



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 3 juli 2012 (20121027 TNBWE) van

DuPont de Nemours (Deutschland) GmbH
Hugenottenallee 173 -175
DE-63263 NEU-ISENBURG
DUITSLAND

tot verkrijging van een toelating als bedoeld in artikel 49, eerste lid, Wet gewasbeschermingsmiddelen en biociden voor de biocide, op basis van de werkzame stof indoxacarb,

DuPont Advion Mieren Gel

gelet op artikel 56, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Toelating

1. Het middel DuPont Advion Mieren Gel is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 13880 N met ingang van datum dezes. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 31 december 2019.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I onder A bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 50, eerste lid, sub d, Wet gewasbeschermingsmiddelen en biociden,

1. De aanduidingen, welke ingevolge artikelen 9.2.3.1 en 9.2.3.2 van de Wet milieubeheer en artikelen 14, 15a, 15b, 15c en 15d van de Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten op de verpakking moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: RB lokmiddel (klaar voor gebruik)

<i>werkzame stof:</i>	<i>gehalte:</i>
indoxacarb	0,050 %

letterlijk en zonder enige aanvulling:

andere zeer giftige, giftige, bijtende of schadelijke stof(fen): -

gevaarsymbool: *aanduiding:*

Waarschuwingzinnen: -

Veiligheidsaanbevelingen: -

Specifieke vermeldingen:

DPD11 -Bevat indoxacarb. Kan een allergische reactie veroorzaken.

2. Behalve de onder 1. bedoelde en de overige bij de Wet Milieugevaarlijke Stoffen en Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:
 - a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.
 - b. hetzij letterlijk, hetzij naar zakelijke inhoud:
de gebruiksaanwijzing
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel DuPont Advion Mieren Gel (13880 N), een middel op basis van de werkzame stof indoxacarb. Het middel wordt aangevraagd als middel ter bestrijding van mieren, inclusief de zwarte wegmier, de faraomier en de Argentijnse mier voor professioneel gebruik.

2.2 Informatie met betrekking tot de stof

Er zijn in Nederland reeds andere middelen op basis van de werkzame stof indoxacarb toegelaten.

Indoxacarb is een nieuwe, geplaatste stof (PT18) per 1 januari 2010 (Richtlijn 2009/87/EG dd 29 juli 2009).

2.3 Karakterisering van het middel

De naam van het middel in Groot-Brittanië is: DuPont Advion Ant Gel

The baits once ingested result in death of the ant within 24-60 h. Upon ingestion by the ant the Indoxacarb is metabolised to the active metabolite (N-decarbomethoxylated DPX-KN128) which binds to the sodium channels within the insect blocking sodium movement into the cell resulting in mild convulsions, paralysis and ultimately death.

2.4 Voorgeschiedenis

De aanvraag is op 25 juli 2012 ontvangen; op 6 juli 2012 zijn de verschuldigde aanvraagkosten ontvangen.

3.6 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel DuPont Advion Mieren Gel op basis van de werkzame stof indoxacarb voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu (artikel 49, Wet gewasbeschermingsmiddelen en biociden).

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 7 december 2012

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN
BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

Dit middel is uitsluitend bestemd voor professioneel gebruik

BIJLAGE I bij het besluit d.d. 7 december 2012 tot toelating van het middel DuPont Advion Mieren Gel, toelatingnummer 13880 N

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van mieren, inclusief de zwarte wegmier, de faraomier en de Argentijnse mier. Het middel dient uitsluitend buitenshuis in lokdozen en binnenshuis door pleksgewijze toepassing in naden en kieren te worden toegepast.

Restricties

- Gebruik het product alleen op plaatsen die niet toegankelijk zijn voor kinderen, vogels en (huis)dieren.
- Om in het water levende organismen te beschermen dient voorkomen te worden dat middelresten op het riool worden geloosd.
- Niet toepassen op plaatsen die in aanraking kunnen komen met voedsel of diervoeders, of die worden afgenomen met water (bijvoorbeeld badkamer- en keukenvloeren).
- Middelresten met papieren tissues opvegen en deze tissues in de afvalbak deponeren.
- Houder niet opnieuw vullen of hergebruiken, lege houders veilig verwijderen als gevaarlijk afval (cf. Eural).
- Niet toepassen op plaatsen waar de temperatuur boven de 50°C kan komen.

De dosering zoals aangegeven in de gebruiksaanwijzing moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.

GEBRUIKSAANWIJZING

Algemeen

DuPont™ Advion® Mieren Gel is effectief tegen mieren. Met behulp van een speciaal doseerpistool (baitgun) kan, uitsluitend binnenshuis, de gel worden aangebracht op de te behandelen plekken, naden en kieren en uitsluitend buitenshuis in lokdozen.

Toepassingen

1. Binnenshuis

- Vóór het gebruik van Advion® Mieren Gel moeten de schuilplaatsen en de populatiegrootte onderzocht worden ook in aangrenzende ruimten.
- Voor een betere bestrijding en om het bestrijdingseffect van het product te versnellen, is het noodzakelijk een goede hygiëne in acht te nemen, zodat - afgezien van het lokaas - zo weinig mogelijk voedsel voor de mieren beschikbaar is.
- Advion® Mieren Gel moet worden aangebracht in de buurt van schuilplaatsen, looproutes en plaatsen waar veel mieren gezien worden.
- Advion® Mieren Gel niet aanbrengen op plaatsen waar water gebruikt wordt of waar het middel mogelijkerwijs door routinematige reiniging wordt verwijderd.

- Vermijd toepassing van Advion® Mieren Gel op oppervlakken die onlangs met insectwerende bestrijdingsmiddelen behandeld zijn. Gebruik geen insectwerende bestrijdingsmiddelen op plaatsen die behandeld zijn met Advion® Mieren Gel.

2. Buitenshuis

- Gebruik Advion® Mieren Gel bij ingangsoeningen van gebouwen of mogelijke schuilplaatsen en plaatsen waar mieren veel gezien worden.
- Advion® Mieren Gel niet aanbrengen op plaatsen waar het product met water in contact kan komen of waar het middel mogelijkwijs door routinematige reiniging wordt verwijderd.
- Vermijd toepassing van Advion® Mieren Gel op oppervlakken die onlangs met insectwerende bestrijdingsmiddelen behandeld zijn. Gebruik geen insectwerende bestrijdingsmiddelen op plaatsen die behandeld zijn met Advion® Mieren Gel.
- Advion® Mieren Gel bij buitengebruik plaatsen in toegestane lokaasdoosjes om te verzekeren dat het product ontoegankelijk is voor kinderen, vogels en (huis)dieren.

Na gebruik handen wassen.

Dosering

- 1 tot 5 druppels met een diameter van 5 mm (0,1g) of een dunne gelstrook van 5 cm lang en 0.3 mm breed (0.4 g) per vierkante meter aanbrengen, afhankelijk van de grootte van de populatie.
- Advion® Mieren Gel dient te worden toegepast in kleine hoeveelheden. Meerdere kleine toedieningen in een bepaald gebied zijn effectiever dan 1 of 2 grotere toedieningen.

Vervolg bestrijdingsactie

- Na 2 tot 3 dagen controleren of er nog voldoende middel beschikbaar is. Indien het lokaas volledig is verdwenen en de plaag nog onvoldoende bestreden is, dient de toepassing te worden herhaald. Ga daarna regelmatig de hoeveelheid aanwezige Advion® Mieren Gel na en vul aan waar nodig.
- Tijdens de gehele behandeling dient er gel aanwezig te zijn.

Product Assessment Report

DuPont Advion Mieren Gel

01-11-2012

Internal registration/file no:	20121027
Authorisation/Registration no:	13880
Granting date/entry into force of authorisation/ registration:	07-12-2012
Expiry date of authorisation/ registration:	31-12-2019
Active ingredient:	Indoxacarb
Product type:	PT18

Biocidal product assessment report related to product
authorisation under Directive 98/8/EC

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1 General information about the product application

1.1 Applicant

DuPont de Nemours (Deutschland) GmbH
Hugenottenallee 173-175
Neu-Isenburg
D-63263
Germany

1.2 Current authorisation holder¹

Not applicable

1.3 Proposed authorisation holder

DuPont de Nemours (Deutschland) GmbH

1.4 Information about the product application

Application for authorization based on mutual recognition. The primary assessment has been carried out by reference member state United Kingdom. The name of the product in the UK is DuPont Advion Ant Gel. The baits once ingested result in death of the ant within 24-60 h. Upon ingestion by the ant the Indoxacarb is metabolised to the active metabolite (N-decarbomethoxylated DPX-KN128) which binds to the sodium channels within the insect blocking sodium movement into the cell resulting in mild convulsions, paralysis and ultimately death.

1.5 Information about the biocidal product

Productname: DuPont Advion Mieren Gel
PT: 18
Active substance: Indoxacarb

¹ Applies only to existing authorisations

2 Summary of the product assessment

2.1 Identity related issues

For the assessment of the identity related issues we refer to Product Assessment Report of the original authorisation.

2.2 Classification, labelling and packaging

2.2.1 Proposal for the classification and labelling of the formulation concerning physical chemical properties

No classification is required based on the physical and chemical properties of the product based on both 1999/45/EC and Reg (EC) 1272/2008.

Supported shelf life of the formulation: two years in PE/PP.

Packaging

Professional use

	Packaging authorised by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	pre-filled plastic cartridge tubes with nozzle and plunger, containing 30g gel bait product, which are sealed with a screw cap. Product is supplied as 4 x 30g tubes	4 x 30g product in PP syringe with PE plunger in PET outer packaging	4 x 30g product in PP syringe with PE plunger in PET outer packaging

2.2.2 Proposal for the classification and labelling of the formulation concerning health

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	-	Indication of danger:	-
R phrases	-		-
S phrases	-		-
Special provisions:	DPD11	Contains indoxacarb. May produce an allergic reaction	
DPD-phrases			
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:

Hazard symbol:	-
Risk phrases:	-
Safety phrases:	S35 is not indicated, as no R-phrases are assigned.
Other:	DPD11 is assigned as the product contains indoxacarb, which is classified as R43.

2.2.3 Proposal for the classification and labelling of the formulation concerning the environment

No classification is required based on the properties of the product regarding the environmental.

2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties we refer to Product Assessment Report of the original authorisation.

2.4 Risk assessment for Physico-chemical properties

For the risk assessment for physico-chemical properties we refer to Product Assessment Report of the original authorisation.

2.5 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to Product Assessment Report of the original authorisation. The conclusions of the RMS are acceptable.

2.5.1 The label claim

The applicant has provided a Dutch WG-GA. This has been adapted to our standards.

Target species

We have removed efficacy against “de spookmier” (Ghost ant, *Tapinoma melanocephalum*) from the label as there are no laboratory and field tests reported in the PAR against this species, only a single small lab-test against another Tapinoma species (*Tapinoma sessile*) was provided.

Dosage

We have added the size indication in the PAR and SPC of 5 cm x 0.3mm for the thin gel bead and adapted the Dutch translation from “dunne geldruppels” to “dunne gelstrook”

Follow up

We have added a period indication of 2-3 days for the first check on the presence of sufficient bait.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

For the description of the intended use(s) we refer to Product Assessment Report of the original authorisation.

2.6.2 Assessment of exposure to humans and the environment

For the assessment of the exposure to humans we refer to Product Assessment Report of the original authorisation.

In the PAR the environmental risk assessment is performed for industrial, professional and non-professional use of the product DuPont Advion Ant Gel 0.05% (hereafter named Dupont Advion Mierengel) which is a frame formulation containing 0.03%-0.05% indoxacarb.

