Product Assessment Report
Related to product authorisation under Regulation (EU) No 528/2012

Racumin 3D

Type of application National authorisation (Ref-MS: Sweden)	Product type PT 14 (rodenticide)
Type of evaluation New registration	Date of decision/Entry into force 09 September 2020
Active substances Coumatetralyl (0.038 %) Cholecalciferol (0.01 %)	Date of expiry 08 September 2025

Product (trade) names	Authorisation No in Ref-MS	Decision	User category	Reference Case Number in R4BP
Racumin 3D Racumin DUO Racumin PLUS Racumin PRO Racumin NEO Racumin Jump Racumin Boost	5626	Authorisation	Professional use (Class 2 in Ref-MS) Trained professional use (Class 1 So in Ref-MS)	R4BP3: BC-FM010437-44 R4BP2: 2013/35381/8740/SE/ANP/11177

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1 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

1.1 APPLICANT

Company Name:	Bayer S.A.S.
Address:	16 rue Jean-Marie Leclair, CS 90106
City:	Lyon Cedex 09
Postal Code:	69266
Country:	France
Telephone:	[redacted]
Fax:	-
E-mail address:	[redacted]

1.1.1 Person authorised for communication on behalf of the applicant

Name:	[redacted]
Function:	European Regulatory Manager
Address:	16 rue Jean-Marie Leclair, CS 90106
City:	Lyon Cedex 09
Postal Code:	69266
Country:	France
Telephone:	[redacted]
Fax:	-
E-mail address:	[redacted]

1.2 PROPOSED AUTHORISATION HOLDER

Company Name:	Bayer AB
Address:	c/o Bayer A/S Arne Jacobsens Allé 13
City:	Köpenhamn S, Denmark
Postal Code:	2300
Country:	Denmark

Telephone:	-
Fax:	-
E-mail address:	[redacted]
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Yes

1.3 INFORMATION ABOUT THE PRODUCT APPLICATION

Application received:	30th of August 2013
Type of application:	New registration
Further information:	The application was put on hold while awaiting the approval of cholecalciferol as active substance in PT14

1.4 INFORMATION ABOUT THE BIOCIDAL PRODUCT

1.4.1 General information

Trade names:	Racumin 3D Racumin DUO Racumin PLUS Racumin PRO Racumin NEO Racumin Jump Racumin Boost
Manufacturer's development code number(s), if appropriate:	80978316
Product type:	Rodenticide (Product Type 14)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see Confidential Annex):	Active substance: Coumatetralyl 0.0375 % w/w (pure), 0.038 % w/w (technical material) Active substance: Cholecalciferol 0.01 % w/w (pure), 0.01 % w/w (technical material)
Formulation type:	Ready to use bait (RB) paste
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); or Has the product the same identity and composition like the product evaluated in connection with the	No No

approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	

1.4.2 Identity related issues

1.4.2.1 Assessment of the endocrine properties relating to Racumin 3D

Racumin 3D is a rodenticide bait formulation that contains coumatetralyl and cholecalciferol as active substances, and co-formulants. All the formulants of Racumin 3D were thoroughly checked by the applicant through the endocrine disruptor (ED) references (please refer to the Confidential Annex - ED assessment). Please note that at the time the application was submitted the scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council had not been established. [1]

An ED-assessment has been conducted, but this was finalised prior to the harmonised guideline on how to assess endocrine disruption (ED) properties of co-formulants in biocidal products was made available.

From this follows that the ED-assessment will have to be updated during the renewal of the product in line with the stepwise approach presented in the document "Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products -instructions for applicants" which was agreed to by the Coordination Group (CG) at ECHA during CG- 34.

Assessment of endocrine properties relating to the active substances

Cholecalciferol is a pro-hormone and therefore fulfils the criteria for having endocrine disrupting properties laid down in Article 5(1)d of Regulation (EU) No 528/2012 and further defined in Regulation (EU) No 2017/2100.

Assessment of endocrine properties relating to the non-active substance(s) in the product

According to the assessment, none of the non-active substance contained in the product are regulatory identified as endocrine disruptors. However, one non-active substance is currently being evaluated in the frame of REACH for potential ED properties. Hence, it was not possible to conclude whether the non-active substance should be considered to have ED properties before the end of the assessment and therefore the process will be concluded at the post-authorisation stage.

Conclusion

Racumin 3D is considered as having endocrine disrupting properties and should not be used for the general public according to Article 19(4)(d) of Regulation (EU) No 528/2012.

1.4.2.2 Candidates(s) for substitution

As a consequence of the harmonised classification, the active substance coumatetralyl meets the criteria for exclusion according to Article 5(1) (c). In addition, the active substance cholecalciferol meets the criteria for exclusion according to Article 5(1) (d) of the BPR. Therefore, Racumin 3D shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

Regulation (EU) No 528/2012 is met. An assessment of whether at least one of the conditions of Article 5(2) is met in the Reference Member State Sweden has been made. It is presented in section 3.1.3.

Both active substances meets the conditions laid down in Article 10 of Regulation (EU) 528/2012, and are consequently candidates for substitution. A comparative assessment has been made. It is presented in section 3.1.4.

1.4.2.3 Information on substance(s) of concern

The biocidal product does not contain any substances of concern.

