



## **HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

### **1 TOELATING**

Gelet op de aanvraag d.d. 13 augustus 2013 (20131174 TNBWE) van

Physalys sarl  
3 Rue de L 'Arrivee  
F-75749 PARIS ,CEDEX 15  
FRANKRIJK

tot verkrijging van een toelating als bedoeld in artikel 19 van de Verordening (EU) 528/2012, op basis van de werkzame stof alfachloralose,

#### **Rentokil Alpha Rapid Bait Blocks**

Mede gelet op artikel 89 lid 2 juncto artikel 91 van de Verordening (EU) 528/2012, juncto artikel 44, eerste lid, Wet gewasbeschermingsmiddelen en biociden zoals deze luidde voor de inwerkingtreding van Verordening (EU) 528/2012

**BESLUIT HET COLLEGE** als volgt:

#### **1.1 Toelating**

1. Het middel Rentokil Alpha Rapid Bait Blocks is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14344 N met ingang van datum dezès. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 30 juni 2021.

#### **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 bij dit besluit is voorgeschreven.

### 1.4 Classificatie en etikettering

Gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

*aard van het preparaat:* Lokmiddel (klaar voor gebruik)

<i>werkzame stof:</i>	<i>gehalte:</i>
alfachloralose	3,4 %

*de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:*

-

### PICTOGRAM(MEN)

*pictogram:*  
GHS09-milieu

### SIGNAALWOORD

Waarschuwing

### Gevarenaanduidingen

H400	Zeer giftig voor in het water levende organismen.
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### Voorzorgsmaatregelen

P102	Buiten het bereik van kinderen houden.
P273	Voorkom lozing in het milieu.
P501	Inhoud/verpakking afvoeren naar inzamelpunt voor gevaarlijk of bijzonder afval.

Behalve de 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 Rentokil Alpha Rapid Bait Blocks (14344 N), een middel op basis van de werkzame stof alfachloralose. Het middel wordt aangevraagd als middel ter bestrijding van huismuizen in afgesloten ruimten.

### **2.2 Informatie met betrekking tot de stof**

Er zijn in Nederland eerder middelen op basis van de werkzame stof alfachloralose toegelaten. De werkzame stof alfachloralose is bij Richtlijn 2009/93/EG, dd 31 juli 2009 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG voor pt14.

### **2.3 Karakterisering van het middel**

Rentokil Alpha Rapid Bait Blocks is a solid fat based green triangle block. It is designed for placing inside tamper resistance bait boxes which are designed to permit pest controllers easy retrieval of uneaten bait at the end of a treatment for re-use where possible. It is used for the control of mice and can only be used indoors. The product is for professional use only.

Alphachloralose acts by retarding the metabolic processes. It acts on the nervous system causing a depression in brain activity, slowing the heart and respiration. This results in a lowering of body temperature, causing the mouse to die of hypothermia.

### **2.4 Voorgeschiedenis**

De aanvraag is op 26 augustus 2013 ontvangen; op 7 november 2013 zijn de verschuldigde aanvraagkosten ontvangen.

### **2.5 Eindconclusie**

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Rentokil Alpha Rapid Bait Blocks op basis van de werkzame stof alfachloralose voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

*Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht 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 maart 2014

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN  
BIOCIDEN,

ir. J.F. de Leeuw  
voorzitter

## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

**BIJLAGE I** bij het besluit d.d. 7 maart 2014 tot toelating van het middel Rentokil Alpha Rapid Bait Blocks, toelatingnummer 14344 N

### A.

#### WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van huismuizen in afgesloten ruimten, met dien verstande, dat het middel moet worden uitgelegd in speciaal hiervoor bestemde lokaasdoosjes. Plaats het lokaas in lokaasdoosjes buiten bereik van andere dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen. Verwijderd houden van eet- en drinkwaren en van diervoeder.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

### B.

#### GEBRUIKSAANWIJZING

##### **Toepassingen:**

Alpha Rapid Bait Blocks is een kant-en-klaar lokaasblokje tegen huismuizen dat uitsluitend binnenshuis mag worden toegepast. De blokjes wegen 5 of 10 gram. Alpha Rapid Bait Blocks is een acuut werkend rodenticide en eenmalige opname is doorgaans genoeg om snel resultaat te bereiken. Alpha Rapid Bait Blocks wordt toegepast voor bestrijdingsperioden van 7-10 dagen.

Het product is minder effectief bij temperaturen boven de 16°C.

Plaats het lokaas in de hiervoor geschikte lokaasdoosjes of -kisten. De doosjes of kisten vervolgens uitzetten op plaatsen waar de muizen geregeld komen: in de nabijheid van holingen, op looppaden (sporen!), in verborgen ruimten zoals verlaagde plafonds en op plaatsen waar de dieren voedsel halen of knagen. Het middel dient gedurende een aantal dagen in voldoende mate te worden gegeten door de knaagdieren.

Plaats het lokaas in lokaasdozen buiten bereik van andere dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen. Het lokaas zo vastmaken dat het niet weggesleept kan worden. De lokaasdoosjes niet toepassen in de buurt van waterafvoersystemen waar het middel met water in contact kan komen. De lokaasdoosjes markeren zodat duidelijk is dat ze rodenticide bevatten. Na gebruik handen wassen.

##### **Dosering:**

Plaats de lokaasdoosjes op een afstand van 1-3 meter van elkaar. Vul de lokaasdoosjes met 20 gram lokaas per lokaasdoosje.

##### **Vervolg bestrijdingsactie:**

Controleer de eerste opname na 3 dagen en vervolgens regelmatig op basis van opname (wekelijks of elke 14 dagen). Ververs of vul het lokaas daar waar nodig is aan tot er in het geheel geen opname meer plaatsvindt. Middel dat beschimmeld of verontreinigd is totaal vervangen. Indien het lokaas geheel opgegeten is, onmiddellijk lokaas hervullen en meer

lokaaspunten inrichten en/of de controlefrequentie verhogen. In de meeste gevallen zal de bestrijding met behulp van dit middel binnen 10 dagen voltooid zijn. Indien na 10 dagen nog activiteit van muizen wordt waargenomen, moet de mogelijke oorzaak hiervan worden onderzocht en maatregelen worden getroffen. Nadat de opname van lokaas gestopt is, de resten van het lokaas verzamelen en veilig verwijderen als gevaarlijk afval (cf. Eural).

Dode dieren verzamelen en in plastic verpakt in het vuilnisvat deponeren, opdat huisdieren en andere dieren niet door het opeten van de kadavers worden vergiftigd. Katten en honden tijdens een bestrijdingsactie extra goed voeren. Verder de nodige maatregelen (laten) treffen in het belang van muiswering (ingangen afdichten, mogelijk voer verwijderen, etc.). Indien in aangebouwde ruimten muizen aanwezig zijn, zullen de resultaten slechts blijvend zijn, wanneer ook daar een bestrijdingsactie wordt uitgevoerd.

Gebruik van dit middel moet worden gecombineerd met de implementatie van een integrated pest management systeem (IPM).

**Resistentiemanagement:**

Voor de werkzame stof aanwezig in het middel, alphachloralose, is er een risico dat muizen resistentie ontwikkelen. Gebruik dit middel daarom bij voorkeur niet bij temperaturen hoger dan 16°C en in gevallen dat resistentie waarschijnlijk is, bijvoorbeeld in gevallen dat vorige bestrijdingsacties met alphachloralose bevattende middelen niet hebben geresulteerd in een duidelijke vermindering van de populatie. Gebruik dan een middel met een andere actieve stof en een andere werking.

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE II** bij het besluit d.d. 7 maart 2014 tot toelating van het middel Rentokil Alpha Rapid Bait Blocks, toelatingnummer 14344 N

# **Product Assessment Report Mutual Recognition**

## **Rentokil Alpha Rapid Bait Blocks**

31-01-2014

Internal registration/file no:	20131174
Authorisation/Registration no:	14344N
Granting date/entry into force of authorisation/ registration:	07-03-2014
Expiry date of authorisation/ registration:	30-06-2021
Active ingredient:	Alphachloralose
Product type:	14

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Biocidal product assessment report related to product authorisation under Regulation 528/2012/EC

# Contents

<b>1</b>	<b>General information about the product application .....</b>	<b>1</b>
1.1	Applicant.....	1
1.2	Current authorisation holder .....	1
1.3	Proposed authorisation holder.....	1
1.4	Information about the product application .....	1
1.5	Information about the biocidal product.....	1
<b>2</b>	<b>Summary of the product assessment.....</b>	<b>2</b>
2.1	Identity related issues.....	2
2.2	Classification, labelling and packaging .....	2
2.2.1	Proposal for the classification and labelling of the formulation concerning physical chemical properties.....	2
2.2.2	Proposal for the classification and labelling of the formulation concerning health3	
2.2.3	Proposal for the classification and labelling of the formulation concerning the environment.....	3
2.3	Physico/chemical properties and analytical methods .....	4
2.4	Risk assessment for Physico-chemical properties .....	4
2.5	Effectiveness against target organisms .....	4
2.6	Exposure assessment .....	4
2.6.1	Description of the intended use(s).....	4
2.6.2	Assessment of exposure to humans and the environment.....	4
2.7	Risk assessment for human health.....	7
2.8	Risk assessment for the environment.....	7
2.9	Measures to protect man, animals and the environment.....	8
<b>3</b>	<b>Proposal for decision .....</b>	<b>10</b>

# **1 General information about the product application**

## **1.1 Applicant**

Physalys SARL  
Rue de l'Arrivee 3  
BP215-F75749  
Paris, Cedex 15  
France

## **1.2 Current authorisation holder<sup>1</sup>**

Not applicable

## **1.3 Proposed authorisation holder**

Physalys SARL

## **1.4 Information about the product application**

Application for authorisation based on mutual recognition. The primary assessment has been carried out by reference member state UK.

## **1.5 Information about the biocidal product**

Productname: Rentokil Alpha Rapid Bait Blocks  
Productname in RMS: Physalys Expresse Professional  
PT: 14  
Active substance: Alphachloralose

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<sup>1</sup> 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 Reg (EC) 1272/2008.

Supported shelf life of the formulation: 24 months in polyethylene and polystyrene

The proposed classification and labelling of the preparation is identical to that proposed in the Product Assessment Report by the competent authority UK.

#### Professional use

	Packaging authorised/evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	Cardboard outer packaging containing a polythene inner pack with a polystyrene tray containing up to 12 'winged inserts'; each winged insert contains a 5g solid bait block	Cardboard outer packaging containing a polythene inner pack with a polystyrene tray containing up to 12 'winged inserts'; each winged insert contains a 5g solid bait block*	Cardboard outer packaging containing a polyethylene inner pack with a polystyrene tray containing up to 12 'winged inserts'; each winged insert contains a 5g solid bait block containing a minimum of 800g per packaging
Packaging size and type	Cardboard outer packaging containing a polythene inner pack with a polyethylene moulded tray; each tray contains up to forty-eight 5g or 10 g solid bait blocks.	Cardboard outer packaging containing a polythene inner pack with a polyethylene moulded tray; each tray contains up to forty-eight 5g or 10 g solid bait blocks.*	Cardboard outer packaging containing a polyethylene inner pack with a polyethylene moulded tray; each tray contains up to forty-eight 5g or 10 g solid bait blocks containing a minimum of 800g per packaging

\*To comply with the Dutch requirement that rodenticide packagings for professional use should contain a minimum amount of product of 800g, the applicant will pack multiple trays per outer packaging.

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

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The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	-	Signal word:	-
H-statements:	-		-
P-statements:	P102	Keep out of the reach of children	
Supplemental Hazard information:	-	-	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

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Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	No P-statements have been proposed by the applicant. Based on the risk assessment for children, P102 is assigned by the Ctgb.
Other:	-

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\* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

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

### Professional use

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Pictogram:	GHS09	Signal word:	Warning
H-statement:	H400	Very toxic to aquatic life.	
P-statements:	P273	Avoid release to the environment.	
	P501	Dispose of contents/container to hazardous or special waste collection point	
Supplemental Hazard information:	-		

### Explanation

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Pictogram:	Classification based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008
H-statement:	Classification based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008
P-statements:	The applicant proposed P-statements P273 and P501. The proposal of the applicant has been accepted.
Other:	-

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The proposed classification and labelling of the preparation deviates from that proposed in the Product Assessment Report by the competent authority (R50/53 – Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment). No chronic data are available and due to the rapidly degradability of the substance, according to CLP guidelines, the acute data could not be used as chronic data for the active substance. Therefore, the H-statement does not include ‘...with long lasting effects.’

## **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 label (WG/GA). This has been adapted to our standards.

#### Professional/non-professional use

In the PAR efficacy was demonstrated for professional and non-professional use. However, authorisation for this product in NL was only requested for professional use.

## **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**

#### Toxicology

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

The formulation Rentokil Alpha Rapid Bait Blocks is a wax block bait containing 4% alphachloralose as active substance and is intended for the use against mice inside buildings (PT14). The intended maximal dose is 10 g formulation per one bait point. The formulation is supplied in polystyrene trays containing “winged inserts”, each containing 5 g solid blocks, or in polyethylene trays containing solid bait blocks of 5 g and 10 g and is intended for professional use only. The plastic winged inserts are designed that the operator would not need to touch the bait block during the loading. The operator detaches the section of the tray containing the bait block by holding the plastic “wings”. The Product Assessment Report (PAR) was prepared by the RMS UK.

Alphachloralose is an existing active substance, included in the Union List of Approved Substances under Regulation 528/2012/EC. The classification and labelling of alphachloralose in the PAR is identical to classification and labelling of brodifacoum in the final CAR of alpha-chlorasole (2007, RMS Portugal).

The applicant has proposed the read-across of the formulation data with the reference products Alphablock and Alphakil Block in the CAR of alpha-chlorasole. This suggestion was accepted by the RMS UK and is also considered acceptable by the Ctgb. However, no studies with the formulations Alphablock and Alphakil Block were submitted at the stage of the substance evaluation by the RMS Portugal, therefore classification and labelling will be performed based on the calculation rules according to Regulation 1272/2008/EC.

For dermal absorption the value of 3.11% was derived in the CAR of alphachloralose based on the study with the reference product. The RMS UK considered it acceptable to use this value in the risk assessment of Rentokil Alpha Rapid Bait Blocks. The Ctgb agrees with the RMS.

The following AEL values were derived in the CAR of alphachloralose:  $AEL_{\text{long-term, medium term}} = 0.15 \text{ mg/kg bw/day}$  and  $AEL_{\text{acute}} = 0.2 \text{ mg/kg bw/day}$ . The same values were used in the risk assessment by the RMS UK.

The exposure assessment was performed by the RMS UK in the same way as the exposure assessment in the CAR of alpha-chlorasole. The exposure estimates were derived based on the operator exposure study, in which professional operators were placing alpha-chloralose bait blocks into bait boxes. Two different bait box loading scenarios were included in the study, the loading of the bait box with 10 g solid bait block, or loading of the bait box with the "winged inserts" of 5 g. For two scenarios, either five or seven operators were handling 100 blocks to load 50 bait boxes each.

The following assumptions were used to determine professional exposure:

- The operator loads 30 new bait boxes per day (visiting 2 sites and placing 15 new boxes at each site) and cleans 20 boxes per day
- The exposure during placing of 15 boxes was recalculated from the indicative exposure for the loading of 50 bait boxes derived in the study, by developing a regression model which took into account that exposure after only a single manipulation is higher than would be expected by simple interpolation when manipulations are repeated. Using this model the ratio for converting from 50 bait boxes to 15 is 3.1.

There were no exposure data for the cleaning of the boxes, but it was presumed that securing blocks in the bait boxes will lead to higher exposure than during the cleaning. Therefore the exposure during cleaning was presumed to be equal during the exposure during the loading. Using the regression model conversion factor from 50 bait boxes to 20 was 2.4.

Based on this the following internal exposure estimates were derived in the CAR of alphachloralose and taken over in the PAR by the RMS UK, considering 4% concentration of alphachloralose in the formulation, 3.11% dermal absorption and 60 kg professional user body weight:

For the loading of 30 bait boxes with "winged inserts": 0.001 mg/kg bw/day

For the loading of 30 bait boxes with solid blocks: 0.011 mg/kg bw/day

For the cleaning of 20 bait boxes: 0.014 mg/kg bw/day.

In total:

Loading to 30 bait boxes with “winged inserts” and cleaning of 20 bait boxes: 0.015 mg/kg bw/day

Loading of 30 bait boxes with solid blocks and cleaning of 20 bait boxes: 0.025 mg/kg bw/day.

It should be noted that according to the HEEG opinion endorsed at TM III 2010 on the harmonization of manipulations in the assessment of rodenticides the performance of 60 loading and 15 cleaning operations per day for professional user needs to be considered. However, the HEEG opinion is aimed at anticoagulant rodenticides, where alphachloralose is a CNS depressant. Therefore the exposure estimates as derived in the CAR of alphachloralose are considered acceptable by the Ctgb.

If these values are compared with the  $AEL_{\text{medium/long-term}}$  of 0.15 mg/kg bw/day, the following risk indices are derived:

For the “winged inserts”:  $(0.015/0.15 = )$  0.1

For the solid blocks:  $(0.025/0.15 = )$  0.17.

Based on this no adverse effects from exposure to alphachloralose is expected for unprotected professional users due to the application of Rentokil Alpha Rapid Bait Blocks supplied as “winged inserts” of 5 g or solid blocks of 10 g against mice.

The RMS UK has also assessed two secondary exposure scenarios, which were also assessed in the CAR of alphachloralose: exposure of an adult or a child handling a dead rodent, or exposure of an infant incidentally ingesting the bait. For the handling of dead rodent a dislodgeable amount of 1 g is assumed. Considering body weights of 60 kg for an adult and 15 kg for a child, 4% alphachloralose concentration and 3.11% dermal absorption, the resulting systemic exposure is 0.021 mg/kg bw/day and 0.082 mg/kg bw/day for an adult and a child, respectively.

As adults and children are not expected to handle dead rodents on a regular basis, the derived exposure estimates can be compared with the  $AEL_{\text{acute}}$  of 0.2 mg/kg bw/day. In that case the following risk indices are derived:

For an adult:  $0.021/0.2 = 0.11$

For a child:  $0.082/0.2 = 0.41$

For an infant incidentally ingesting the bait an ingestion of either 10 mg bait is assumed according to TNsG, or 5 g based on the user guidance. Based on this the following internal exposure estimates are derived (considering 4% concentration, 100% oral absorption and 10 kg body weight):

For the ingestion of 10 mg of bait:

$10 \times 4\% \times 100\% / 10 = 0.04$  mg/kg bw/day.

For the ingestion of 5 g of bait:

$5000 \times 4\% \times 100\% / 10 = 20$  mg/kg bw/day

As the ingestion of a bait is expected to occur only incidentally, the derived exposure estimates can be compared with the  $AEL_{\text{acute}}$  of 0.2 mg/kg bw/day. In that case the following risk indices is derived:

For the ingestion of 10 mg of bait:  $(0.04 / 0.2 = )$  0.2.

For the ingestion of 5 g of bait:  $(20 / 0.2 = ) 100$ .

Based on this, no adverse effects are expected for the secondary exposure of adults and children of alpha-chlorasole from handling the dead rodents, or for an infant incidentally ingesting 10 mg of bait. The formulations contains a bittering agent, which reduces the amount ingested; however, adverse effects for an infant incidentally ingesting 5 g of bait cannot be excluded.

Therefore the following precautionary phrases should be added to the product label:

- Keep out of the reach of children (P102)
- Prevent access to bait by children, domesticated animals and pets, (particularly cats, dogs and pigs).

When these risk management measures are taken into consideration, the risk of secondary exposure for children is considered to be mitigated.

#### Environment:

The product is intended for the professional control of mice indoors. Exposure of the environment may occur through landfill, after deposition of dead mice. As the active substance is mobile in soil and the intended use is indoors, exposure of the soil compartment (agricultural soil and grasslands) is considered negligible and was not considered. Exposure of the water compartment has been considered.

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 are expected for unprotected professional user from the exposure to alphachloralose due to the application of Rentokil Alpha Rapid Bait Blocks supplied as “winged inserts” or solid wax blocks against mice.

Based on the risk assessment, adverse effects from exposure of alphachloralose for an infant incidentally ingesting 5 g of Rentokil Alpha Rapid Bait Blocks bait cannot be excluded. Therefore the following precautionary phrases should be added to the product label:

- Keep out of the reach of children (P102)
- Prevent access to bait by children, domesticated animals and pets, (particularly cats, dogs and pigs).

When these risk management measures are taken into consideration, the risk of secondary exposure for children is considered to be mitigated.

## **2.8 Risk assessment for the environment**

The product contains the active substance alphachloralose (4% w/w).

In addition to alphachloralose, the product contains SoC1 (0.005% w/w) and SoC2 (max 0.012% w/w). These substances have been identified as potential substances of concern

for the environment, with risk statements H410 for SoC1 and H412 for SoC2. These substances are not present in sufficient concentrations to the classification of the biocidal product according to Regulation EC 1272/2008. Therefore, there is no need to consider these substances further in the risk assessment.

In addition, alphachloralose is considered non-biodegradable and hydrolytically stable, and therefore metabolites are not considered in the risk assessment as their environmental risks are expected to be covered by the parent substance alphachloralose.

The intended use of Rentokil Alpha Rapid Bait Blocks is the professional control of mice indoors only. Risks of exposure of the active substance to groundwater, STP and the freshwater compartment through landfill, was determined and considered acceptable. As the active substance is not likely to bioaccumulate, the risk for secondary poisoning is expected to be negligible. Furthermore, as the active substance does not clearly fulfil the B criterion, it is not considered to be a PBT or vPvB substance. For details on the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.

**Overall conclusion for the aspect environment:** The conclusions in the risk assessment of the RMS are valid.

## 2.9 Measures to protect man, animals and the environment

Measure	In WG/GA	WG/GA (in Dutch)
For professional use only	Yes	<i>Het middel is uitsluitend bestemd voor professioneel gebruik.</i>
For indoor use only	Yes	<i>In afgesloten ruimten</i>
Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry).	Yes	<i>Plaats het lokaas in lokaasdozen buiten bereik van andere dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen</i>
For use only in tamper-resistant bait stations. Keep containers tightly closed and do not try to open boxes or use the material in any way other than as directed.	Yes	<i>Toegestaan is uitsluitend het gebruik als middel ter bestrijding van muizen <u>in afgesloten ruimten</u> met dien verstande, dat het middel moet worden uitgelegd in speciaal hiervoor bestemde lokaasdoosjes.</i>
Bait should be laid for periods of at most 7-10 days.	Yes	<i>Alpha Rapid Bait Blocks wordt toegepast voor bestrijdingsperioden van 7-10 dagen.</i>
Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children.	Yes	<i>Plaats het lokaas buiten bereik van dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen.</i>
Where possible, secure baits so that they cannot be dragged away.	Yes	<i>Het lokaas zo vast maken dat het niet weggesleept kan worden.</i>
Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.	Yes	<i>Dode dieren verzamelen en in plastic verpakt in het vuilnisvat deponeren, opdat huisdieren en andere dieren niet door het opeten van de kadavers worden vergiftigd.</i>
Dispose of dead rodents in accordance with local requirements. In the UK	Yes	

<p>poisoned rodents may be disposed of by the waste producer at an incinerator or landfill permitted to accept that type of waste, or collected by a registered waste carrier and taken for disposal at a suitably permitted site. For further information on disposal contact the Environment Agency (<a href="http://www.environment-agency.gov.uk">http://www.environment-agency.gov.uk</a>) or SEPA (<a href="http://www.sepa.org.uk">http://www.sepa.org.uk</a>).</p>		
<p>Particulars of likely direct or indirect adverse effects and first aid instructions –</p> <p>Excessive concentrations may cause nervous system depression, cv headache and weakness leading to unconsciousness. No antidote. Treat symptomatically</p>	<p>Nee</p>	<p><i>The first aid measures are usually not included in WG/GA, unless it concerns a specific antidote (which is not available in this case).</i></p>
<p><b>Additional:</b></p>		
		<p><i>Na gebruik handen wassen</i></p>
		<p><i>Het gebruik van dit middel is alleen toegestaan indien het een onderdeel vormt van een integrated pest management systeem (IPM).</i></p>
		<p><i>Het product is minder effectief bij temperaturen boven de 16°C</i></p>
		<p><i>De lokaasdozen niet toepassen in de buurt van waterafvoersystemen waar het middel met water in contact kan komen</i></p>
		<p><i>Katten en honden tijdens een bestrijdingsactie extra goed voeren</i></p>



### 3 Proposal for decision

The authorisation of Rentokil Alpha Rapid Bait Blocks is based on mutual recognition of the authorisation 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 concluded that the application of Rentokil Alpha Rapid Bait Blocks according to the use instructions, will be effective and that there will be no harm for the health of humans 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:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS09	Signal word:	Warning
H-statements:	H400	Very toxic to aquatic life.	
P-statements:	P102	Keep out of the reach of children	
	P273	Avoid release to the environment	
	P501	Dispose of contents/container to hazardous or special waste collection point	
Supplemental Hazard information:	-	-	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable