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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Rentokil RapidPro
(Alpha Paste)

Product type 14

Alphachloralose

Case Number in R4BP: BC-CS005323-43

Evaluating Competent Authority: Belgium

Initial PAR Date: 10/2016

MIC Date: 08/2022

Table of Contents

OVERVIEW OF APPLICATIONS

Overview regarding all relevant applications

Application type	refMS	cMS	Case number in the refMS	Decision date	Assessment carried out
NA-APP	BE	AT, DK, FR, DE, IE, IT, LT, NL, NO, PT, CH, ~~UK~~, ES	BC-CS005323-43	07/10/2016	First authorisation (and NA-MRP)
NA-ADC (grouped submission)	BE	LU, DK, ~~UK~~, DE, CH, FR, ES	BC-KC030472-61	10/05/2017	Addition of a manufacturer of the active substance: Lodi SAS + Only in FR, change of the biocidal product name
NA-TRS	BE	AT, CH, DE, DK, ES, FR, IE, IT, LU, LT, NO, NL, PT	BC-FL044295-38	09/07/2019	Transfer of the authorisation to a new holder established in the European Economic Area (EEA): Rentokil Initial Limited
NA-ADC	IT	IT	BC-XK061101-40	23/07/2020	Addition of a trade name, RattiPro
NA-MIC (grouped submission)	BE	IT	BC-GH074931-39	On going	Increase shelf life from 12 months to 24 months
/	BE	RO	/	On going	NA-MRS (BC-EF074530-55) submitted in RO 21/03/2022

1 CONCLUSION

The product can be authorised for use as an indoor rodenticide (PT14) for professional use against mice only. Optimal efficacy is achieved at low room temperatures, i.e. preferably as low as or lower than +16°C. The product is efficacious at +16°C±2°C and not at +21°C±2°C, according to the 90 % criteria defined by TNsG. Please note that the influence of temperature on the efficacy of the a.s/product has been clearly established and reported in the CAR for alphachloralose and in this dossier. Therefore, PCO have to take this parameter into account in order to achieve an optimal efficacy of the product.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
Trade name: Rentokil RapidPro IUCLID Dossier name: Alpha Paste[1] R4BP3 product name: Rentokil Rapid Pro	BE

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Rentokil Initial Ltd.
	Address	Hazel House Millennium Park - Naas IE
	Contact	[redacted]
Authorisation number	BE2016-0006	
Date of the authorisation	07/10/2016	
Expiry date of the authorisation	06/10/2026	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Rentokil Initial Supplies
Address of manufacturer	Webber Road Knowsley Industrial Park Kirkby Merseyside, L33 7SR United Kingdom
Location of manufacturing sites	Webber Road Knowsley Industrial Park Kirkby Merseyside, L33 7SR United Kingdom

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

Active substance	Alphachloralose
Name of manufacturer	SBM Développement S.A.S.
Address of manufacturer	60 chemin des Mouilles – 69130 Ecully / FRANCE
Location of manufacturing sites	Excel Estate, S.V. Road, Goregaon (West),

[1] Initially the dossier was filed under the name 'Rentokil Alpha Paste' but during the evaluation phase the applicant decided to introduce the trade name 'Rentokil RapidPro', this name will be used throughout this PAR since it is the only name that will be used on the Belgian market and this way coherence between PAR, SPC, Labels & safety data sheets is ensured. All the test reports that were submitted by the applicant refer to 'Rentokil Alpha Paste', this name has also been upheld for the IUCLID dossier.

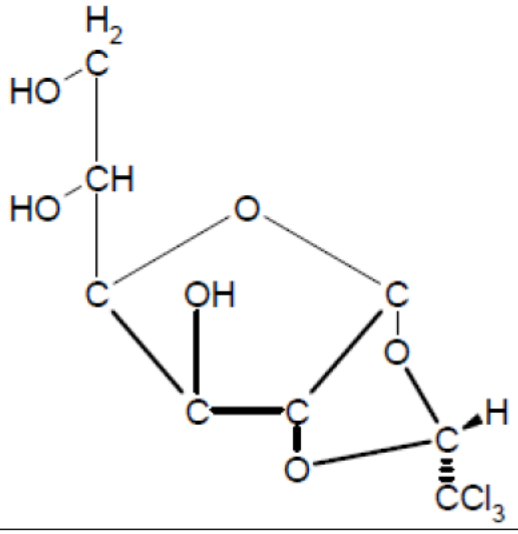
	MUMBAI - 400 062 - INDIA
Name of manufacturer	Lodi S.A.S
Address of manufacturer	Parc d'Activites des Quatre Routes 35390 Le Grand Fougeray France
Location of manufacturing sites	LODI Group Site HIKAL Ltd. T-21. MIDC Industrial Area Taloja Raigad District 410208 Maharashtra India

2.1.2 Product composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Alphachloralose[2]
IUPAC or EC name	(R)-1,2-O-(2,2,2-Trichloroethylidene)-α-D-glucofuranose
EC number	240-016-7
CAS number	15879-93-3
Index number in Annex VI of CLP	605-013-00-0
Minimum purity / content	≥ 825 g/kg alphachloralose The specification for purity is based on the combined concentration of both isomers. This isomeric composition of Chloralose is made up of ≥ 85% alphachloralose (≥97% w/w) and ≤15% betachloralose (CAS 16376-36-6). ßetachloralose was proven to have no activity. Alphachloralose does not contain other impurities above or equal to the concentration limit of 0.1 %w/w.
Structural formula	

[2] Some confusion exists whether to use 'alphachloralose' or 'chloralose' when referring to the substance, in principle only the R-isomer (alphachloralose) is the active substance but the mixture including 15% of the S-isomer betachloralose is also often referred to as 'alphachloralose'. While 'chloralose' is sometimes also used for solely 'alphachloralose'. Commission directive 2009/93/EC, the inclusion directive for the active substance Alphachloralose refers only to alphacloralolse as the R-isomer with the appropriate CAS number and a minimal purity of 825g/kg, hence considering beta chloralose rather as an impurity to alphaachloralose than as a compound in a mixture of different isomers. In this PAR we will refer to alphachloralose as such and only refer to the pure (R)-isomer when explicitly mentioned.

2.1.2.2 Candidate(s) for substitution

Not applicable, alphachloralose is not a candidate for substitution.

2.1.2.3 Quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
Alphachloralose	(R)-1,2-O-(2,2,2-Trichloroethylidene)-a-D-glucofuranose	Active substance	15879-93-3	240-016-7	3.996

Full composition available in confidential annex.

2.1.2.4 Information on the substance(s) of concern

The product contains no SoC's.

2.1.2.5 Type of formulation

RB – product is a ready to use bait in the form of a paste

2.1.3 Hazard and precautionary statements

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

Classification		
Hazard category	Aquatic Acute 1; Aquatic chronic 1	
Hazard statement	Very toxic to aquatic life (H400); very toxic to aquatic life with long lasting effects (H410)	
Labelling		
Signal words	Warning	
Hazard statements	Very toxic to aquatic life with long lasting effects (H410)	
Precautionary statements	P273: P391: P501:	Avoid release to the environment Collect spillage Dispose of contents/container in accordance with local/regional/national requirements.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Professionial indoor control of mice

Product Type	14, rodenticides
Where relevant, an exact description of the authorised use	Professional indoor control of house mice.
Target organism (including development stage)	house mouse (*Mus musculus*), all stages.
Field of use	Indoor For use indoors only.
Application method	Method: Bait application

	Detailed description: VI.2.1 Bait stations (covered application)
Application rate	Application Rate: Up to 8g per bait point. Dilution (%): Number and timing of application: Up to 8g per bait box (2 x4g) applied with a caulking gun applicator. The number of bait boxes used is dependent on the site of treatment, the context location, the size and severity of the infestation. Place bait boxes 2 to 3 metres apart (3 metres apart in case of low infestation to 2 metres apart in case of high mouse infestation) Check bait boxes frequently. Replace any eaten bait. Replace bait until consumption stops. Replace any mouldy or contaminated bait. The dose or the number of sachets placed per bait station must be adapted to the validated application rates. Inspect and replenish at regular intervals. If all bait is eaten, increase number of bait boxes and / or visit frequency. Bait should be laid for periods of at most 7 – 10 days. If control is not achieved, survey site again to establish reasons and consider re-siting or increasing bait boxes.
Category(ies) of users	Professional users
Pack sizes and packaging material	300g HDPE tube 400g HDPE tube. HDPE tube for use with caulking gun

2.1.4.2 Use-specific instructions for use

See General directions for use

2.1.4.3 Use-specific risk mitigation measures

See General directions for use

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

See General directions for use

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

See General directions for use

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

See General directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read label before use and follow instructions. Before using this product, make sure you have the required training or have received the necessary instructions.

The product must not be used indiscriminately.A thorough survey of the infested area is essential, particularly in secluded and sheltered places,to determine the extent of the infestation.

Do not eat, drink or smoke while handling this product. Wash hands and directly exposed skin after handling product and before eating, drinking,smoking.

Place bait boxes where the rodents are seen in or near burrows and harbourages, on runs and places where they find food or gnaw.

The bait must be placed inside bait boxes out of reach of children, birds, pets and other non-target animals.

Bait boxes must be clearly marked to show that they contain rodenticides and must not be disturbed.

Remove all baits after treatment.

When control has been achieved, consider control measures (plug holes, remove potential food, etc.) to reduce the likelihood of reinvasion.
Optimal efficacy is achieved at low room temperatures, i.e. preferably as low as or lower than 16°C.

The delay of action is between 24-48h.

Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.

Dead rodent bodies, remains of unused bait or any fragments of bait must be disposed of in accordance with local requirements.

2.1.5.2 Risk mitigation measures

Do not place bait boxes near water drainage systems where they can come into contact with water.

To maximize the bait take, ensure that alternative food sources have been removed wherever possible.

Do not use product where it can come into contact with food, drinking water, animal feeding stuffs, utensils that have contact with food.

Do not clean bait boxes between applications.

Rodents can be disease carriers (e.g. Leptospirosis). Wear adequate protective gloves when disposing off dead rodents.

Minimum information to be given on the bait box: Name and telephone number of the company responsible for the treatment, product name and maximum amount of product used (in the bait box), name and concentration of the active substance and the text:"In case of accidents or if you feel unwell, seek medical advice or contact the Poisons Information Centre”

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

Excessive concentrations may cause nervous system depression, headache and weakness leading to unconsciousness. No antidote. Treat symptomatically. If swallowed, seek medical advice immediately and show this container or label.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Remove all baits after treatment and dispose of them in accordance with local and regional requirements. Dispose of contents/container in accordance with local and regional requirements

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

Store product only in closed, original container in a dry, cool place.Keep away from children and non-target animals.Keep away from food, drink and animal feeding stuff. Stability: 24 months.

2.1.6 Other information

This product is hazardous to wildlife.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Tube	400g	HDPE	HDPE cut-off cap	Professional	Yes
Tube	300g	HDPE	HDPE cut-off cap	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The applicant has submitted the results of additional efficacy testing an accellerated storage stability trials performed with the product Rentokil RapidPro. A succint listing of these new data is available in annex 3.1. All additional test results have been included in the IUCLID file.

2.1.8.2 Access to documentation

A letter of access has been submitted by the applicant stating that Physalys sarl grants the applicant the right to refer to and use all the data on the active substance alphachloralose and the reference product included in the application for the annex 1 listing under directive 98/8/EC and subsequently approval under regulation (EU) no. 528/2012

2.2 Assessment of the biocidal product

2.2.1 Intended uses applied for by the applicant

Table 2. Intended use # 1 – Professional mice control

Product Type	14
Where relevant, an exact description of the authorised use	Control of mice (*Mus musculus*) indoor by professionals
Target organism (including development stage)	Mice (*Mus musculus)* juvenile and adult stages
Field of use	Pest control
Application method(s)	Ready to use bait as a paste to be applied in tamper resistant bait boxes with a caulking gun.
Application rate(s) and frequency	Place bait boxes 3 meters apart in case of a low infestation to 2 meters apart in case of high mouse infestation.
Category(ies) of user(s)	professionals
Pack sizes and packaging material	400g & 300g HDPE tubes;

2.2.2 Physical, chemical and technical properties

Initial assessment (2016)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	/	/	Solid paste	Doc IIIB: B3_1
Colour at 20 °C and 101.3 kPa	/	/	Green	Doc IIIB: B3_1
Odour at 20 °C and 101.3 kPa	/	/	No detectable odour	Doc IIIB: B3_1
Acidity / alkalinity	Rentokil RapidPro is a solid paste bait product thus a 1% aqueous solution, an emulsion or dispersion cannot be made. We therefore cannot measure the acidity/alkalinity of Rentokil RapidPro. Doc IIIB: B3_5			
Relative density / bulk density	Rentokil RapidPro is a solid paste bait formulation, and therefore do not meet the criteria for requiring relative density to be measured Doc IIIB: B3_6			
Storage stability test – **accelerated storage**	CIPAC Method MT46.3: 2 weeks accelerated storage trial at 54 ±2°C	Rentokil RapidPro: 3.9% Alphahloralose	T0 (10/11/2014): 3.743% w/w T2 (24/11/2014): 3.587% 4.2% reduction in active ingredient content: Ok Pack type: 400g plastic tube	Rentokil Initial 1927 plc, 2014 Doc IIIB: B3_7_01
Storage stability test – long term storage at ambient temperature	12 month ambient aged sample, analysed by	Identical to specification given in section 2. Total chloralose: 3.996%w/w	Content after 12 months: Alphachloralose: 3.242% m/m	B3.7/01_Feb2016 Rentokil Initial 1927 plc (2015) GSC Analytical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Reverse Phase Liquid Chromatography.		Betachloralose: 0.579% m/m Total chloralose: 3.821% m/m	Services Report Determination of Alpha-chloralose and Beta-chloralose in Alpha Paste by Reverse Phase Liquid Chromatography Storage Stability: 12 month SOP:AM 155, Issue 7 GARN E32 (Applicant's reference number ALPCHL 398)
Storage stability test – low temperature stability test for liquids	Not applicable: Rentokil RapidPro is a solid			
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	From the alphachloralose CAR "The US EPA method entitled Fate, Transport and Transformation Test Guidelines OPPTS 835.2210 Direct Photolysis Rate in Water by Sunlight states that the test method is applicable to all chemicals which have a UV/absorption maxima in the range of 290-800nm. Chloralose has a UV absorption maxima of 194.5 nm and accordingly to this the test is not technically feasible to perform." Therefore, Alphachloralose is not expected to undergo abiotic degradation by photolysis in water or to undergo degradation by sunlight.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	n/a			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	n/a			
Wettability	Rentokil RapidPro is not diluted for use			
Suspensibility, spontaneity and dispersion stability	n/a			
Wet sieve analysis and dry sieve test	n/a			
Emulsifiability, re-emulsifiability and emulsion stability	n/a			
Disintegration time	n/a			
Particle size distribution, content of dust/fines, attrition, friability	Rentokil RapidPro is supplied as a solid paste bait therefore it is not necessary to measure particle size. Doc IIIB: B3_11			
Persistent foaming	n/a			
Flowability/Pourability/Dustability	Rentokil RapidPro is a solid paste bate			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning rate — smoke generators	n/a			
Burning completeness — smoke generators	n/a			
Composition of smoke — smoke generators	n/a			
Spraying pattern — aerosols	n/a			
Physical compatibility	Rentokil RapidPro is a ready to use formulation. It is not designed to be used in conjunction with any other product or active ingredient. It is not expected to be incompatible with any other products or active substances. Doc IIIB: B3_9			
Chemical compatibility				
Degree of dissolution and dilution stability	n/a			
Surface tension	Surface tension is defined as the force acting on the surface of a liquid, tending to minimise the area of the surface. Rentokil RapidPro is a solid paste bait, therefore it is neither informative nor possible to measure the surface tension. Doc IIIB: B3.10_1			
Viscosity	Viscosity is a measure of the flowability of a liquid. RentokilRapidPro is a solid paste bait. Therefore it is neither informative nor possible to measure the viscosity of Rentokil RapidPro. Doc IIIB: B3.10_2			

Minor change (2022)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – long term storage at ambient temperature	24 month ambient aged sample, analysed by Reverse Phase Liquid Chromatography.	Alpha Paste – batch RMS268/2 (Identical to specification given in section 2.) 3.9% chloralose	Content values (% w/w): 1) Alpha-chloralose: Initial : 3.127 T6m : 3.353 (+7.23%) T12m : 3.242 (+3.68%) T18m : 3.320 (+6.17%) T24m : 3.412 (+9.11%) 2) Beta-chloralose: Initial : 0.569 T6m : 0.574 (+0.88%) T12m : 0.579 (+1.76%) T18m : 0.573 (+0.70%) T24m : 0.572 (+0.53%) 3) Total chloralose: Initial : 3.696 T6m : 3.927 (+6.3%)	[redacted] (2016), Report nr. 2016/244/99 [redacted] (2016a), Study nr. 244/99 [redacted] (2016b), Study nr. 244/99

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T12m : 3.821 (+3.4%) T18m : 3.893 (+5.3%) T24m : 3.984 (+7.8%) Weight change vs. Initial : T6m : +0.2 g T12m : +0.2 g T18m : + 0.3 g T24m : + 0.3 g Appearance: No visible change throughout the 24m duration of the test. Pack integrity and appearance: Initial: White plastic HDPE tube with pre-printed paper label stuck to tube T6m: No change T12-18-24m: No change apart from the white paper label which was *crinkly* yet still readable.	

Conclusion on the physical, chemical and technical properties of the product
The product is a ready to use green solid paste with no detectable odour. Accelerated 2 weeks storage stability test suggests that the product is stable for 24 months, which has been confirmed by ambient storage and efficacy palatability test results on the aged product.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	None of the components of Rentokil RapidPro are classified as explosive and all are stable under normal conditions.			
Flammable gases	Not applicable, Alpha PasteRapidPro is a solid			
Flammable aerosols	Not applicable, Rentokil RapidPro is a solid			
Oxidising gases	None of the components of Rentokil RapidPro are classified as oxidising and all are stable under normal conditions.			
Gases under pressure	Not applicable, Rentokil RapidPro is a solid			
Flammable liquids	Not applicable, Rentokil RapidPro is a solid			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable solids	None of the components of Rentokil RapidPro are classified as flammable and all are stable under normal conditions.			
Self-reactive substances and mixtures	n/a			
Pyrophoric liquids	n/a			
Pyrophoric solids	n/a			
Self-heating substances and mixtures	n/a			
Substances and mixtures which in contact with water emit flammable gases	n/a			
Oxidising liquids	n/a			
Oxidising solids	n/a			
Organic peroxides	n/a			
Corrosive to metals	n/a			
Auto-ignition temperatures of products (liquids and gases)	n/a			
Relative self-ignition temperature for solids	n/a			
Dust explosion hazard	n/a			

Conclusion on the physical hazards and respective characteristics of the product
The product has no physical hazards.

2.2.4 Methods for detection and identification

The product Rentokil RapidPro containing 3.966% m/m Alphachloralose (nominal)[3] was analysed by reversed phase liquid chromatography. The method consisted of sample dissolution in hexane, followed by partition into methanol then determination using HPLC. The method was fully validated on the basis of linearity, accuracy, precision, specificity.

The results of the analytical testing are reported in the tables below

[3] Including 0.6% m/m Betachloralose (nominal) as an impurity

Analytical methods for the analysis of the product as such including the active substance, impurities and residues										
Analyte	Analytical method	Number of measurements	Linearity	Specificity	Range	Mean % (m/m)	RSD	Recovery %	Limit of quantification (LOQ)	Reference
Alpha-chloralose[4]	Rentokil RapidPro analysed by reversed phase liquid chromatography	6 measurements	Pearson product moment correlation coefficient 0.998845	Fully specific to the analyte		3.34	2.24	101.52	0.09% (m/m)	Rentokil Initial 1927 plc, 2014 Doc IIIB: B4_1e
Beta-chloralose			Pearson product moment correlation coefficient 0.996824	Fully specific to the analyte		0.38	3.11	102.70	0.08% (m/m)	

Analytical methods for soil									
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
ADS: Letter of acces from Physalys to access data for alphachloralose: The analytical procedure consisted of extraction with acetone followed by liquid/liquid partition in dichloromethane. The extracts were then derivatised by Tri-Sil Z, reconstituted in hexane and then analysed by GC-MS using a SGE BPX5 column. LOQ is 0.05 mg/kg.									Doc IIIB: B4_2

Analytical methods for air									
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
ADS: Letter of acces from Physalys to access data for alphachloralose: Waived									Doc IIIB: B4_2

[4] pure

Analytical methods for water									
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
ADS: Letter of acces from Physalys to access data for alphachloralose: The method performed was analysis of alphachloralose and betachloralose standards, extracted from drinking water and surface water by retention on a C_{18} solid phase extraction cartridge and elution with acetone after drying. The extract was dissolved in HPLC mobile phase followed by determination by LC/MS/MS with mulitple reaction monitoring (MRM). LOQ is 0.1 µg/L									Doc IIIB: B4_2

Analytical methods for human body fluids and tisues									
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
ADS: Letter of acces from Physalys to access data for alphachloralose: Waived									Doc IIIB: B4_2

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
ADS: Letter of acces from Physalys to access data for alphachloralose: From plant origin: The analytical procedures consisted of extraction from cucumber, wheat, oil-seed rape and lemon with solvent followed by a clean up procedure, if appropriate, and determination by GC-ECD and GC-MS (except on wheat which was only by GC-ECD). The extracts were then									Doc IIIB: B4_2

derivatised by Tri-Sil Z. Quantification of extracts was performed by linear or quadratic regression using peak areas of external calibration standards or peak area ratios using an internal standard. LOQ of 0.01 mg/kg validated for cucumber From animal origin: The analytical procedures consisted of extraction from meat with solvent followed by a clean up procedure, if appropriate, and determination by GC-ECD and GC-MS. The extracts were then derivatised by Tri-Sil Z. Quantification of extracts was performed by linear or quadratic regression using peak areas of external calibration standards or peak area ratios using an internal standard. No LOQ validated.	

Conclusion on the methods for detection and identificationof the product
The methods discussed and evaluated in de alphachloralose CAR are applicable to this product as well.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG03: Pest Control
PT14 Rodenticides
Rentokil RapidPro is a ready-to-use solid pasta bait rodenticide containing 3.996% m/m of Alphahloralose (CAS N° 15879-93-3), fat blend and flour. The product does also contain an aversive agent (i.e. bitrex) and a green dye. The product is supplied in a tube (made of HDPE) which is applied via a caulking gun and is intended to be placed into a tamper resistant bait station (8g per bait box).
This product is intended to be used by professional operators to control mice (*Mus musculus* - code I.1.1.3) in buildings (including farm and horticulture buildings) only.

Rentokil RapidPro is not intended for use by the general public.

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

For the control of house mice (*Mus musculus*).

Rodent control has immeasurable benefits – preventing damage to the fabric of buildings, to electrical wiring and plumbing. Rodents cause enormous economic loss to farmers, food manufacturers and processors as well as causing damage to the structure and fabric of buildings. As well as actually eating food they damage packaging and packaged food, and also contaminate stored food with hairs droppings and urine. Also rodents cause considerable damage by gnawing and burrowing. Burrowing has caused land slips on railway embankments, and irrigation canals and caused dykes to cave in leading to flooding. Rodents will gnaw practically anything including plastic, lead, aluminium and even steel. The losses caused by gnawing depend on what is gnawed. It may be intrinsic loss of what is gnawed eg a painting, or loss may be as a consequence of gnawing; an elderly person was poisoned whilst asleep in bed by gas escaping from a pipe which had been gnawed. Electrical fires have started as a result of rodents gnawing cables

2.2.5.3 Effects on target organisms, including unacceptable suffering

Exposure of mice to alphachloralose results in a lowering of body temperature, causing the mouse to die of hypothermia. Because mice are small they have a large surface area in relation to their volume from which to lose heat.

Convulsive effects prior to insensibility have been reported when using alphachloralose as a pesticide. Convulsions are suggestive of extreme distress but these occur in relatively few animals. According to human data these convulsions are of shorter duration and far less extreme, than those induced by strychnine. Animals that ingest non-lethal doses of alphachloralose rapidly recover. Regarding this alphachloralose can be considered to be a relatively humane rodenticide for control of mice.

2.2.5.4 Mode of action, including time delay

Alphachloralose does kill mice by retarding 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

Pharmacological mode of action of Alphachloralose is based on sedation, CNS depression, narcosis, inducing death by hypothermia. Optimal efficacy is achieved at low room temperatures, i.e. preferably as low as or lower than +16°C, against small animals with rapid metabolism.

The delay of action is between 24h (with fresh baits) and 5 days (with 12 months-aged baits).

2.2.5.5 Efficacy data

2.2.5.5.1 Efficacy data on the representative product of the Alphachloralose CAR

Alphablock (a RTU fat based bait solid block) is the accompanying product in the Assessment Report for inclusion to Annex I, which also contains 3.996% w/w Alphachloralose.
Several lab choice-tests were performed on mice at 16°C and 21°C to evaluate the palatability and efficacy of fresh and 2-week accelerated aged ***Alphablock*** (4% w/w) : regardless temperature, complete mortality was accomplished in 29.5 hours. Laboratory tirals showed that efficacy is not affected by temperature in the range used (16°C and 21°C). The palatability is unaffected when using two week accelerated aged samples.

Efficacy of *Alphablock*				
Test organism	Test conditions	Results	Comments	Reference[5]
Mus musculus Albino TO	Palatability and Efficacy of Fresh ***Alphablock*** 4% Bait at +16°C (+/- 2°C) or at +21°C (+/- 2°C). Choice test with fresh bait/ Test period 4 days /5♀ + 5♂	At +16°C : • 100% mortality within 22 h • Mean bait intake (of the total food consumption) = 17.7% At +21°C : • 100% mortality within 22 h • Mean bait intake (of the total food consumption) = 41.1%	Requirements according requirements in the TN_sG PT14 Product Evaluation : - Mean bait intake (of the total food consumption) > 20%* - Mortality > 90% within 20 days In trials performed with fresh samples at +16°C, the intake of contaminated food was 17.7% and 15.4% of the total food consumption. As the final mortality was 100% in both trials, this can be accepted.	Doc IIIB_B5.10.2
Mus musculus Albino TO	Palatability and Efficacy of 2-week accelerated aged ***Alphablock*** 4% Bait at +16°C (+/- 2°C) or at +21°C (+/- 2°C). Choice test with 2-week accelerated aged bait/ Test period 4 days /5♀ + 5♂	At +16°C : • 100% mortality within 29.5 h • Mean bait intake (of the total food consumption) = 15.4% At +21°C : • 100% mortality within 24 h • Mean bait intake (of the total food consumption) = 24.1%		

No field studies were performed.

Conclusion : Laboratory studies have demonstrated a sufficient degree of efficacy of alphachlorahloralose (3.996% w/w) against mice.

[5] References to the Alphachloralose CAR

2.2.5.5.2 Efficacy tests on Rentokil RapidPro

An efficacy/palatability lab test on fresh Rentokil RapidPro has been conducted in order to compare this new improved formulation against an existing product Rentokil RapidPro with mice according requirements in the TNsG Product Evaluation for PT14.

Results are resumed below:

Test organism	Test conditions	Results	Comments	Reference[6]
Mus musculus Albino TO	Bioassay : Palatability and Efficacy of Fresh Rentokil RapidPro Choice test with fresh bait (/powdered lab diet) : - Test period 4 days - At +21°C (+/- 2°C) - With 10♀ and 10♂ TO mice in individual cages - Acclimatisation for 72h	Rentokil RapidPro 0100% mortality not reached within 4 days (only 50% mortality within 4 days)	/	Technical Report 2014/248/39
Mus musculus Albino TO	Comparative bioassay : Palatability and Efficacy of Fresh Rentokil RapidPro Choice test with fresh bait (/powdered lab diet) : - Test period 4 days - At 16°C (+/- 2°C) - With 10♀ and 10♂ TO mice in individual cages - Acclimatisation for 72h	Rentokil RapidPro • 100% mortality within 24 h • Mean bait intake (of the total food consumption) = 23%	According to requirements in the TN_sG Product Evaluation, all the results are acceptable: - Mean bait intake (of the total food consumption) > 20% - Mortality > 90% within 20 days	Technical Report 2014/248/47
Mus musculus Oaklease wild mice	Comparative bioassay : Palatability and Efficacy of aged (12 months at ambient temperature) Rentokil RapidPro Choice test with fresh bait (/powdered lab diet) : - Test period 4 days - At 16°C (+/- 2°C) - With 12 mice in individual cages - Acclimatisation for 72h	Rentokil RapidPro • 100% mortality within 5 days . • Mean bait intake (of the total food consumption) = 27%	According to requirements in the TN_sG Product Evaluation, all the results are acceptable: - Mean bait intake (of the total food consumption) > 20% - Mortality > 90% within 20 days	Technical Report 2014/248/50

According to the results of the efficacy tests, efficacy has only been tested at +16°C±2°C and +21°C±2°C. From a scientific point of view, the only overall conclusion possible should be : "The product is efficacious at +16°C±2°C and not at +21°C±2°C, according to the 90 % criteria defined by TNsG".Optimal efficacy is then achieved at low room temperatures, i.e. preferably as low as or lower than +16°C

Three field trials have been submitted on support of fresh Rentokil RapidPro and were carried out on mice (*Mus domesticus*).

6 The references in this table and the next are refer to documents in the Alpha Paste dossier

Results are resumed below:

Test organism +	Test conditions	Results	Comments	Reference

MICE (*Mus domesticus*)	Efficacy of Fresh Rentokil RapidPro in a **Field trial** – at an animal feed manufacturer SCA Nutrition Nutech, Naas, Co Kildare (Ireland) : - With a very large mouse infestation - The trial site have a large amount of food sources available to mice - Mice have been seen by workers and Rentokil personnel and droppings and gnawing damage are evident in many parts of the building - Measure of mouse activity with infra-red detection unit (3 days) - Test carried out in 7 areas with 156 bait boxes (with 8g Rentokil RapidPro each) deployed / 93 m^2 ⇔ 1.6 bait boxes / m^2 - Treatment baits were in place for 6 days	Method and report with a lot of details. Efficacy based on total census bait take = 90.6% (processing areas of the site) with dead mice observed in the vicinity of the bait boxes. = 80% (in 2 areas where re-infestation from external sources was strongly suspected) CONCLUSION : 1.6 bait boxes (with 8g Rentokil RapidPro each) / m^2 is quickly effective against house mice infestation even in case of a very large mouse infestation and in the presence of huge amounts of alternative food sources.	Reliability 2 (study not conducted to GLP standards)	Technical Report 2014/AP1

MICE (*MUS DOMESTICUS*)	Efficacy of Fresh Rentokil RapidPro in a **Field trial** – at Kilashee House Hotel, Naas, Co Kildare (Ireland) in 2 sites (Gymnasium canteen and Grayden Wing Boiler Room and Basement) : - With a discreet infestations of house mice - Mice have been seen by hotel staff in several areas - Measure of mouse activity with infra-red detection unit (3 days) - Two trial sites with a certain amount of food sources (i.e. with a discarded room service) available to mice : ➢ Gymnasium canteen : 15 bait boxes (with 8g Rentokil RapidPro each) ⇔ 1 bait box / m^2 ➢ Grayden Wing Boiler Room and Basement : 48 bait boxes (with 8g Rentokil RapidPro each) ⇔ 1.7 bait boxes / m^2 - Treatment baits were in place for 7 days	Method and report with a lot of details. Efficacy based on total census bait take = 100% CONCLUSION : 1-1.7 bait boxes (with 8g Rentokil RapidPro each) / m^2 is quickly effective against house mice even in the presence of huge amounts of alternative food sources.	Reliability 2 (study not conducted to GLP standards)	Technical Report 2014/AP2
MICE (*Mus domesticus*)	Efficacy of Fresh Rentokil RapidPro in a **Field trial** – at an animal feed and fertilizer manufacturer (Grennan's, Rath, Co Offaly, Ireland) : - With a moderate mouse infestation - The trial site have a large amount of food sources available to mice - Mice have been seen by workers and Rentokil personnel and droppings and urine pillars are evident in many parts of the building - Measure of mouse activity with infra-red detection unit (3 days) - Test carried out in 4 areas with 120 bait boxes (with 8g Rentokil RapidPro each) deployed / 110 m^2 ⇔ 1 bait box / m^2 - Treatment baits were in place for 14 days	Method and report with a lot of details. Efficacy based on total census bait take = 96.3% (processing areas of the site) with dead mice observed in the vicinity of the bait boxes. = 83.5% (including boiler house with the largest mouse infestation and higher temperature) CONCLUSION : 1 bait box (with 8g Rentokil RapidPro each) / m^2 is quickly effective against house mice	Reliability 2 (study not conducted to GLP standards)	Technical Report 2015/AP3

Minor change 2022 : increase shelf life from 12 months to 24 months

Mus musculus Albino TO	Bioassay : Palatability and Efficacy with 24 months stored Rentokil RapidPro Choice test with 24 months old bait (vs powdered lab diet) : - Test period 4 days - At 16°C (+/- 2°C) - With 5♀ and 5♂ TO mice in individual cages - Acclimatisation for 72h	Rentokil RapidPro 90% mortality reached within 4 days	Chloralose is a fast acting rodenticide.	Technical Report 2016/248/51

For rodenticide bait products without preservatives, palatability is assessed in a bait choice feeding test after the claimed shelf life. In this case, comparison with normal food intake is inappropriate. Since for a fastacting rodenticides a reduction in feeding activity is caused when only very small quantities of bait are required to cause effect. Therefore, the main criterion is not the percentage of consumed bait but the mortality resulting from poison uptake.
In the bait choice feeding test, where 24 months product stored at ambient temperature is used, 90% mortality is achieved, supporting the shelf life of 24 months.

Conclusion on the efficacy of the product
The BE MRS considers that the results demonstrate that fresh and aged (24 months at ambient temperature) Rentokil RapidPro with 3.996% w/w of Alphachloralose has a very good efficacy against house mice (*Mus domesticus*): One bait box (with 8g Rentokil RapidPro each) / m^2 is quickly effective to control house mice (Mus domesticus) even in case of a moderate mouse infestation. 2 bait boxes/m^2 may be considered in case of high infestation: place bait boxes (with 8g Rentokil RapidPro each) 3 meters apart in case of a low infestation to 2 meters apart in case of high mouse infestation..

2.2.5.6 Occurrence of resistance and resistance management

Statement mentioned in the CAR : "There are no reports of resistance to Alphachloralose found. There have been reports that mice can build up tolerance. Results from trials performed using 2% w/w bait and from trial performed with Wild-derived mice, group-housed in a pen using 4% w/w Alphachloralose bait may indicate some kind of behavioural resistance or tolerance. In order to assess these issue further tests should be performed"

2.2.5.7 Known limitations

Boxes containing bait should be placed in protected situations.
Even if the product is demonstrated effective in the presence of huge amounts of alternative food, preferably apply treatment in rooms without alternative food sources.
The product is efficacious at +16°C±2°C and not at +21°C±2°C, according to the 90 % criteria defined by TNsG..

- Optimal efficacy is achieved at low room temperatures, i.e. preferably as low as or lower than +16°C : Apply in rooms preferably at temperatures below +16°C (i.e. not near hot pipes, ovens etc).
- Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

2.2.5.8 Evaluation of the label claims

The label claim ‘Indoor control of house mice. Professional use only’ is acceptable and fully supported by the submitted test reports and documentation.

Applicable label claims/restrictions:

Only for indoor treatment
Only for house mice
Application rate : place bait boxes (with 8g Rentokil RapidPro each) 3 meters apart in case of a low infestation to 2 meters apart in case of high mouse infestation.
For optimal results :
- Optimal efficacy is achieved at low room temperatures, i.e. preferably as low as or lower than +16°C (i.e. not near hotpipes, ovens etc).

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

Not applicable

2.2.6 Risk assessment for human health

Remark from the e-MS:
The product under evaluation is not identical to the reference product from the CAR both are nonetheless very similar. 2 crucial properties are the identical: the active substance content and the application as a mouse-bait. Given the high degree of similarity no additional testing has been asked nor submitted for the evaluation of Rentokil RapidPro consequently the risk assessment for human health has been performed relying solely on data from the alphachloralose CAR.

Alphachloralose classification will change, as a RAC opinion with the following classification of alphachloralose has been adopted: H301, H336, H400, H410, M= 10 (acute and chronic). In the present evaluation we followed the harmonised classification until the new proposal is endorsed. The new classification will not change classification of the product (regarding toxicology).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation
The formulation of Rentokil RapidPro is based on food stuffs fit for human consumption. Two component, Bitrex and Butylated hyroxyanisole (BHA) are classified as hazardous according to the Classification, Labelling and Packaging Regulation (CLP/GHS), Regulation (EC) N°1272/2008 (Skin irrit. 2, H315). These component are present at less than the CLP generic cut-off limits of 1% (Annex I, part 1.1.2.).
No consideration need be taken to these components and the information provided for the active substance can be used for the product (see below).

Test on active substance

Skin irritation properties of active substance were observed in 3 animals (rabbit). After an exposure period of 4 hours, all bindings were removed and the remaining test susbstance was removed with a dray gauze patch. Very slight erythema was noted within 48h. It not reach criteria for classification.
It is concluded that alphachloralose is not irritating to the rabbit skin.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, Duration of exposure	Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings	**Remarks** (e.g. major deviations)	Reference[7]
EC Method B.4. GLP 1	Rabbit New Zealand White 3/groups	Vehicle: water Dose: single dose of 500 mg Vehicle : water (0.5 ml) 4h exposure Post exposure observation: 1, 24, 48 and 72 hrs.	Erythema: 24h: 0.6 48h: 0.3 72h: 0.0 Edema: 24h: 0.0 48h: 0.0 72h: 0.0 Reversibility: No Very slight erythema was noted within 48h.	As the mean scores for erythema and for 2 out of 3 animals did not reach the criteria values for irritation, under the test conditions alphachloralose	DocIIIA_ A6 1.4

[7] All references made in this chapter are references to the alphachloralose CAR

				is considered as non irritant when administered by the cutaneous route	

Human data not available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The active substance is not irritating. Two substances (Bitrex and BHA) are classified in this category but there are under the CLP generic cut-off limit of 1%.
Classification of the product according to CLP and DSD	None

Eye irritation
The formulation of Rentokil RapidPro is based on food stuffs fit for human consumption. Two component, Bitrex and, Butylated hyroxyanisole (BHA) are classified as hazardous according to the Classification, Labelling and Packaging Regulation (CLP/GHS), Regulation (EC) N°1272/2008 (respectively Eye dam. 1, H318 and Eye irrit. 2, H315). These component are present at less than the CLP generic cut-off limits of 1% (Annex I, part 1.1.2.).
No consideration need be taken to these components and the information provided for the active substance can be used for the product (see below).

Test on active substance

Test substance was applied on the left eye of 3 rabbits new Zealand white at dose 100 mg. the right eye of the test animal remained untreated, and served as control. No ocular reactions were observed.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance,Dose levels, Duration of exposure	Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility	**Remarks** (e.g. major deviations)	Reference [8]
EC Method B5 GLP 1	Rabbit New Zealand white 3/group	As given in section 2. 100 mg 72 h exposure The right eye of the test animal remained untreated, and served as control.	Cornea: 24h: 0.0 48h: 0.0 72h: 0.0 Iris: 24h: 0.0 48h: 0.0 72h: 0.0 Conjunctiva; redness: 24h: 0.0 48h: 0.0 72h: 0.0	Under test conditions chloralose is considered as non irritant when administered by the ocular route	Doc IIIA_A6.1.4b

[8] All references made in this chapter are references to the alphachloralose CAR

			Conjunctiva; chemosis: 24h: 0.0 48h: 0.0 72h: 0.0 Reversibility: N/A. No effects observed		

No human data available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The two substances classified in this category are below the CLP generic cut-off limits of 1% (Annex I, part 1.1.2.). The active substance is not eye irritant.
Classification of the product according to CLP and DSD	None

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	No studies are available but the product is not expected to cause any irritation of the respiratory tract. Due to its physical state (a very viscous liquid) and the physical & chemical properties of the various substances in its composition inhalation exposure is not likely to occur. According to the harmonized classification and labelling of alphachloralose, the active ingredient is not irritant to the respiratory tract.
Classification of the product according to CLP and DSD	none

Skin sensitization

None of the components of Rentokil RapidPro are classified as a sensitiser according to Directive 67/548/EC. Alphachloralose was tested for sensitising potential using the Guinea pig maximisation test and was found negative (see below). Because Rentokil RapidPro does not contain any components that are known sensitisers, and there are no reactions know between the components that would result in a sensitiser, it is not considered necessary to test the product for sensitising potential.

Test on active substance

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, duration of exposure Route of exposure *(topical/intradermal, if relevant)*	Results (EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)	Remarks (e.g. major deviations)	Reference [9]
EC Method B.6 GLP 1	Guinea pigs, Dunkin-Hartley Test group:10 M and 10 F. Controlpositive: 5M & 5F (Dinitro-2,4 Chlorobenzene) Controle negative: 5M &5F	Alphachloralose Adjuvant Intradermal injection 1% alphachloralose in sterile isotonic aqueous NaCl solution at 0.9% Topical challenge 500 mg alphachloralose. In it's original form	0/10 animals showed signs of allergic reaction 24 h after challenge 0/10 animals showed signs of allergic reaction 48h after challenge. Under experimental conditions, and according to the maximisation method established by Magnusson and Kligman, no cutaneous reactions attributable to the sensitisation potential of the test substance alphachloralose, were observed in guinea pigs. It is concluded that alphachloralose is not a skin sensitiser in guinea pigs.		Doc IIIA_A6 1.5

No human data available

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitizing
Justification for the value/conclusion	No cutaneous reactions attributable to the active substance was observe in the Magnusson and Kligman sensitizing test study in guinea pig. Since Rentokil RapidPro contain no other substance knows as skin sentiziser and there are no reactions know between the components that would result in a sensitiser.
Classification of the product according to CLP and DSD	None

[9] All references made in this chapter are references to the alphachloralose CAR

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	
Justification for the value/conclusion	No studies are available but the product is not expected to cause any respiratorysensitization. Due to its physical state (a very viscous liquid) and the physical & chemical properties of the various substances in its composition inhalation exposure is not likely to occur. According to the harmonized classification and labelling of alphachloralose, the active substance is is not a respiratory sensitizer.
Classification of the product according to CLP and DSD	None

Acute toxicity
Acute toxicity by oral route
The formulation of Rentokil RapidPro is based on food stuffs fit for human consumption. The only hazardous component where the hazard carries through to the product is the active substance alphachloralose (Acute tox. 4, H302). Two other component Bitrex and Butylated hyroxyanisole (BHA) are also classified as hazardous according to the Classification, Labelling and Packaging Regulation (CLP/GHS), Regulation (EC) N°1272/2008 (Acute tox. 4, H302). These component are present at less than the CLP generic No consideration need be taken to these components and the information provided for the active substance can be used for the product (see below).

Test on active substance

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	Species, Strain, Sex, No/group	Test substance Dose levelsType of administration *(gavage, in diet, other)*	**Signs of toxicity** (nature, onset, duration, severity, reversibility)	Value LD50	**Remarks** (e.g. major deviations)	Reference [10]
EC method B1 GLP 1	Rat Sprague-Dawley CD (SD) BR 10 ind /sex/group	Dose level: 125, 200, 320, 2000 mg/kg bw/day Applied as a single dose. Post exposure period was 14 days.	Sedation, lateral decubitus, dyspnoea and coma were observed within the hours following administration of the test substance at the doses of 125, 200 and 320 mg/kg. Clinical signs had reversed on day 2. At 2000 mg/kg tonic and clonic convulsions were noted before death of animals. The rate of death was 10%, 10%, 50% and 100% at 125, 200, 320 and 2000 mg/kg respectively. Deaths were noted within 4 hours post-treatment.	Males: 611 mg/kg Females: 212 mg/kg Combined : 341 mg/kg	At 200 mg/kg the mortality rate was 10%	DocIIIA _A6.1.1

Value used in the Risk Assessment – Acute oral toxicity	
Value	341 mg/kg bw.
Justification for the selected value	/
Classification of the product according to CLP and DSD	-Active substance has an oral LD_{50} 341 mg/kg. At 3.996%, this is not trigger classification in this category for the product RapidPro according the calculation by additivity formula (Annex I, part 3.1.3.6 Regulation (EC) N°1272/2008).

[10] All references made in this chapter are references to the alphachloralose CAR

Acute toxicity by inhalation
The formulation of Rentokil RapidPro is based on food stuffs fit for human consumption.
The only hazardous component where the hazard carries through to the product is the active substance alphachloralose (Acute tox 4, H332). Bitrex is also classified as hazardous according to the Classification, Labelling and Packaging Regulation (CLP/GHS), Regulation (EC) N°1272/2008 (Acute tox. 4, H332). This component is present at less than the CLP generic cut-off limits of 1% (Annex I, part 1.1.2.).
No consideration need be taken to this component and the information provided for the active substance can be used for the product (see below).

Test on active substance

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	Species, Strain, Sex, No/group	Test substance, form *(gas, vapour, dust, mist)* and particle size (MMAD) Actual and nominal concentration, Type of administration *(nose only / whole body/ head only)*	**Signs of toxicity** (nature, onset, duration, severity, reversibility)	LC50	**Remarks** (e.g. major deviations)	Reference[11]
EC Method B.2. GLP 1	Rat Sprague-Dawley ICO: OFA SD (IOPS Caw) 3 groups of 10 animals 5 ind /sex/group	1.04 mg/L 1.99 mg/L 4.55 mg/L Applied for 4 hours. Post exposure period of 14 days.	Increased respiratory rate and laboured respiration was noted in many animals from the 3 groups. Ataxia and clonic convulsions in both sexes. All these effects disappeared in a few day. In group 2 (1.99 mg/L) one female was found dead one day after exposure. One female was also found dead in the high dose group after 167 minutes exposure.	LC50 is > 1.99 mg/L (the highest concentration at which the actual exposure is certain).	The actual exposure of the rats during the highest concentration tested is uncertain since: The exposure concentration varied by more than 15% of the mean value (4.55 mg/L); Only 40.9% of particles were less than 4µm (respirabl	Doc IIIA_A 6 1.3a.

[11] All references made in this chapter are references to the alphachloralose CAR

					e particle size); and Also the relative humidity was very low, ranging from 25-35%.	

No human data available

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	->1.99 mg/L
Justification for the selected value	/
Classification of the product according to CLP and DSD	Active substance has an inhalatory LC_{50} >1.99 mg/L. At 3.996%, this does not trigger classification in this category for the product RapidPro according to the calculation by additivity formula (Annex I, part 3.1.3.6 Regulation (EC) N°1272/2008).

Acute toxicity by dermal route

None of the components of RapidPro are classified as Acute toxciciy by dermal route according to Directive 67/548/EC. Alphachloralose was tested for this hazard route (see below) and showed to be non hazardous by dermal route.

Test on active substance

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	Species, strain, Sex, No/group	Test substance, Vehicle, Dose levels, Surface area	**Signs of toxicity** (nature, onset, duration, severity, reversibility)	LD50	**Remarks** (e.g. major deviations)	Reference[12]
EC Method B.3	Rat Sprague Dawley ICO: OFA SD (IOPS Caw)	Single dose of 2000 mg/kg. Duration of exposure was 24 hours.	No death, no clinical signs and cutaneous reactions were observed during the study	>2000 mg/kg	None	Doc IIIA_A6 1.2.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>2000 mg/kg
Justification for the selected value	

[12] All references made in this chapter are references to the alphachloralose CAR

Classification of the product according to CLP and DSD	Active substance has an dermal LD_{50} >2000 mg/kg. At 3,996 % w/w, this does not trigger classification in this category for the product RapidPro according to the calculation by additivity formula (Annex I, part 3.1.3.6 Regulation (EC) N°1272/2008).

Information on dermal absorption

Based on the absorption of alphachloralose, the partition coefficient log Kow 0.85 and the water solubility 4.84 g/l an assessment of dermal absorption of alphachloralose from the product Rentokil RapidPro has been made.

Based on the physico chemical properties of Alphachloralose and a suggestive result of an in vitro dermal absorption study with human skin, it is considered justified to use a dermal penetration value of 3.11% (for details see Doc IIIB, B6.4/01 and as reported in the Chloralose CAR issued by Portugal dated May 2008).

Data on active substance

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	Species, Number of skin samples tested per dose, Other relevant information about the study	Test substance, Doses	Absorption data for each compartment and final absorption value	**Remarks** (e.g. major deviations)	Reference [13]
OECD 428 GLP 2 *(*deficiencies in the reporting regarding the omission of (1) the surface area of skin tested, (2) the exact concentration of active substance in the test formulation, and (3) the calculations of LOQ/LOD*)*	In-vitro, Human skin. Exposure period : 8 hrs Sampled: 24 hrs 2 skin sample/dose	Alpha-chloralose 2 and 20 µg Chloralose/cm² Control: [^{14}C]-testostérone	See Table (A) below Dermal penetration range of 0.58-3.11%		Doc IIIB_B6.4

Table (A):

	Cell N°	% Recovered at 24 hours		
		Receptor Fluid (RF)	Skin	RF + Skin
αchloralose	2	1,16	0,58	1,74
	3	1,04	2,07	3,11
	9	0,2	0,76	0,96
	10	0,31	1,08	1,39

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Alpha-chloralose
Value(s)	3.11
Justification for the selected value(s)	During a period of 24 hours the maximum dermal penetration of chloralose was 3.11%. In this test system the recovery of the test compound was 100% of the applied dose

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

[13] All references made in this chapter are references to the alphachloralose CAR

BHA and BHT are suspected endocrine disruptor, and that since they are not classified according to the temporary criteria, the classification will not carry throught the product.

Available toxicological data relating to a mixture
Not relevant

2.2.6.2 Exposure assessment

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

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	N/A	Negligible	N/A	N/A	N/A	negligible	N/A
Dermal	N/A	Yes	N/A	N/A	N/A	negligible	N/A
Oral	N/A	Negligible	N/A	N/A	N/A	Yes	N/A

List of scenarios
Rentokil RapidPro is a ready to use product which requires no mixing, diluting or similar. Rentokil RapidPro is supplied as a ready-to-use paste bait, in a tube which is applied via a calking gun.

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Exposure study	Primary exposure. Operator exposure: Difenard.	Professionals
2.a	Indirect exposure	TNsG part 3. Ingestion of paste by children	Public
2.b	Indirect exposure	TNsG part 3. Dermal exposure du to handling dead rodents	Public

Industrial exposure
Manufacturing of active substance and formulation of products is not covered by BPR, otherwise the product is not used in an industrial way.

Professional exposure
Scenario 1

An exposure study was conducted by Rentokil Initial[14] *in which exposures associated with all activities involved in using a paste bait were monitored, including application and loading paste bait into tamper resistant bait boxes, both with and without separate plastic bait box inserts and then the inspection, clean-up and disposal. In this study, 10 replicates were performed at 50 manipulations (eg filling one bait point with up to 8g of paste bait, both with and without separate plastic bait box inserts). Dermal exposure to the hands was monitored during both activities, application of bait into bait boxes and then inspection, clean –up and disposal.*

For the inspection, clean up and disposal manipulations, with and without the use of plastic bait box inserts, all levels of contamination were below the Limit of Detection. All manipulations involving application and loading with the use of plastic bait box inserts were also below the Limit of Detection. All but two manipulations within the

14 The actual study was performed on the product 'Difenard': Rentokil Pest Control Technical committee report 09/01 Operator Exposure: Difenard. The full study has been submitted as well as sufficient justification. In the IUCLID dossier summaries are available.

application and loading process where plastic bait box inserts were not used were also found to be below the Limit of Detection.

Dermal exposure data reported in the study were calculated on a "per manipulation" basis for use in the risk assessment. The arithmetic mean exposure estimates below are based on the average exposures measured in the study, and the maximum exposure estimates below are based on the maximum exposures measured in the study.

Note from the RMS: The Difenard is a paste like biocidal product with a similar manual use and same application than Alphapaste. Thus Difenard study data can be used in this evaluation.

Where residues were non-detectable, a residue level of 0.75µg; equal to one half of the Limit of Detection has been used in the calculations.

Exposure estimates for use in this risk assessment were calculated from data reported in the Rentokil Initial study as summarised in the following tables:

Application and loading – hand residues per replicate without using plastic bait box inserts	
Manipulation	*50*
	(mg/product/manipulation)
Maximum	*2.86*
Arithmetic mean	*0.49*

Inspection, clean-up and disposal – hand residues per replicate without using plastic bait box inserts	
Manipulation	*50*
	(mg/product/manipulation)
Maximum	*ND < 1.5µg*
Arithmetic mean	*0.000015*

Application and loading – hand residues per replicate using plastic bait box inserts	
Manipulation	*50*
	(mg/product/manipulation)
Maximum	*ND < 1.5µg*
Arithmetic mean	*0.000015*

Inspection, clean-up and disposal – hand residues per replicate using plastic bait box inserts	
Manipulation	*50*
	(mg/product/manipulation)
Maximum	*ND < 1.5µg*
Arithmetic mean	*0.000015*

The daily exposure frequency and its division between different tasks are based on a survey organised by CEFIC[15] and on an agreement between MS on the common approach for exposure assessment (see HEEG 10 opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)).
In a worst case assumption we have only take the values without plastic bait box.
4

Description of Scenario 1		
Professionnal use (without plastic bait box)		
	Parameters	Value
Tier 1	Manipulation per day (application and loading) Manipulation per day (Inspection, clean-up and disposal)	11 3
	Gloves not worn	100%
	Concentration of ai in products	4.0%
	Dermal penetration	3.11%
	Body weight of adult operator [kg]	60
	Amount of bait on hands/forearms per manipulation [mg] (application and loading) Amount of bait on hands/forearms per manipulation [mg] (Inspection, clean-up and disposal)	2.86 1.5E-03
Tier 2	Gloves	10%

Calculations for Scenario 1
Values in the table below results from the following calculation:

a. Application and loading:

- Without gloves (tier 1)

(11*4.0%*2.86*3.11)/60= 0.00652mg/kg bw/day

- With gloves (tier 2)

(11*4.0%*2.86*3.11*10%)/60= 0.000652 mg/kg bw/day

b. Inspection, clean-up and disposal:

[15] As referred to in de Difenard exposure study

- Without gloves (tier 1)

(3*4.0%*1.5E-03*3.11)/60= 9.33 E-08 mg/kg bw/day

- With gloves (tier 2)

(3*4.0%*1.5E-03*3.11*10%)/60= 9.33E-09 mg/kg bw/day

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 1 Application and Loading	1 without PPE	n/a	0.00652 mg/kg bw/day	n/a	0.00652 mg/kg bw/day
Scenario 1 Inspection, clean-up and disposal	2 with PPE	n/a	0.000652 mg/kg bw/day	n/a	0.0000652 mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios 1 Application and Loading + Inspection, clean-up and disposal	n/a n/a	0.00652 mg/kg bw/day 0.000652 mg/kg bw/day	n/a n/a	0.00652 mg/kg bw/day 0.000652 mg/kg bw/day

Exposure of the general public

Scenario 2: Indirect exposure

When used in rodent control programs, this product may result in potential secondary exposures. two scenario are considered below: ingestion of paste by an infant (scenario 2.a) and dermal exposure due to handling dead rodents (scenario 2.b). Theses scenarios are listed in Appendix 7.2.1 of TNsG Part 3 as recommended for evaluation of wax baits, and it has been adapted to paste baits in this assessment. These scenarios are not likely to lead to long-term exposures, whereas acute exposures may be experienced.

Ingestion of paste.

In this scenario, an infant is assumed to ingest 0.01 g of paste on a single occasion according to the TNsG. It is assumed that the use of taste deterrent effectively prevents infants from eating the baits.

On the other hand, according to User Guidance, 5 g of bait could potentially be ingested by an infant. This default better reflects the fact that taste deterrents in applicable amounts may not deter the youngest form bait-eating. Acute exposure according to both assumptions is estimated below.

Description of Scenario 2.a		
Indirect exposure infants ingestion of paste (Appendix 7.2.1 TNsG part 3)		
	Parameters	Value
Tier 1	Concentration of a.i. in product	4.0%
	Body weight (kg)	10 kg
	Quantity ingested (g)	5.0 g
Tier 2	- Quantity ingested (g) (considering taste deterrent)	0.01g
Tier 3	-	-

Calculations for Scenario 2.a

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2.a	Tier 1/ no PPE (Ingestion of 5.0g)	N/A	N/A	20 mg/kg bw/day	20 mg/kg bw/day
	Tier 2/no PPE (Ingestion of 0.01g, considering taste deterrent)	N/A	N/A	0.04 mg/kg bw/day	0.04 mg/kg bw/day

Handling of dead rodents

Description of Scenario 2.b		
Dermal exposure due to handling dead rodents (Appendix 7.2.1 TNsG part 3)		
	Parameters	Value
Tier 1	Amount of product dislodged to skin	1g
	Concentration of a.i. in product	4%
	Dermal absorption	3.11%
	Body weight	60 kg (adult) 23.9 kg (child) (HEEG 17)
Tier 2	-	-
Tier 3	-	-

Thus systemic exposure is estimated as follow 4% of 1 g gives 40 mg of alphachloralose. With a dermal absorption of 3.11 % and body weight of 60 kg and 23.9 kg for adult and child respectively. Systemic exposure is 0.021 mg/kg bw for adult and 0.082 mg/kg bw for child.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2.b	Tier 1	N/A	0.021 mg/kg bw (adult) 0.082 mg/kg bw (child)	N/A	0.021 mg/kg bw (adult) 0.082 mg/kg bw (child)

2.2.6.1 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	Subacute rat oral study (28 days)	20 mg/kg/bw	100 (inter-& intraspecific differences)	100%	0.2 mg/kg bw/day
AELmedium-term	Subchronic rat oral (90 days)	15 mg/kg bw/d	100 (inter-& intraspecific differences)	100%	0.15 mg/kg bw/day
AELlong-term	Subchronic rat oral (90 days)	15 mg/kg bw/d	100 (inter-& intraspecific differences)	100%	0.15 mg/kg bw/day
ARfD	Not applicable, as not intended for use on food or feed				
ADI	Not applicable, as not intended to be applicable in foodstuffs.				

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Exposure study Total exposure	1 without PPE	150 mg/kg bw/d	0.15 mg/kg bw/d	0.00652	4.34	Yes
Exposure study Total exposure	2 With PPE	150 mg/kg bw/d	0.15 mg/kg bw/d	0.0000652	0.43	Yes

Local effects
No local effects are expected, since the product is not skin corrosive/irritant, eye irritant nor has sensitizing properties.

Conclusion
Nomal use of Rentokil RapidPro by professionals has a sufficiently large safety margin

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Indirect exposure TNsG part 3. Ingestion of pastes by children Scenario 2.a	1	150 mg/kg bw/d	0.15 mg/kg bw/d	20	13333	No
Indirect exposure TNsG part 3. Ingestion of paste by children Scenario 2.a	2	150 mg/kg bw/d	0.15 mg/kg bw/d	0.04	26	Yes
Indirect exposure TNsG part 3 dermal exposure due to handling dead rodents	1	150 mg/kg bw/d	0.15 mg/kg bw/d	0.021 (adult) 0.082 (child)	14 (adult) 54.6 (Child)	Yes

Conclusion
It should be noted that in the Chloralose CAR issued by Portugal dated May 2008 it says infant mouthing of unsecured bait (i.e. not in bait box) resulted in a total systemic exposure of alphachloralose of 20 mg/kg bw/day. This exposure scenario exceeds the safety reference values indicating a significant health risk. However, as the product is only to be used in tamper resistant bait boxes with a bittering agent, this scenario is very unlikely to occur.
Indirect exposure of adult, child associated with handling dead mice showed high safety margins indicating negligible risk.

Risk for consumers via residues in food

Not applicable, as not intended for use on food or feed

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

Since there is one active substance and no substance of concerns. HI (Hazard Idex) equals the HQ (Hazard Quotient). Since HI < 1 the risk is acceptable.

2.2.7 Risk assessment for animal health

Not relevant, product is not used on animals.

2.2.8 Risk assessment for the environment

Appart from the active substance, Rentokil RapidPro contains. two other components that are classified for environmental hazard: the bitrex and the butylated hydroxytoluene. Nevertheless the concentrations of these two components are very low, below 0.01%. Therefore they are not considered to be of concern for the environment within Rentokil RapidPro.

A letter of access from Physalys was presented by Rentokill to access the data of the (alpha)chloralose assessment repport.

The product Rentokil RapidPro containing 3.996% w/w alphachloralose and Alphablock which is the representative product in the assessment repport for the active substance contains 4% of alphachloralose. The intended uses are identical: mice control by professional operators and amateur users indoors.

Therefore no new studies on the product Rentokil RapidPro are necessary to conduct the environmental risk assessment which is identical as the one presented in the active substance assessment report.

2.2.8.1 Effects assessment on the environment

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

No additional ecotoxicological assessments have been performed on the product itself. All relevant data have been taken from the alphachloralose CAR since both active substance concentration and use are identical to the reference product.

- Ecotox values relevant fort he environmental classification follwing the regulation 1272/2008:

  The table below present the lowest ecotox values from the list of endpoints in the active substance assessment report :

Parameters		Value
96h LC_{50} fish	[mg/L]	2.4
48h EC_{50} daphnia	[mg/L]	0.027
72h ErC_{50} algae	[mg/L]	4.90
Rapidely biodegradable		NO
NOEC fish	[mg/L]	/
NOEC daphnia	[mg/L]	/
NOEC algae	[mg/L]	0.02

- PNEC values

  From the assessment report:
  PNECaqua = 0.099µg/L
  PNECµoor = 70.29mg/L
  All other compartments were considered not relevant

Further Ecotoxicological studies

No further data available

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

No further data available

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

No further data available

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

No further data available

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

Not relevant.

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

Please refer to fate and distribution section of the alphachloralose car

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

No further data available

Leaching behaviour (ADS)
Not relevant

Testing for distribution and dissipation in soil (ADS)

No further data available.

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

No further data available.

Testing for distribution and dissipation in air (ADS)

Nofurther data available.

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

Not relevant

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

Not relevant

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 14
Assessed scenarios	the route of exposure to the environment being considered is through waste disposal of unspent product in landfill. Given the properties of the active substance, the most important route of environmental emission from landfill sites for Chloralose would be leaching with water. Risk characterization for sewage treatment plant, surface water and groundwater will be performed.
ESD(s) used	Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC) (model of a sanitary landfill included on RIVM report 601450009)
Approach	Calculation for a certain year of the maximum quantities of Chloralose loads to percolating water, from the first year after the start of utilisation of the landfill up to 5 years after closure.
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	derived from the predicted environmental concentration in porewater, PECsoil,porewater
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: No Service life: Yes
Remarks	Rentokil RapidPro is very similar in composition and use to Alphablock which served as reference product in the alphachloralose assessment report. An extensive environmental risk assessment is present in the CAR. Therefore the assessment is not reapeated, only the conclusions regarding the risks for the environment are included in this PAR.

2.2.8.3 Risk characterisation

Atmosphere

There are not expected to be any adverse effects in the atmosphere and there is negligible exposure of Chloralose to the air. Given the zero level of exposure expected to the atmosphere from the use of chloralose in the rodenticide product for professional use there is no risk to the atmospheric compartment.

Sewage treatment plant (STP)

Since the sanitary landfill model used for calculation of PEC's covers a period of 20 years (landfill utilization period of 15 years plus 5 years after closure), the PEC/PNEC ratios through the same period are presented in the following table:

Summary table on calculated PEC/PNEC values	
Year (i)	$PEC/PNEC_{STPi}$
1	3.17E-09
2	8.25E-09
3	1.79E-08
4	3.03E-08
5	4.44E-08
6	5.91E-08
7	7.34E-08
8	8.62E-08
9	9.66E-08
10	1.04E-07
11	1.09E-07
12	1.10E-07
13	1.08E-07
14	1.03E-07
15	9.65E-08
16	1.61E-08
17	1.75E-08
18	1.88E-08
19	2.00E-08
20	2.12E-08

Conclusion: No risk for the STP

Aquatic compartment

Surface water :

Since the sanitary landfill model used for calculation of PEC's covers a period of 20 years (landfill utilization period of 15 years plus 5 years after closure), the PEC/PNEC ratios through the same period are presented in the following table:

Summary table on calculated PEC/PNEC values	
Years	$PEC/PNEC_{water}$
1	2.25E-04
2	5.86E-04
3	1.27E-03
4	2.15E-03
5	3.15E-03
6	4.20E-03
7	5.21E-03
8	6.12E-03
9	6.86E-03
10	7.40E-03
11	7.71E-03
12	779E-03
13	7.66E-03
14	7.33E-03
15	6.85E-03
16	1.14E-03
17	1.24E-03
18	1.33E-03
19	1.42E-03
20	1.51E-03

Sediments:

Log Kow for Chloralose is 0.89, according to TGD, effects assessment do not need to be performed and an unaccepted risk is not expected to occur for sediment.

Conclusion: No risk for the surface water and for sediment

Terrestrial compartment

Under normal conditions of use, there will be no exposure of Alphachloralose to the terrestrial environment, when it is used in the rodenticide product for professional use. There is no mechanism for the Chloralose to be released directly into the terrestrial ecosystem because it is only for use indoors in discrete tamper resistant bait boxes. Other routes such as from rodent urine, faeces or carcasses and from disposal of unused bait have been considered and found to be negligible (cf CAR alphachloralose, reference for Doc II B, section 3.4.4). This means that the use of Chloralose in the rodenticide product for professional use will not affect the terrestrial environment.

Conclusion: No risk for the terrestrial compartment

Groundwater

The concentration in groundwater is calculated for indirect exposure of humans to Chloralose through drinking water. The maximum permissible concentration stated by Directive 80/778/EEC (amended by Directive 91/692/EEC and Directive 98/83/EC) is 0.1 µg/L.

As described on Document II B, section 3.4.2.3, PECgroundwater was derived from the predicted environmental concentration in porewater, PECsoil,porewater, considering that a fraction of the leachate would penetrate into the subsoil of the landfill. The following table includes the ratios between the calculated PEC's and the above mentioned permissible limit, throughout the landfill life cycle:

Summary table on calculated PEC/PNEC values	
Year (i)	PEC/0.1µg/L$_i$
1	7.35E-03
2	2.00E-02
3	4.54E-02
4	8.06E-02
5	1.24E-01
6	1.75E-01
7	2.29E-01
8	2.85E-01
9	3.41E-01
10	3.94E-01
11	4.41E-01
12	4.82E-01
13	5.16E-01
14	5.41E-01
15	5.60E-01
16	5.80E-01
17	6.29E-01
18	6.77E-01
19	7.22E-01
20	7.64E-01

Secondary poisoning

There is unlikely to be an issue of secondary poisoning since a limited exposure to the environment is expected. Chloralose is for indoor use only and immobilisation of mice occurs shortly after bait consumption. In addition, an assessment of n-octanol/water partition coefficient, adsorption capacity and molecular mass indicated that Chloralose is not likely to bioaccumulate in aquatic or terrestrial species, which leads to a negligible risk of secondary poisoning.

Overall conclusion on the risk assessment for the environment of the product
The proposed use poses no unacceptable risks to the environment.

2.2.9 Measures to protect man, animals and the environment

[See Summary of Product Characteristics (SPC).]

2.2.10 Comparative assessment

Comparative assessment not relevant, the active substance is not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

All studies and their summaries are included in the 'Alpha Paste' IUCLID dossier.

Initial assessment

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
Rentokil Initial 1927 plc	2014	GSC Analytical Services Report GARN D5 D6 Determination of Chloralose in Alpha Paste by Reverse Phase Liquid Chromatography. Applicant's reference number ALPHCL 376	Y	ORG	April 2014
Rentokil Initial 1927 plc	2014	Acclerated Storage Stability: Alpha Paste (2) Study number 298/65 Study Report Number 2014/298/65 / GLP / Unpublished (Applicant's reference number ALPCHL 388)	Y	ORG	November 2014
Rentokil Initial 1927 plc	2015	GSC Analytical Services Report Determination of Alpha-chloralose and Beta-chloralose in Alpha Paste by Reverse Phase Liquid Chromatography Storage Stability: 12 month SOP:AM 155, Issue 7 GARN E32 / Unpublished (Applicant's reference number ALPCHL 398)	Y	ORG	February 2016
Rentokil Initial 1927 plc	2014	Method Validation Alpha Paste Project number 302/06 Project Report Number 2014/302/06 Applicant's reference ALPHCHL 389	Y	ORG	November 2014
Rentokil Initial 1927 plc	2014	Comparison of the Biocidal Products Difenard and Alpha Paste Unpublished Applicant's reference number: Alphchl 377	Y	ORG	April 2014
Rentokil Initial 1927 plc	2014	[redacted]	Y	ORG	April 2014

Rentokil Initial 1927 plc	2014	SDSs for the coformulants in the product Alpha Rapid	N	PUB	Nov 2014
Rentokil Initial 1927 plc	2014	[redacted]	Y	ORG	November 2014
Rentokil Initial 1927 plc	2014	[redacted]	Y	ORG	December 2014
Rentokil Initial 1927 plc	2014	[redacted]	Y	ORG	December 2014
Rentokil Initial 1927 plc	2014	[redacted]	Y	ORG	May 2015
Rentokil Initial plc	2009	Determination of Difenacoum from Difenard on dosimeter gloves by reverse phase liquid chromatography. SOP:AM No. 209 Issue 1 / Unpublished / Applicant's reference number DIFEN 176	Y	Rentokil Initial 1927 plc	August 2009
Rentokil Initial plc	2009	Rentokil Pest Control Technical Committee Report 09/03 Method validation: Difenard on dosimeter gloves. Study 302/01 / GLP / Unpublished / Applicant's reference number DIFEN: 192	Y	Rentokil Initial 1927 plc	August 2009

Rentokil Initial plc	2009	Overall Use Pattern & Primary Human Exposure Scenarios - Difenard / Target Mouse Bait. Unpublished / Applicant's reference number: DIFEN: 183	Y	ORG	March 2010

Minor change (2022)

Sharon Keay	2016a	Determination of Alpha-chloralose and Beta-chloralose in Alpha Paste by Reverse Phase Liquid Chromatography Storage Stability: 18 month	Y	Rentokil Initial 1927 plc	April 2022
Sharon Keay	2016b	Determination of Alpha-chloralose and Beta-chloralose in Alpha Paste by Reverse Phase Liquid Chromatography Storage Stability: 24 months	Y	Rentokil Initial 1927 plc	April 2022
Sharon Keay	2016	GSC Analytical Services Report Determination of Alpha-chloralose and Beta-chloralose in Alpha Paste by Reverse Phase Liquid Chromatography Storage Stability: 24 month SOP:AM 155, Issue 7 GARN F62 / Unpublished	Y	Rentokil Initial 1927 plc	April 2022
Rentokil Initial 1927 plc	2016	[redacted]	Y	Rentokil Initial 1927 plc	April 2022

3.2 Output tables from exposure assessment tools

Not relevant

3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

Not relevant

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

Not relevant (IUCLID file available)

3.6 Confidential annex

See separate file