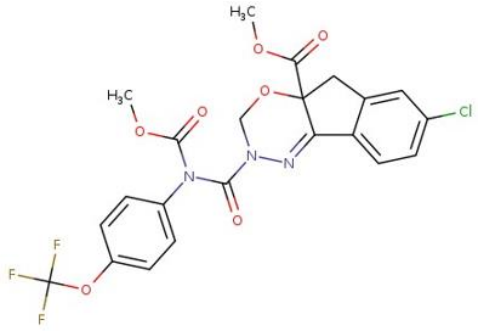
Summary table on substance identity	
ISO name	Indoxacarb (enantiomeric reaction mass *S:R* 75:25)
IUPAC name	methyl 7-chloro-2-{(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]carbamoyl}-2,5-dihydroindeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate;reaction mass of (*S*)- Indoxacarb and (*R*)-Indoxacarb 75:25
EC number	604-398-2
CAS number	144171-61-9
BAS number	64
Molecular formula	$C_{22}H_{17}ClF_3N_3O_7$
Molecular weight or molecular weight range	unavailable
Structural formula	

Table 17: Physico-chemical properties of the alternative [11]

Physical and chemical properties of the active substance	
Physical state (appearance) at 25°C and 101.3 kPA	Powdered solid
Colour at 25°C and 101.3 kPA	White
Odour at 25°C and 101.3 kPA	Faint ethyl acetate odour
Melting point	87.1°C – 141.5 °C (purity 99.4%)
Boiling point	Not measurable, substance decomposes
Thermal stability / Temperature of decomposition	Indoxacarb may be considered stable at room temperature
Vapour pressure	Not determined
Henry's law constant	Not determined
Water solubility at 20 °C	0.225 ± 0.036 µg/ml
Partition coefficient (n-octanol/water) and its pH dependency	Not determined

Table 18: Hazard properties of the alternative

Harmonised classification according to CLP	
Classification	
Hazard Class and Category Code(s)	Acute Tox. 3 Skin Sens. 1B Acute Tox. 4 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement Code(s)	H301 H317 H332 H372 (blood, nervous system, heart) H400 H410
Labelling	
Pictogram, Signal Word Code(s)	GHS08, GHS09, GHS06, Dgr
Hazard statement Code(s)	H301 H317 H332 H372 (blood, nervous system, heart) H410
Specific Conc. Limits, M-factors and ATEs	Acute: M = 1 Chronic: M = 1
Signal words	Danger

Table 19: Exclusion criteria of the alternative

Conclusion on exclusion criteria	
Conclusion on CMR	Not determined
Conclusion on ED assessment	Not determined
Conclusion on PBT and vP/vB criteria	Not PBT, vP/vB not determined
Conclusion on substitution criteria	Not applicable
Conclusion on LRTAP/POP assessment	Not determined

Table 20: Overview of the intended use of the alternative

1	Product Type	PT-18 (insecticides, acaricides and products to control other arthropods
2	Product name	Advion Cockroach Gel
3	Target organisms (including development stage)	Adult and nymph cockroaches
4	Description of use(s)	A ready-to-use gel bait containing Indoxacarb (0.6% w/w), for use only as an insecticide by professional operators indoors and outdoors around buildings for the control of cockroaches and Lepismas as a crack, crevice and spot treatment and for use in bait stations for the protection of public health and hygiene.
5	Objects to be protected	Public health
6	Concentration of active substance in the in-use formulation/product	The product is supplied in pre-filled plastic cartridge tubes with nozzle and plunger, containing 30g gel bait product, which are sealed with screw cap. Cartridge tubes are supplied in packs of up to four.
7	Application rate(s)	Application Rate: 0.2 to 0.5 g/m^2 Dilution (%): 0 Number and timing of application: Apply between 0.2 g (4 spots, diameter 0.5 cm) and up to 0.5 g (10 spots, diameter 0.5 cm or 2 spots, diameter 1 cm) of gel per m^2, or apply a single thin bead of gel up to 5cm long per m^2. Increase the application rate up to 0.5 g/m^2 depending on the severity of infestation and species present. For application into bait stations apply gel to the chamber of the bait station to deliver a minimum of 0.2 g and up to 0.5 g of gel m^2. Increase the application rate up to 0.5 g/m^2 depending on the severity of infestation and species present. Spot size of diameter 0.5 cm - weighs approximately 0.05 g. Spot size of diameter 1 cm - weighs approximately 0.25 g. Thin bead 5 cm long × 0.3 cm wide - weighs approximately 0.35 g.
8	Frequency of application	Increase the application rate up to 0.5 g/m^2 depending on the severity of infestation and species present. Bait placements should be re-inspected every 7-14 days for consumption and bait reapplied if necessary.
9	Field of use (indoors/outdoors)	Indoor and outdoor use To be used in/at: • Industrial/commercial premises • Households/private areas. • Public area (e.g., Hospitals, Nursing Homes)
10	Category(ies) of user(s)	Professional
11	Instruction for use	Apply in appropriate locations that target active trails, areas of harbourage and areas linked to pest activity. Application site can include, but not limited to, pest entry sites, wall voids, behind cabinets or equipment under counters or appliances along skirting boards and pipework. To apply the gel, remove the cap on the nozzle and whilst touching the tip of the nozzle to the holding chamber of a bait station or to the surface to be treated, slowly depress the plunger until sufficient gel is dispensed. Recap the dispenser once treatment is complete. Bait should be applied as small spots of material, or alternatively, thin beads of gel. Several small applications distributed within an area are more effective than 1 or 2 applications of large quantities.

		Apply in areas that are inaccessible to infants, children, companion animals and non-target animals. Do not apply in or around drains. Remove alternative food source that may be in competition from nearby areas. Do not apply to areas where food/feed, food utensils or food processing surfaces may come into contact with or be contaminated by the product. When used indoors do not apply to areas that are frequently cleaned as this will remove the gel bait. When used outdoors, ensure the product is applied to areas that are inaccessible to wet washing or wash-out by rain. Wipe up product spills or excess product at the end of treatments with paper towel and dispose of used paper towel to landfill.

6.1.1.1.2 Reduction of overall risk

A comparison of the harmonised classification according to CLP for both active substances (Table 3 for dinotefuran and Table 18 for Indoxacarb (enantiomeric reaction mass *S:R* 75:25)) demonstrates that dinotefuran has less hazardous properties and is less toxic than Indoxacarb (enantiomeric reaction mass *S:R* 75:25).

Conclusion on the reduction of overall risk of using the alternative:

It is concluded that the alternative Indoxacarb (enantiomeric reaction mass *S:R* 75:25), with CAS number 144171-61-9, cannot be considered having a significantly better profile than dinotefuran for human and animal health or environment based on the harmonised classification and labelling.

6.1.1.1.3 Technical feasibility

A comparison of the harmonised classification according to CLP for both active substances (Table 3 for dinotefuran and Table 18 for Indoxacarb (enantiomeric reaction mass *S:R* 75:25)) demonstrates that dinotefuran has less hazardous properties and is less toxic than Indoxacarb (enantiomeric reaction mass *S:R* 75:25).

Conclusion on the technical feasibility of the alternative:

It is concluded that the alternative Indoxacarb (enantiomeric reaction mass *S:R* 75:25), with CAS number 144171-61-9, is not considered technically feasible as an alternative due to having a worse profile than dinotefuran regarding human and animal health or environment based on the harmonised classification and labelling.

6.1.1.1.4 Economic feasibility

The economic comparison was based on prices from the two chemical providers MERCK (previous name Sigma Aldrich) and Santa Cruz Biotechnology and was carried out on 05 September 2023. The costs are based on location in Switzerland and are presented in currency Swiss Franc (CHF).

MERCK

Indoxacarb, with CAS number 144171-61-9, costs

152.00 CHF for 25 mg - product no. 33969 and product name: PESTANAL®, analytical standard

Or

153.00 CHF for 25 mg – product no. CRM67344 and product name: certified reference material, *Trace*CERT®

Dinotefuran, with CAS number 165252-70-0, costs

305.00 CHF for 50 mg (equals to 152.50 CHF for 25 mg) - product no. 32499 and product name: PESTANAL®, analytical standard

Or

306.00 CHF for 50 mg (equals to 153.00 CHF for 25 mg) – product no. CRM69091 and product name: certified reference material, *Trace*CERT®

Santa Cruz Biotechnology

Indoxacarb, with CAS number 144171-61-9, costs

99.00 CHF for 25 mg – catalog no. sc-228343

Dinotefuran, with CAS number 165252-70-0, costs

347.00 CHF for 250 mg (equals to 34.70 CHF for 25 mg) - product no. sc-484393

Conclusion on the economic feasibility of the alternative:

The price of the alternative Indoxacarb (enantiomeric reaction mass *S:R* 75:25), with CAS number 144171-61-9, was compared to dinotefuran using two chemical providers MERCK (previous name Sigma Aldrich) and Santa Cruz Biotechnology. Both, the alternative and dinotefuran have the same price in Switzerland from the first provider, MERCK. The second provider, Santa Cruz Biotechnology, offers the same amount of dinotefuran as Indoxacarb for a price almost 3 times lower than Indoxacarb. Considering the price comparison, the Applicant does not see any economic advantages with using the alternative.

6.1.1.1.5 Availability

The alternative is available as Advion Cockroach Gel on the market in the following countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Conclusion on the availability of the alternative:

The alternative is available on the European market.

6.1.1.1.6 Other relevant information

6.1.1.1.7 Conclusion on the suitability and availability of alternative 1

It is concluded that the alternative Indoxacarb (enantiomeric reaction mass S:R 75:25), with CAS number 144171-61-9 and authorized product Advion Cockroach gel, should not be considered as a suitable alternative to dinotefuran in Dinotefuran 2% bait or Addict gel cockroach based on harmonised classification and labelling comparison of Indoxacarb and dinotefuran.

A comparison of the harmonised classification according to CLP for both active substances (Table 3 for dinotefuran and Table 18 for Indoxacarb (enantiomeric reaction mass *S:R* 75:25)) demonstrates that dinotefuran has less hazardous properties and is less toxic than Indoxacarb (enantiomeric reaction mass *S:R* 75:25). Thus, it is reasonable to assume that Indoxacarb (enantiomeric reaction mass *S:R* 75:25) and authorised product Advion Cockroach is not a suitable alternative for dinotefuran and Dinotefuran 2% bait or Addict gel cockroach.

7. EFFORTS TAKEN BY THE APPLICANT TO DEVELOP NEW ALTERNATIVES

The Applicant has been working on development of new products. However, so far, no alternatives to dinotefuran have been found.

8. OVERALL CONCLUSION

In order to identify possible alternatives to dinotefuran and dinotefuran-containing products, data searches were carried out using publicly available tools and databases, as outlined in the *ECHA's Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance from January 2023*. The following public

databases and tools were searched: ECHA biocides database, Blue Angel database, PRIO Inventory tool, SUBSPORTplus, ChemSec Marketplace, CORDIS database, SAAToolbox as well as scientific literature (PubMed database) and patent database (Espacenet).

As a first step, the search results were carefully reviewed against biocidal products matching target organisms of dinotefuran-containing products, namely cockroaches, ants and houseflies (see "Data searches" for details). As a second step, biocidal products effective against matching target organisms were reviewed further and a decision was made if the alternative was selected or rejected for further assessment.

The alternatives were reviewed regarding the application method and category of users as well as description of use in comparison to dinotefuran-containing products (see Table 14 for details). Only one substance, Indoxacarb (enantiomeric reaction mass *S:R* 75:25) with CAS number: 144171-61-9 was identified as possible alternative to Dinotefuran 2% bait and Addict gel cockroach biocidal products (see Table 15 for details) and the substance in question was reviewed in detail in Section Indoxacarb (enantiomeric reaction mass *S:R* 75:25).

It was concluded that Indoxacarb (enantiomeric reaction mass *S:R* 75:25) in Advion Cockroach cannot be considered as a suitable alternative to dinotefuran in Dinotefuran 2% bait or Addict gel cockroach based on more hazardous and toxic properties of Indoxacarb specified in the harmonised classification according to CLP. No other alternatives to dinotefuran and dinotefuran-containing products were found during the analysis of alternatives.

9. REFERENCES

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ANNEX I – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[1]

Table of justification for confidentiality in the Annex of the confidential version of the analysis of alternatives:

Redacted item reference	Page number	Justification for confidentiality
Blank #1	4	Personal data (name)