DuPont Advion Mierengel is a gel bait containing 0.05% indoxacarb for use by professional operators only. It is for use indoors and outdoors as a crack, crevice and spot treatment in single and multi-family residential buildings, commercial and industrial facilities, public and institutional buildings and transportation equipment.

Application rate for all uses:

The product is applied as a ready for use gel bait via a 30 g syringe at the following application rates:

Apply a minimum of 1 spot of gel per m², up to 5 spots per m², or as a thin bead of gel. A spot size of 5 mm diameter weighs approximately 0.1g.

For details on the assessment of the exposure to the environment we refer to Product Assessment Report of the original authorisation.

2.7 Risk assessment for human health

For the risk assessment for human health we refer to Product Assessment Report of the original authorisation.

Based on the risk assessment no adverse effects from the exposure to indoxacarb are expected for unprotected professional operators when applying DuPont Advion Mieren Gel.

2.8 Risk assessment for the environment

For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.

Substances of concern

The product contains the active substance indoxacarb (0.05% w/w). The only component of the product that is classified in relation to its potential to cause adverse effects in the environment is the active substance. There are no other substances of concern.

Assessment of metabolites

In the water compartment a single major metabolite, IN-KT413, was identified with a DT50 of 30.3 d (at 12 °C). In the sediment compartment, the major metabolites formed were IN-JT333 and IN-KT413, with DT50's of 55 and 43.6 d (at 12 °C) respectively.

Acute and chronic ecotoxicity endpoints are provided in the CAR for indoxacarb for the effects assessment of the soil compartment. These endpoints suggest that IN-JT333 has higher toxicity to the soil compartment than the parent compound. However, as this metabolite was shown not to be of concern when tested under realistic field conditions, where this metabolite was not significantly formed (all < 10 % applied parent) The degradation rates of the major metabolites have only been addressed for IN-JT333 and a DT50 of 6 d at 20 °C provided. A PNECsoil for this substance has not been derived. No relevant ecotoxicity endpoint for metabolite IN-KT413 was available and is not considered necessary by the RMS UK as under realistic field conditions this metabolite was also not shown to be of concern. The available data show a similar degradation pattern for

IN-KT413 suggesting that a similar half-life as for IN-JT333 could be assumed. Therefore, a PNECsoil for this substance has not been derived either.

Furthermore, the data obtained from field soil degradation studies included in the CAR for indoxacarb indicate that the both the parent compound and its main metabolites, IN-JT333 and IN-KG433 have low potential for mobility under realistic field conditions.

The UK CA has concluded from this study that the identified metabolites, which were of concern in the laboratory environment, provided no area of concern. This was also the conclusion of the review under PPPD (91/414/EEC) (EC, 2005a, 2005b). Therefore, the risk assessment for the soil compartment will assume that there are no metabolites of concern and that the parent compound is immobile.

The water and sediment metabolites IN-KT413 and IN-JT333 were included in the risk assessments of the CAR for indoxacarb and the PAR for DuPont Advion Ant Gel 0.05%.

Comparative risk assessment

In the PAR the RMS UK has compared the proposed area of use and application rate of a similar gel bait product (Dupont Advion Cockroach gel containing 0.6% indoxacarb) to those of the product 'Dupont Advion Ant Gel'/'Dupont Advion Mierengel', an insecticide (PT18) containing 0.05% indoxacarb which is in the form of a ready to use bait product for the control of ants. Dupont Advion Cockroach gel is already authorised in the NL and UK. The Dutch name of the product is Dupont Advion kakkerlakken gel (13434 N).

The comparison of the product Dupont Advion Mierengel with Dupont Advion kakkerlakken gel is shown in the table below.

Trade name	Current product Dupont Advion Mierengel		Authorised product Dupont Advion kakkerlakken gel	
Ingredient of preparation	Function	Content (%) w/w)	Function	Content (%) w/w)
Indoxacarb as pure a.i.	Active ingredient	0.05	Active ingredient	0.6
Manner and area of use	For use by professional operators only and applied in areas inaccessible to children or pets. Indoor and outdoor use as a crack, crevice and spot treatment in and around residential homes, industrial facilities, offices, warehouses, commercial kitchens, hospitals, schools, nursing homes, hotels, buses, trains, aircraft retail and commercial establishments.		For use by professional operators only and applied in areas inaccessible to children or pets. Indoor and outdoor use as a crack, crevice and spot treatment in and around residential homes, industrial facilities, offices, warehouses, commercial kitchens, hospitals, schools, nursing homes, hotels, buses, trains, aircraft retail and commercial establishments.	
Application rates	application rate: from 0.2 g product /m² up to 0.5 g product /m² apply a minimum of 1 spot of gel per m ² , up to 5 spots of gel per m ² . <i>Note :</i> A spot size of 5 mm diameter weighs approximately 0.1 g		application rate: from 0.2 g product /m² up to 0.5 g product/m² apply a minimum of 2 spots of gel up to 5 spots of gel per m ² . <i>Note :</i> A spot size of 5 mm diameter weighs approximately 0.1 g	

The RMS UK assessment concluded the following:

The use of indoxacarb within an insecticide gel product has been previously assessed and authorised within the product 'DuPont Advion Cockroach Gel'. As can be seen within the table above, the proposed use of 'DuPont Advion Ant Gel' is within that approved for 'DuPont Advion Cockroach Gel' as the critical application for both products is 0.5g

product/m² and the percentage of indoxacarb in 'DuPont Advion ant Gel' (0.05% w/w) is considerably less than that approved for use within the product 'DuPont Advion Cockroach Gel' (0.6% w/w). As all areas of use stated within the application of 'DuPont Advion Ant gel' were considered within the 'DuPont Advion Cockroach Gel' assessment, it can be concluded that the application of 'DuPont Advion Ant Gel' will result in less indoxacarb exposure than that considered within the assessment of 'DuPont Advion cockroach Gel', and no further consideration is required at this time.

Thus it can be considered that the indoxacarb exposure expected to occur after application of the product 'DuPont Advion Ant Gel' is within that proposed for the product 'DuPont Advion Cockroach Gel' and no new PEC calculations are required as part of this assessment.

Therefore the predicted exposure from 'DuPont Advion Ant Gel' is within that assessed and approved for 'DuPont Advion Cockroach Gel'. The formulation of 'DuPont Advion Ant Gel' is summarised in R4BP. The co-formulants are not considered to increase the toxicity of the product, with the main components being sugars (sucrose and dextrose) and water. Therefore the same conclusions made for 'DuPont Advion Cockroach Gel' are applicable, however as the active ingredient content is <0.25% the risk phrases R52/53 that were applicable to DuPont Advion Cockroach Gel are not applicable to DuPont Advion Ant Gel.

There is a possible risk from secondary poisoning of birds and mammals from the consumption of ants containing or carrying indoxacarb as a result of the proposed use of Dupont Advion Ant Gel outdoors. The concentration of indoxacarb in food for birds and mammals (ant) is calculated assuming consumption of an amount of bait accounting for 10% from the weight of an ant. Furthermore it is assumed that 10% of the food of birds and mammals consists of ants having consumed the bait. The concentration in the diet of birds and mammals is:

$$5 \text{ mg/kg food (PECoral} = 0.5 \text{ g/kg bait} \times 1/10 \times 1/10 = 5 \text{ mg/kg food)}$$

For PNEC derivation endpoints for toxicity to birds and mammals are available in the CAR for indoxacarb. The TGD uses a protection level for chronic exposure for PNEC derivation. Considering the intended use an acute risk is more likely to be expected. The assessment factors for secondary poisoning are 3000, 30 and 90 for acute, short-term and long term tests respectively. In the current application acute studies are used for the evaluation of an acute risk (direct poisoning). It is therefore considered acceptable to correct the assessment factor of 3000 with a factor 10.

For the risk assessment a small bird and mammal with body weights (bw) of 10 and 6 gram respectively and a daily food intake (dfi) of 2.9 g for birds and of 1.025 g for mammals is assumed.

Table 1 PEC/PNEC_{oral} for secondary poisoning of birds and mammals

Time scale	Toxicity endpoint	AF	PNEC _{oral}	Tier 1 PEC/PNEC	Tier 2 PEC/PNEC	
Birds						
acute	LD50 98 mg/kg bw.d	3.45*	300	4.42 mg/kg feed	1.1	0.011
long-term	NOEC 144 mg/kg feed		30	4.8 mg/kg feed	1.0	0.01
Mammals						
acute	LD ₅₀ 268 mg/kg bw.d	5.85*	300	5.23 mg/kg feed	0.96	0.096
short-term	NOAEL 2.13 mg/kg bw.d	5.85*	90	0.14 mg/kg feed	36.1	0.36
long-term	NOAEL 0.55 mg/kg bw.d	5.85*	30	0.11 mg/kg feed	46.6	0.47

* bw/dfi = 10/2.9 = 3.45 for birds, bw/dfi = 6/1.025 = 5.85 for mammals

An acute LD50 is available from the CAR for indoxacarb to assess the toxicity of IN-JT333 to birds.

- Northern bobwhite quail (*C. virginianus*): LD50 (14 d): 1750 mg/kg

According to the TGD such an acute lethal dose is not acceptable for derivation of a PNEC_{oral}, and therefore no PNEC_{oral} can be derived for IN-JT333.

From the Tier 1 assessment (Table 1) of secondary poisoning of birds and mammals it can be concluded that there is a small risk during acute exposure of birds through 100% consumption of contaminated ants. The following reservations can be made regarding the risk calculated:

In the Netherlands there are no animals having a diet that completely exists of ants. Furthermore considering the type use and the local application, birds and mammals will be exposed periodically and only via a small portion of the diet, also because the feeding area of birds and mammals is considerably larger than the treated area. Therefore a more realistic exposure will be in the range of 1% of the consumption (Tier 2 see Table 1). From this it can be derived that the criteria for secondary poisoning of birds and mammals are met. To lower the risk and to shorten the exposure it is recommended, however, that during the campaign dead ants should be collected and be removed on a daily basis and at the end of the campaign rests of product should be collected and removed as hazardous waste (cf. Eural). Furthermore when used outdoors the product needs to be applied in baitboxes in order to minimise exposure of children, birds and mammals (including pets).

The Annex I assessment recommended various label phrases to minimise exposure of non-target organisms. Most of these have been included on the draft label, with the following being currently omitted but recommended for inclusion on the label:

- *Do not use where a significant number of birds are known to actively feed on the ants being treated, without removing access to the area by birds e.g. netting over the ground*

This restriction sentence does not need to be included in the proposed label (WGGA) as according to the risk assessment performed in the PAR there is no risk for secondary poisoning of birds and mammals through consumption of contaminated food. Furthermore, this restriction measure is not realistic and not practically feasible.

It is noted that the proposed formulation for 'DuPont Advion Ant Gel' has a higher proportion of sugar compared to the approved formulation for 'DuPont Advion Cockroach Gel'. Therefore there is potential that the gel is more attractive to non-target organisms, such as bees. No assessment was made for Annex I or 'DuPont Advion Cockroach Gel', and the issue was not discussed at the Technical Meeting. There is also currently no risk assessment scheme for bees in the Technical Guidance Document. As such, the UK CA proposes that the label phrase recommended for Annex I ('Do not place bait where non-target animals can gain access') be changed to the following and included on the label:

- *Cover bait to ensure access by non-target animals is minimised*

Overall conclusion for the aspect environment: The conclusions in the risk assessment of the RMS are valid and with the risk mitigations included in the WG/GA, the use of Dupont Advion Mierengel will not cause unacceptable risks to the environment.

2.9 Measures to protect man, animals and the environment

Measure	In WG/GA	WG/GA (in Dutch)
For use only as an insecticide	Yes	Toegestaan is uitsluitend het gebruik als middel ter bestrijding van mieren, inclusief de zwarte wegmier, de

For use only by professional operators	Yes	faraomier en de Argentijnse mier Het middel is uitsluitend bestemd voor professioneel gebruik
Use appropriate protective clothing	No	Not required, as no protective clothing is necessary according to the risk assessment.
For use only in areas that are inaccessible to infants, children, companion animals and non-target animals	Yes	Gebruik het product alleen op locaties die niet toegankelijk zijn voor kinderen, huisdieren of niet-doelwit organismen.
Do not apply in or around drains	Yes	Om in het water levende organismen te beschermen dient voorkomen te worden dat middelresten op het riool worden geloosd.
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	Yes	Niet toepassen op plaatsen die in aanraking kunnen komen met voedsel or diervoeders.
Do not apply to areas that are frequently cleaned as this will remove the gel bait	Yes	Advion® Mieren Gel niet aanbrengen op plaatsen waar het product met water in contact kan komen of waar het middel mogelijk door routinematige reiniging wordt verwijderd. Bij gebruik buitenshuis: ter bescherming van in water levende organismen niet toepassen in de buurt van waterafvoersystemen waar het middel met water in contact kan komen.
When used outdoors, ensure the product is applied to areas that are inaccessible to wet washing or wash-out by rain	Yes	Advion® Mieren Gel niet aanbrengen op plaatsen waar het product met water in contact kan komen of waar het middel mogelijk door routinematige reiniging wordt verwijderd.
Do not apply to surfaces where temperature can exceed 50°C as this could cause the gel to liquefy and lose effectiveness. Examples include, but are not limited to, parts of stoves, ovens, grills, fume hoods, saunas, heat lamps, fryers, dishwashers and hot water pipes	Yes	Niet toepassen op plaatsen waar de temperatuur boven de 50°C kan komen.
Avoid contact with skin, eyes or clothing	No	This sentence is equal to S24/25 which is not assigned based on the risk assessment
Wash thoroughly with soap and water after handling the product	Yes	Na gebruik handen wassen.
Wipe up product spills or excess product at the end of treatments with paper towel and dispose of	Yes	Middelresten met papieren tissues opvegen en deze tissues in de afvalbak deponeren.

used paper towel to landfill		
Do not refill or re-use the gel bait dispenser; empty dispensers must be disposed in a safe manner	Yes	Houder niet opnieuw vullen of hergebruiken, lege houders veilig verwijderen als gevaarlijk afval (cf. Eural).
Store in original packaging in a locked, dry place, avoiding extremes in temperature that is inaccessible to children and non-professional people	No	Remark: "inaccessible to children" is equal to S2, which is not indicated for professional users. It is also not expected that non-professional users will come in contact with the stored product.
Do not use where a significant number of birds are known to actively feed on the ants being treated, without removing access to the area by birds e.g. netting over the ground	No	Not needed as according to the risk assessment performed in the PAR there is no risk for secondary poisoning of birds and mammals through consumption of contaminated food. Furthermore, this restriction measure is not realistic and not practically feasible.
Cover bait to ensure access by non-target animals is minimised	No	This sentence is covered by "Gebruik het product alleen op locaties die niet toegankelijk zijn voor kinderen, huisdieren of niet-doelwit organismen".

3 Proposal for decision

The authorization of DuPont Advion Mieren Gel is based on mutual recognition of the assessment of RMS UK. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is expected that the application of DuPont Advion Mieren Gel according to the use instructions, will be effective and that there will be no harm for the health of humans, for those who use the product, and for the environment.

Proposal for the classification and labelling of the formulation

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment, the following labelling of the formulation is proposed:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-		
Symbol:	-	Indication of danger: -
R phrases	-	-
S phrases	-	-
Special provisions:	DPD11	Contains indoxacarb. May produce an allergic reaction
DPD-phrases		
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable