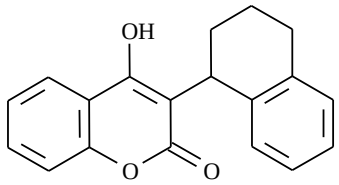
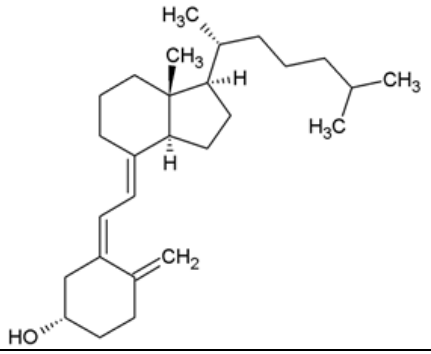
2 SUMMARY OF THE PRODUCT ASSESSMENT

2.1 GENERAL PRODUCT INFORMATION

2.1.1 Identification of the product

Trade names	Racumin 3D Racumin DUO Racumin PLUS Racumin PRO Racumin NEO Racumin Jump Racumin Boost	
Manufacturer´s development code number(s)	80978316	
Ingredient of preparation	Function	Content (% $^{w}/_{w}$)
Coumatetralyl CAS No.	Active ingredient 5836-29-3	0.0375% w/w (pure) 0.038 % w/w (technical material)
Cholecalciferol CAS No.	Active ingredient 67-97-0	0.01% w/w (pure) 0.01% w/w (technical material)
Other components	Please refer to Confidential Annex	
Physical state of preparation	Highly viscous soft block paste	
Nature of preparation	Ready to use bait (RB) paste	

2.1.2 Identity of ingredients of the biocidal product

Trade name	IUPAC Name	CAS-No.	EC-No.	Molecular formula	Structural formula	Classification
Coumatetralyl	4-hydroxy-3-(1, 2, 3, 4-tetrahydro-1-naphthyl)coumarin	5836-29-3	227-424-0	$C_{19}H_{16}O_3$		See section 2.2.1 below.
Cholecalciferol (Vitamin D3)	(3β,5Z,7E)-9,10-secocholesta-5,7,10(19)-trien-3-ol	67-97-0	200-673-2	$C_{27}H_{44}O$		See section 2.2.2 below.
Other components	Please refer to Confidential Annex.					

2.1.3 Physico-chemical properties

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
Appearance (IIB3.1/Pt. I-B3.1)							
Physical state and nature	Visual assessment	Coumatetralyl 0.0375% Batch: 2012-004743	Soft block, highly viscous paste.		Y	Manka, S. (2013a)	**Acceptable**
Colour	Visual assessment	Coumatetralyl 0.0375% Batch: 2012-004743	Blue		Y	Manka, S. (2013a)	**Acceptable**
Odour	Olfactory assessment	Coumatetralyl 0.0375% Batch: 2012-004743	Cereal odour		Y	Manka, S. (2013a)	**Acceptable**
Explosive properties (IIB3.2/Pt. I-B3.2)	EC Method A14	Coumatetralyl 0.0375% Batch: 2012-004743	No explosive properties observed in mechanical (friction and shock) or thermal sensitivity tests.		Y	Krack, M. (2012a)	**Acceptable**
Oxidising properties (IIB3.3/Pt. I-B3.3)	Structural assessment					Brux, A. (2012a)	**Acceptable** Theoretical reasoning based on structure of all components in Racumin 3D.
Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)							

Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reference**	**Official use only**
Flash point				Not relevant to a solid / paste RB product.			**Acceptable**
Autoflammability	EC Method A16	Coumatetralyl 0.0375% Batch: 2012-004743	391°C		Y	Krack, M. (2012b)	**Acceptable**
Other indications of flammability	EC Method A10	Coumatetralyl 0.0375% Batch: 2012-004743	Not flammable		Y	Brux, A. (2012b)	**Acceptable**
Acidity/Alkalinity (IIB3.5/Pt. I-B3.5)	CIPAC MT 75.3	Coumatetralyl 0.0375% Batch: 2012-004743	pH of a 1% solution: 6.6		Y	Manka, S. (2013a)	**Acceptable**
Relative density/bulk density (IIB3.6/Pt. I-B3.6)	EC Method A3	Coumatetralyl 0.0375% Batch: 2012-004743	1.183 g/cm^3		Y	Manka, S. (2013b)	**Acceptable**
Storage stability - stability and shelf life (IIB3.7/Pt. I-B3.7)							
Effects of temperature	CIPAC MT 46.3	Coumatetralyl 0.0375%, Cholecalciferol 0.01% Batch: 2016-012137-01	No significant changes, no leakages or other interactions observed in the appearance of the cardboard box and sachet packaging material were observed following storage at 54°C for 2 weeks. The loss of active ingredient Cholecalciferol relative to		Y	Frank, C. (2017a)	**Acceptable**

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
			the initial concentration is 5.3 %. No loss of coumatetralyl is observed. Based on the results obtained the test item is considered to be stable for 2 weeks at 54 °C. Results of individual parameters are presented in Table 2.1.3-1 below.				
Effects of temperature	CIPAC MT 46.3	Coumatetralyl 0.0375%, Cholecalciferol 0.01% Batch: 2016-012137-01	No significant changes, no leakages or other interactions observed in the appearance of the PP-pail with PE inliner packaging material were observed following storage at 54°C for 2 weeks. The loss of active ingredients Coumatetralyl and Cholecalciferol relative to the initial concentration are 1.4% and 2.7% respectively. Based on the results obtained the test item is considered to be stable for 2 weeks at 54 °C. Results of individual parameters are presented in Table 2.1.3-2 below.		Y	Frank, C. (2017b)	**Acceptable**
Storage stability test - long term storage at ambient temperature	TGD Chapter 2 part B 3 years at ambient temperature:	Coumatetralyl 0.0375%, Cholecalciferol 0.01%	No significant changes, no leakages or other interactions observed in the appearance of the cardboard box with PE	A statement (Boecker 2016) explaining the loss of active substances	Y	Garcia Sanchez, M.T.(2016a)	**Acceptable (in combination with the statement from Boecker 2016)**

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
		Batch N°2012-004743	sachet packaging material were observed following storage for 3 years at ambient temperature. The loss of active ingredients Coumatetralyl and Cholecalciferol relative to the initial concentration are 24% and 50% respectively. Results of individual parameters are presented in Table 2.1.3-3 below.	content is provided detailing investigations into the storage stability and enhancement of the extractability of cholecalciferol from Racumin 3D.			
Storage stability test - long term storage at ambient temperature	TGD Chapter 2 part B 3 years at ambient temperature:	Coumatetralyl 0.0375%, Cholecalciferol 0.01% Batch N°2012-004743	No significant changes, no leakages or other interactions observed in the appearance of the PP-bucket with PE inliner packaging material were observed following storage for 3 years at ambient temperature. The loss of active ingredients Coumatetralyl and Cholecalciferol relative to the initial concentration are 23% and 49% respectively. Results of individual parameters are presented in Table 2.1.3-4 below.	A statement (Boecker 2016) explaining the loss of active substances content is provided detailing investigations into the storage stability and enhancement of the extractability of cholecalciferol from Racumin 3D.	Y	Garcia Sanchez, M.T.(2016b)	**Acceptable (in combination with the statement from Boecker 2016)**
Storage stability test	CIPAC MT 46.3 2 weeks at 54°C & 3 years at ambient temperature:	Coumatetralyl 0.0375%, Cholecalciferol 0.01%	A three year stability study of the paste bait formulation coumatetralyl (0.03755) + cholecalciferol (0.01%) RB originally gave a recovery of only 51% cholecalciferol and	A statement is provided detailing investigations into the storage stability and enhancement of	N	Boecker, T. (2016)	**Acceptable** The findings in this report support the theory that coumatetralyl and cholecalciferol are not degraded over time. By using

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
	Stability statement		76 % coumatetralyl at the 3 year time point. A new extraction step was applied to the three year old storage stability samples of coumatetralyl + (0.03755) + cholecalciferol (0.01%) RB and improved recovery was observed. Cardboard box/in-liner: Content (% w/w): Cholecalciferol: Initial: 0.0101 t (3 years): 0.0099 recovery: 98.02% Coumatetralyl: Initial: 0.0357 t (3 years): 0.0331 recovery: 92.72% PP bucket/LDPE bag: Content (% w/w): Cholecalciferol: Initial: 0.0100 t (3 years): 0.0100 recovery: 100% Coumatetralyl: Initial: 0.0342 t (3 years): 0.0325 recovery: 95.03%	the extractability of cholecalciferol from Racumin 3D.			the adapted extraction method the bound coumatetralyl and cholecalciferol could be released from the matrix.

Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reference**	**Official use only**
Effects of light			Not required, as packaging precludes light.				**Acceptable**
Reactivity towards container material	CIPAC MT 46.3	Coumatetralyl 0.0375% Cholecalciferol 0.01% 2016-012137-01	The commercial packaging (cardboard box with sachet) remained in sound condition, sealed and without leakages following storage at 54°C for two weeks and at ambient temperature for 3 years.		Y	Frank, C. (2017a) and Garcia Sanchez, M.T.(2016a)	**Acceptable**
Reactivity towards container material	CIPAC MT 46.3	Coumatetralyl 0.0375% Cholecalciferol 0.01% 2016-012137-01	The commercial packaging (PP pail with PE inliner) remained in sound condition, sealed and without leakages following storage at 54°C for two weeks and at ambient temperature for 3 years.		Y	Frank, C. (2017b) and Garcia Sanchez, M.T.(2016b)	**Acceptable**
Other				No other parameters tested.			-
Technical characteristics (IIB3.8/Pt. I-B3.8)							
Wettability/ Suspensibility				Not relevant to a solid / paste RB product.			-
Wet sieve analysis				Not relevant to a solid / paste RB product.			-

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
Emulsifiability				Not relevant to a solid / paste RB product.			-
Disintegration time				Not relevant to a solid / paste RB product.			-
Attrition/friability of granules; integrity of tablets				Not relevant to a solid / paste RB product.			-
Persistence of foaming				Not relevant to a solid / paste RB product.			-
Flowability/Pourability				Not relevant to a solid / paste RB product.			-
Dustability				Not relevant to a solid / paste RB product.			-
Loss on drying	CIPAC MT 17.4	Coumatetralyl 0.0375% Batch: 2012-004743	4.28%		Y	Manka, S. (2013a)	**Acceptable**
Compressive deformation	-	Coumatetralyl 0.0375% Batch: 2012-004743	77N		N	Manka, S. (2013a)	**Acceptable**
Compatibility with other products (IIB3.9/Pt. I-B3.9)				Not relevant to a solid / paste RB product.			-

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference	Official use only
Surface tension (Pt. I-B3.10)				Not relevant to a solid / paste RB product.			-
Viscosity (Pt. I-B3.10)				Not relevant to a solid / paste RB product.			-
Particle size distribution (Pt. I-B3.11)				Not relevant to a solid / paste RB product.			-

Table 2.1.3-1 Summary of Accelerated Storage Stability Data (Frank, 2017a)

Parameter	Method	Initial	2 Weeks at 54°C
Appearance	Visual	Packed in tea bag paper Paste	Packed in tea bag paper Paste
Colour	Visual	Blue colour with gray particles	Blue colour with gray particles
Packaging	Visual	Cardboard box/COEX sachage	Cardboard box/COEX sachage
Packaging interactions	Visual	Sample in sound condition, no leakages or other interactions observed	Sample in sound condition, no leakages or other interactions observed
Weight change	Gravimetric	877.26	870.46 (0.78% weight loss)
Active substance content Bittering agent	-	Coumatetralyl: 0.036875% Cholecalciferol: 0.009365% Denatonium benzoate: 0.00208083%	Coumatetralyl: 0.036901% (+0.07%) Cholecalciferol: 0.008867% (-5.3%) Denatonium benzoate: 0.00211341% (+1.57%)

Table 2.1.3-2 Summary of Accelerated Storage Stability Data (Frank, 2017b)

Parameter	Method	Initial	2 Weeks at 54°C
Cholecalciferol content (%)	Validated HPLC-UV method	0.0095	0.0093 (-2.7%)
Coumatetralyl content (%)	Validated HPLC-UV method	0.0373	0.0368 (-1.4%)
Denatonium benzoate content (%)	Validated HPLC-UV method	0.0021	0.0022 (+6.3%)
Appearance (physical state, colour)	Visual inspection	Blue paste with grey particles, packed in a tea bag paper.	Blue paste with grey particles, packed in a tea bag paper.
Packaging Stability	Visual inspection	Polypropylene pail with polyethylene liner. No leakage or other interactions observed.	Polypropylene pail with polyethylene liner. No leakage or other interactions observed.
Weight (%)	Gravimetric	2801.93 g	2798.48 g (0.12% loss)

Table 2.1.3-3 Summary of Long Term Storage Stability Data (Garcia Sanchez, 2016a)

Parameter	Method	Initial	36 months at room temperature
Active substance content	HPLC-UV	Coumatetralyl: 0.0357% Cholecalciferol: 0.0101%	Coumatetralyl: 0.0270% (-24%) Cholecalciferol: 0.0051% (-50%)
Denatonium benzoate content	HPLC-UV	0.0019% w/w	0.0017% (-11%)
Physical state	Visual	Paste packed in a tea bag paper	Paste packed in a tea bag paper
Colour	Visual	Blue with grey and white spots	Blue with grey and white spots
Packaging	Visual	Cardboard box with in-liner In-liner: [redacted] LDPE + PES coupled film	Cardboard box with in-liner In-liner: [redacted] LDPE + PES coupled film
Packaging interactions	Visual	Sample in sound condition, no leakages or other interactions observed	Sample in sound condition, no leakages or other interactions observed
Weight	Gravimetric	873.53 g	870.10 g (0.39% loss)

Table 2.1.3-4 Summary of Long Term Storage Stability Data (Garcia Sanchez, 2016b)

Parameter	Method	Initial	36 months at room temperature
Active substance content	HPLC-UV	Coumatetralyl: 0.0342% Cholecalciferol: 0.010%	Coumatetralyl: 0.0263% (-23%) Cholecalciferol: 0.0051% (-49%)
Denatonium benzoate content	HPLC-UV	0.0020%	0.0017% (-15%)
Physical state	Visual	Paste packed in a tea bag paper	Paste packed in a tea bag paper
Colour	Visual	Blue with grey and white spots	Blue with grey and white spots
Packaging	Visual	Polypropylene (PP) bucket with internal polyethylene (PE) bag	Polypropylene (PP) bucket with internal polyethylene (PE) bag
Packaging interactions	Visual	No leakages or other interactions observed	Sample in sound condition, no leakages or other interactions observed
Weight	Gravimetric	2792.06 g	2782.82 g (0.33% loss)

2.1.4 Analytical methods for detection and identification

2.1.4.1 Analysis of active substances as manufactured

Refer to cholecalciferol CAR, Document IIA section 1.4, for details of cholecalciferol analytical methods.

Refer to CAR, Document IIA section 1.4, for details of coumatetralyl analytical methods.

Test substance	Analytical method	Accuracy (%)	Repeatability (% RSD)	Linearity	Interferences / Specificity
Impurity	Headspace Gas-Liquid Chromatography with Flame Ionisation Detection (HS-GLC-FID)	**Limit of quantification (0.382g/kg):** 94.32 – 98.87% (Mean = 96.49%)	1.40% (n = 10)	0.198 – 3.165 g/kg (5 concentrations) r = 0.9999	The MS-spectra showed no spectral differences when reference substances and samples were compared. Chromatograms were found to be free from interfering compounds at the retention time of interest. Analyte identity was further demonstrated with retention time match with analytical standards.
		Limit of specification (1.776 g/kg): 102.68 – 111.38% (Mean = 108.54%)	2.23% (n = 10)		

Ref-MS comment	An analytical method for the determination of one of the impurities in coumatetralyl was missing in the CAR. This analytical method was provided to support product authorisation and is acceptable.

2.1.4.2 Formulation analysis

New analytical method

Test substance (Analyte)	Analytical method	Accuracy (%)	Precision (% RSD) (n)	LOQ	Linearity	Specificity	Reference
Cholecalciferol	HPLC-UV	50% Fort.: 92.1 100% Fort.: 93.3 150% Fort.: 93.0 (n=5 all levels) Overall Mean: 93 (n = 15)	1.4 (6)	0.001%	Calibration was linear over the concentration range of 0.01 – 0.19 mg/25mL (6 concentrations), with a correlation coefficient, r, of 0.9999 (slope = 3.3798, intercept = 0.0018).	No interfering peaks from co-formulants were observed at the retention times of cholecalciferol, demonstrating the specificity of the method. Analyte identity was confirmed by retention time match with reference standards.	Frank, C. (2017c), Validation of an Analytical Method for the Determination of Cholecalciferol, Coumatetralyl and Denatonium Benzoate in the formulation Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01, Currenta GmbH, Germany, Study No.: 2016/0093/01, GLP, unpublished
Coumatetralyl	HPLC-UV	50% Fort.: 91.9 100% Fort.: 94.1 150% Fort.: 93.8 (n=5 all levels) Overall Mean: 93 (n = 15)	0.7 (6)	0.001%	Calibration was linear over the concentration range of 0.04 – 0.70 mg/25mL (9 concentrations), with a correlation coefficient, r, of 1.0000 (slope = 2.9553, intercept = 0.0012).	No interfering peaks from co-formulants were observed at the retention times of coumatetralyl, demonstrating the specificity of the method. Analyte identity was confirmed by retention time match with reference standards.	
Denatonium benzoate	HPLC-UV	50% Fort.: 115.9 100% Fort.: 104.1 150% Fort.: 98.6 250% Fort: 98.0 (n=5 all levels) Overall Mean: 104 (n = 20)	1.4 (6)	0.001%	Calibration was linear over the concentration range of 0.003 – 0.064 mg/25mL (6 concentrations), with a correlation coefficient, r, of 0.9995 (slope = 5.4082, intercept = -0.0035).	No interfering peaks from co-formulants were observed at the retention times of denatonium benzoate, demonstrating the specificity of the method. Analyte identity was confirmed by retention time match with reference standards.	

Ref-MS comment	The above summarized analytical method for the determination of coumatetralyl, cholecalciferol and denatonium benzoate in Racumin 3D is acceptable.

2.1.4.3 Residue analytical methods

Analytical methods for the determination of coumatetralyl in environmental compartments (soil, air and water) as well as body fluids and tissues and food/feed are found in the CAR.

Analytical methods for the determination of cholecalciferol in environmental compartments (soil and water) as well as body fluids and tissues and food of plant origin are found in the CAR. For the analysis of residues in air, an acceptable waiver was submitted based on expected negligible exposure.

2.2 CLASSIFICATION, PACKAGING AND LABELLING

2.2.1 Classification of active substance (1) Coumatetralyl

GHS Pictograms

Classification	Acute Tox. 2, H300 Acute Tox. 3, H311 Acute Tox. 2, H330 Repr. 1B, H360D STOT RE 1, H372 Aquatic Chronic 1, H410
Signal word	Danger
Hazard statement	H300 Fatal if swallowed H311 Toxic in contact with skin. H330 Fatal if inhaled. H360D May damage the unborn child H372 Causes damage to organs through prolonged or repeated exposure (blood) H410 Very toxic to aquatic life with long lasting effects

2.2.2 Classification of active substance (2) Cholecalciferol

GHS Pictograms

Classification	Acute tox. Cat. 2; H300, Acute tox. Cat 2; H310 Acute tox. Cat.2; H330 STOT RE Cat. 1; H372
Signal word	Danger
Hazard statement	H300 Fatal if swallowed H310 Fatal in contact with skin

	H330 Fatal if inhaled H372 Causes damage to organs through prolonged or repeated exposure

2.2.3 Proposed classification for the biocidal product (according to the CLP criteria)

Classification	Repr. 1B; H360D Aquatic Chronic 3; H412
GHS Pictograms	
Signal Word	Danger
Hazard Statement (H-Phrase)	H360D May damage the unborn child. H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements (P-phrase)	P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P501 Dispose of contents/container in accordance with local regulation

2.3 EFFICACY

2.3.1 Function

Racumin 3D is a rodenticide (product type 14) containing 0.038% coumatetralyl and 0.01% cholecalciferol. The product is a ready-for-use bait block, which is intended for trained professional use and professional use against rats and mice.

2.3.2 Organism(s) to be controlled and products, organisms or objects to be protected

This formulation is intended to be used for the control of brown rats (*Rattus norvegicus*) and mice (*Mus musculus domesticus*) in and around buildings for the maintenance of human hygiene.

2.3.3 Effects on target organisms and efficacy

Mortality and control of infestations.

Label Text:

Rodenticide
Racumin 3D is a universal bait for rat and mouse control.
Rodents typically ingest anticoagulant bait repeatedly over two to seven days before first symptoms of poisoning occur. Death of rodents is due to disturbed blood coagulation. Typical symptoms are general weakness, anorexia and reduced locomotion.
Racumin 3D can be used by trained professionals or professionals indoor and outdoor around buildings. *Only relevant in RefMS SE: For use by professional users in Sweden, only against mice.*
Norway Rat (*Rattus norvegicus*)
House Mouse (*Mus musculus domesticus*)
Ready-to-use sachets. No diluents or other substances will be added to Racumin 3D bait.

Direction of uses and mitigation measures:

The terms and conditions of use for Racumin 3D are in agreement with the harmonised and relevant sentences for anticoagulant rodenticides (CA-Nov16-Doc.4.1.b – Final), see section 2.13 *Summary of Product Characteristics (SPC).*

Efficacy studies:

Racumin 3D (containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol) is an effective rodenticide against both Norway rats (*Rattus norvegicus*) and House mice (*Mus musculus domesticus*). Table 2.3.3-1 provides details of studies performed.

In nearly all laboratory studies, 100% mortality occurred within 5-10 days after surplus baiting (or choice testing) using the product, both in Norway rats and House mice. In the choice study of House mice, the palatability in males were low but since the mortality were > 90% in both laboratory studies (also in one supportive laboratory study without colicalciferol), the lower palatability have been accepted. An acceptable palatability can also be supported by the fact that the applicant have lowered the level of denatonium benzoate in the product to half the level used in the efficacy studies. Thus, it can be expected that the palatability of the product could be higher. Moreover, the palatability of a stored product (24 months), has been accepted based on one in choice feeding study of Norway rats. Rats are normally more careful and neophobic than mice, therefore the palatability of the stored product (24 months) have also be accepted for mice.

In the field studies, 90%-100% control of Norway rats and House mice infestations were achieved comparing the pre- and post bating in representative agricultural situations, which is acceptable (i.e. >90%). Therefore, efficacy for Norway rats and House mice can be accepted and the higher tracking activity (14-25%) could be explained by single individuals with bait box shyness.

2.3.4 Mode of action including time delay

Coumatetralyl is a first generation anticoagulant, which blocks the formation of prothrombin thus inhibiting blood coagulation and causing death by internal haemorrhaging.

The mode of action of cholecalciferol at excessive/toxic doses is the induction of hypercalcaemia. However, at the concentration in this product (100 mg/kg), is not considered an excessive/toxic dose. Cholecalciferol is included in the product specifically as a ‘stop-feeding’ agent, preventing the ingestion of multiple lethal doses.

The product has a 2-6 day time delay between first consumption of the bait and the beginning of mortality of rodents.

2.3.5 Occurrence of resistance

Resistance to anticoagulants, such as coumatetralyl, is well documented in some geographical areas. There is no known resistance to cholecalciferol and there is no evidence of cross-resistance to cholecalciferol. No reported cases of resistance in rodents to cholecalciferol have been noted, neither in the EU nor globally.

Table 2.3.5-1 - Experimental data on the effectiveness of the product against target organisms

<table>
<tr><th>Test product</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects, mode of action, resistance</th><th>Reference</th></tr>
<tr><td colspan="5">Laboratory studies on Norway rats</td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus) of a wild strain.</td><td>Choice feeding trial with paste bait (375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol) in Norway rats (Rattus norvegicus) of a wild strain. Challenge diet: Broken wheat, organic quality, fresh from a local supplier.

The palatability and the efficacy of the bait were tested in two unisex groups of a strain of wild Norway rats.

Four female rats and eight male rats were caged in suitable cages under ambient conditions. There was a 7-day acclimatisation period prior to testing where rat and mouse standard lab diet (Höveler) and cereals plus tap water was provided ad libitum, followed by a 4-day test period.

During the exposure period, the test animals were provided with the test bait and a challenge diet of broken wheat (organic quality, fresh from a local supplier) and tap water. The position of the dishes with the test bait and challenge diet were exchanged daily.

Following exposure, the animals were returned to a standard laboratory diet for a maximum of</td><td>Consumption of bait (g), palatability index (PI) and mortality period
<table>
<tr><th>Sex</th><th></th><th>Day 1</th><th>Day 2</th><th>Day 3</th><th>Day 4</th><th>Day 1 to 4</th><th>Mort. Period (days)</th></tr>
<tr><td rowspan="2">M</td><td>Bait</td><td>96.3</td><td>119.2</td><td>20.9</td><td>0.1</td><td>236.5</td><td rowspan="2">4 to 6</td></tr>
<tr><td>PI</td><td>0.54</td><td>0.64</td><td>0.20</td><td>0.0</td></tr>
<tr><td rowspan="2">F</td><td>Bait</td><td>55.7</td><td>40.1</td><td>7.1</td><td>0.1</td><td>103.0</td><td rowspan="2">4 to 5</td></tr>
<tr><td>PI</td><td>0.56</td><td>0.61</td><td>0.23</td><td>0.0</td></tr>
</table>
100% mortality occurred in the choice feeding study after 6 days. The mean mortality period was 4.9 days in males, and 4.5 days in females.

The test bait was consumed in high amounts during the first two days of the treatment. Following this, total consumption (bait + challenge diet) dropped considerably; additionally the proportion of test bait consumption declined.. As mortality occurred after four days, the rapid reduction in food intake was probably due to the onset of poisoning. However, the shift towards consumption of the challenge diet (as expressed in the reduced PI on days three and four of the treatment) can only be explained by a behavioural response to the toxic bait in connection with the ability of the rats to identify the source of the poisonous compound.

Such conditioned taste aversion (CTA) may prevent the ingestion of multiple lethal doses, thus keeping residues at minimum; however it may even prevent the ingestion of a lethal dose if the reaction was time-dependent rather than dose-dependent. From the study it cannot be concluded if the CTA was caused by the dose or by the period. However, all rats ingested a lethal dose and died within six days. Irrespective of the nature of the CTA, it can be concluded therefore that the bait is palatable to rats when attractive alternative food is available, and that it is an effective bait for the control of Norway rats.</td><td>[redacted] (2013c)

IIIB5.10-07</td></tr>
</table>

<table>
<tr><td></td><td></td><td>21 days for post-treatment observation.

Two single sex groups were exposed. The male group contained 8 animals and the female group contained 4 animals.</td><td></td><td></td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus)

Strain: Wild strain derived from the wild rat (Rattus norvegicus).</td><td>No-choice feeding test: conducted according to the Technical Notes for Guidance on Product Evaluation, Appendices to Chapter 7, Product Type 14 “Efficacy Evaluation of Rodenticidal Biocidal Products“, using a treatment length of 10 days (not 4 days).

Six male rats and six female rats were caged singly, in suitable stainless steel cages under ambient conditions. There was a 4-day acclimatisation period prior to testing where a standard lab diet A04 (S.A.F.E.) pellet food plus tap water was provided ad libitum, followed by a 10-day test period, where the bait treatment and tap water were offered. Two day post-treatment observation period.

The soft block paste bait (containing 375 mg/kg coumatetralyl and 100 mg/kg cholecalciferol) was provided as a no-choice feed for 10 days.</td><td>Body weight, bait consumption, mortality & coumatetralyl content in 12 rats
<table>
<tr><th rowspan="2">Rat (sex)</th><th rowspan="2">Loss of body weight (g)</th><th rowspan="2">Bait consumed (g)</th><th rowspan="2">Mean bait consumed per day (g)</th><th rowspan="2">Mortality Period (days)</th><th colspan="2">Coumatetralyl content (µg/g)</th></tr>
<tr><th>Liver</th><th>Carcass</th></tr>
<tr><td>1 (M)</td><td>42</td><td>31.4</td><td>6.3</td><td>5</td><td>5.78</td><td>1.24</td></tr>
<tr><td>2 (M)</td><td>31</td><td>32.0</td><td>6.4</td><td>5</td><td>3.10</td><td>0.16</td></tr>
<tr><td>3 (M)</td><td>+19*</td><td>38.3</td><td>6.4</td><td>6</td><td>3.14</td><td>0.22</td></tr>
<tr><td>4 (M)</td><td>50</td><td>29.6</td><td>4.9</td><td>6</td><td>4.09</td><td>0.51</td></tr>
<tr><td>5 (M)</td><td>28</td><td>40.8</td><td>8.2</td><td>5</td><td>5.05</td><td>0.69</td></tr>
<tr><td>6 (M)</td><td>+25*</td><td>30.5</td><td>6.1</td><td>5</td><td>4.77</td><td>0.29</td></tr>
<tr><td>7 (F)</td><td>26</td><td>17.5</td><td>3.5</td><td>5</td><td>6.66</td><td>0.89</td></tr>
<tr><td>8 (F)</td><td>42</td><td>30.2</td><td>6.0</td><td>5</td><td>3.58</td><td>1.08</td></tr>
<tr><td>9 (F)</td><td>23</td><td>21.6</td><td>3.6</td><td>6</td><td>3.05</td><td>0.81</td></tr>
<tr><td>10 (F)</td><td>64</td><td>24.9</td><td>2.5</td><td>12</td><td><0.01</td><td><0.01</td></tr>
<tr><td>11 (F)</td><td>38</td><td>27.9</td><td>5.6</td><td>5</td><td>1.63</td><td>0.80</td></tr>
<tr><td>12 (F)</td><td>66</td><td>37.9</td><td>6.3</td><td>6</td><td>2.11</td><td>0.34</td></tr>
<tr><td>Mean</td><td>30.5</td><td>30.2</td><td>-</td><td>5.9</td><td>3.58</td><td>0.59</td></tr>
</table>
*Indicates weight gain during test period</td><td>[redacted] (2014b).

IIIB5.10-14</td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus),</td><td>The aim of this study was to test the performance in rats of a batch of 10g paste bait sachets containing coumatetralyl 375</td><td>Consumption of test bait (T) and alternative (A) in six pairs of Norway rats in test ID FRM-15-001. Per cent (%) of consumption given as per cent of total consumption T + A. Test bait stored for 24 months</td><td>[redacted] (2015)

IIIB5.10-17</td></tr>
</table>

	VKORCl strain wild type MHS	mg/kg and cholecalciferol 100 mg/kg, stored for 24 months under GLP, in comparison to a sample stored for two months only. No monitoring of active substance concentration was performed. Choice feeding test (T = Test; A = Challenge diet of broken wheat): Six male and six female rats were caged pairwise in Makrolon-cages Type IV. The bait treatment was offered in a 4 days choice trial. Bait consumption was determined after 4 days and mortality recorded for up to 14 days post-treatment.	

Cage	N[a] & Sex	Body weight (g)		Consumption Days 1-4 (g)				Bait consumed in g/100b BW (g)	Mortality Period (days)	
				T	A	T	A		Rat 1	Rat 2
1	2 M	420,1	409.5	27.5	78.9	25.8	74.2	35.6	6	7
2	2 M	451,7	383,0	40.2	41.5	49.2	50.8	36.8	6	6
3	2 M	506.9	424.8	21.5	73.8	22.6	77.4	31.5	6	6
4	2 F	313,0	294.8	60.6	22.5	72.9	27.1	46.0	6	6
5	2 F	265,8	290.7	24.1	30.1	44.5	55.5	48.5	6	6
6	2 F	193,5	261,5	19.4	92.5	17.3	82.7	38.5	7	7
Sum				193.3	339.3					
(PI)				0.36						

Consumption of test bait (T) and alternative (A) in two pairs of Norway rats in test ID FRM-13-009. Per cent (%) of consumption given as per cent of total consumption T + A. The test was conducted with paste bait containing coumatetralyl 375 mg/kg and cholecalciferol 100 mg/kg. The tested batch (ID2013-002678) was produced on 2013-05-08, the test started on 2013-07-02. Test bait stored for 2 months

Cage	N[a] & Sex	Body weight (g)		Consumption Days 1-4 (g)				Bait consumed in g/100b BW (g)	Mortality Period (days)	
				T	A	T	A		Rat 1	Rat 2
2	2 M	380.9	380.9	43.3	57.4	43.0	57.0	5.7	4	5
4	2 M	265.1	290.5	25.1	68.6	25.1	74.9	4.2	4	8
Sum				66.3	126.0					
(PI)				0.35						

Laboratory studies on Norway rats – supportive study

Racumin 3D	*Rattus norvegicus*, wild outbreed strain MHS, *Rattus norvegicus*, wild outbreed anticoagulant susceptible strain MHS and *Rattus norvegicus*, anticoagulant resistant strain Westphalia homozygote, VKORC1 Y139C.	1. The effect of feeding paste bait containing vitamin D3 (750 mg/kg) was investigated in choice trials with individually caged Norway rats of a wild strain. Rats were fed with experimental bait and broken wheat as alternative food *ad libitum*. Consumption was measured daily. For comparison, data were evaluated of choice feeding trials conducted previously with two anticoagulant rodenticides using the same rat strain and experimental protocol, except the period of the treatment. In the D3 trial, rats had access to the bait for 10 days. Bait: Standard paste bait formulation with A) 0.075% Vitamin D3; B) 0.0375% coumatetralyl; C) 0.0025% difethialone. 2. Free choice feeding trial with individually caged rats, trial no. BES-12-005 with 12 adult rats, 6 males and 6 females. Bait: Standard broken wheat bait with 375 mg/kg coumatetralyl + 100 mg/kg vitamin D3; Challenge diet: Broken wheat; Treatment period: 4 days; Data record: Daily consumption, mortality during 14 days post treatment observation. 3. Trial with rats of an anticoagulant-resistant strain Free choice feeding trial with individually caged rats, trial no. BES-12-004.	**Table 1:** Daily bait ingestion in g bait per 100 g bodyweight, ratios of bait consumption on day 1 and day 1+2, both of total consumption in three treatment groups, and mortality range and mean days. **Bait consumption (g/100BW) per day** / **Bait consumption ratio** / **Mortality** **Test ID** / **compound** / **D1** / **D2** / **D3** / **D4** / **Total** / **D1/Total** / **D1+2/Total** / **Days** **A** / **11-014** / **Vit. D3** / 4.56 / 1.46 / 0.06 / 0.02 / 6.07 / 75.4% / 99.5% / 4-19 (8) **B** / **06-015** / **Coumatetralyl** / 1.52 / 4.86 / 4012 / 2.20 / 12.69 / 12.0% / 50.2% / 4-7 (7) **C** / **97-102** / **Difethialone** / 3.68 / 3.53 / 3.43 / 3.39 / 14.03 / 26.2% / 51.3% / 7-11 (8) **Table 2:** Daily consumption of bait (375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol) in groups of six males and females each. Bait consumption in g/100 g bodyweight, and in per cent of total daily consumption (bait + alternative food). Mortality period (MP) in days. **Bait consumption** / **D1** / **D2** / **D3** / **D4** **Males** / **g/100g BW** / 1.43 / 0.87 / 0.25 / 0.16 **% of total feed** / 25 / 15 / 7 / 3 **Females** / **g/100g BW** / 4.09 / 2.37 / 0.51 / 0.13 **% of total feed** / 48 / 32 / 10 / 5 **Table 3:** Daily bait ingestion in g bait per 100 g bodyweight, ratios of bait consumption on day 1 and day 1+2, both of total consumption, males and females pooled together **Bait consumption (g/100BW) per day** / **Bait consumption ratio** **Test ID** / **compound** / **D1** / **D2** / **D3** / **D4** / **Total** / **D1/Total** / **D1+2/Total** **12-05** / **Couma + Vit. D3** / 2.76 / 1.26 / 0.38 / 0.15 / 4.9 / 55.1% / 89.4% **Table 4:** Consumption of bait containing 375 mg/kg coumatetralyl and 100 mg/kg vitamin D3, and challenge diet in g/100 g bodyweight by eight surviving anticoagulant resistant rats in a choice feeding trial. **g/100g BW** / **D1** / **D2** / **D3** / **D4** / **D6** / **D8** / **D10** **Bait** / 1.97 / 2.18 / 2.66 / 1.44 / 0.25 / 0.08 / 0.18 **Challenge diet** / 4.93 / 3.62 / 3.40 / 3.20 / 1.55 / 2.46 / 4.08 **Total** / 6.90 / 6.00 / 6.06 / 4.64 / 1.80 / 2.54 / 4.26 **Table 5:** Consumption of bait containing 375 mg/kg coumatetralyl and 100 mg/kg vitamin D3, and challenge diet in g/100 g bodyweight by eight surviving anticoagulant resistant rats in a choice feeding trial. **Rel. Bait Consumption** / **D1** / **D2** / **D3** / **D4** / **D6** / **D8** / **D10** **Percent** / 28.6 / 36.3 / 43.9 / 31.0 / 13.9 / 3.1 / 4.2	[redacted] (2012) IIIB5.10-15

<table>
<tr><td></td><td></td><td>Number of animals survived: 8 (3 males and 5 females); Bait: Paste bait with 375 mg/kg coumatetralyl + 100 mg/kg vitamin D3; Challenge diet: Broken wheat; Treatment period: 10 days

Data record: Consumption of bait and challenge diet on days 1, 2, 3, 4, 6, 8, 10.</td><td></td><td></td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus)

Strain: Wild strain derived from the wild rat (Rattus norvegicus).</td><td>No-choice (palatability) feeding test: conducted according to the Technical Notes for Guidance on Product Evaluation, Appendices to Chapter 7, Product Type 14 “Efficacy Evaluation of Rodenticidal Biocidal Products“, using a treatment length of 10 days (not 4 days). Six male rats and six female rats were caged singly, in suitable stainless steel cages under ambient conditions. There was a 4-day acclimatisation period prior to testing where a standard lab diet A04 (S.A.F.E.) pellet food plus tap water was provided ad libitum, followed by a 10-day test period, where the bait treatment and tap water were offered. No post-treatment observation period was necessary, as all but one of the animals died within the 10-day test period.

The soft block paste bait (containing 375 mg/kg coumatetralyl) was provided as a no-choice feed for 10 days.</td><td>Body weight, bait consumption, mortality & coumatetralyl content in 12 rats
<table>
<tr><th rowspan="2">Rat (sex)</th><th rowspan="2">Loss of body weight (g)</th><th rowspan="2">Bait consumed (g)</th><th rowspan="2">Mean bait consumed per day (g)</th><th rowspan="2">Mortality Period (days)</th><th colspan="2">Coumatetralyl content (µg/g)</th></tr>
<tr><th>Liver</th><th>Carcass</th></tr>
<tr><td>1 (M)</td><td>25</td><td>42.3</td><td>14.1</td><td>3</td><td>11.92</td><td>4.16</td></tr>
<tr><td>2 (M)</td><td>21</td><td>47.0</td><td>15.7</td><td>3</td><td>11.13</td><td>3.34</td></tr>
<tr><td>3 (M)</td><td>37</td><td>58.7</td><td>14.7</td><td>5</td><td>14.87</td><td>5.92</td></tr>
<tr><td>4 (M)</td><td>36</td><td>96.1</td><td>9.6</td><td>10</td><td>8.78</td><td>1.25</td></tr>
<tr><td>5 (M)</td><td>26</td><td>41.2</td><td>8.2</td><td>5</td><td>5.17</td><td>2.14</td></tr>
<tr><td>6 (M)</td><td>-</td><td>65.3</td><td>6.5</td><td>(>10)</td><td>-</td><td>-</td></tr>
<tr><td>7 (F)</td><td>40</td><td>65.3</td><td>5.7</td><td>8</td><td>7.35</td><td>2.93</td></tr>
<tr><td>8 (F)</td><td>49</td><td>49.7</td><td>5.0</td><td>10</td><td>8.85</td><td>4.73</td></tr>
<tr><td>9 (F)</td><td>25</td><td>40.8</td><td>8.2</td><td>5</td><td>13.03</td><td>6.44</td></tr>
<tr><td>10 (F)</td><td>23</td><td>74.0</td><td>7.4</td><td>10</td><td>18.81</td><td>8.15</td></tr>
<tr><td>11 (F)</td><td>39</td><td>44.6</td><td>7.4</td><td>6</td><td>13.80</td><td>2.72</td></tr>
<tr><td>12 (F)</td><td>35</td><td>50.7</td><td>8.5</td><td>6</td><td>12.06</td><td>0.84</td></tr>
<tr><td>Mean</td><td>32.4</td><td>56.3</td><td>-</td><td>6.5</td><td>11.43</td><td>3.87</td></tr>
</table></td><td>[redacted] (2014a).

IIIB5.10-13</td></tr>
<tr><td colspan="4">Field studies Norway rats</td></tr>
</table>

Racumin 3D

Norway rats (*Rattus norvegicus*)

[Wild population of bromadiolone resistant Norway rats on a mixed livestock farm, [redacted] Germany].

A broken wheat grain bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol. Study conditions: Ambient (as encountered in and around agricultural buildings in May and June). The field trial was conducted in and around farm buildings. 20 census feed points (bait stations) [20 bait points – different locations to census points] (at 1-2m distance) and 13 tracking patches (20 x 20 cm covered in silver sand) were distributed in the trial area.
The field test was conducted in four phases:
(a) Implementation of trial: As part of BCR testing.
(b) Pre-treatment census (5 days; 1 day gap): Census feed points/tracking patches were positioned. Four days after the bromadiolone bait was removed, 200g of rolled oats was presented at each of the 20 census points (bait trays), per day, for 5 days, with a 1 day gap prior to treatment) diet consumption on day 4 was used to determine the size of the rat population, plus use of tracking patches (resurfaced daily) to determine level of rat activity, providing a daily activity index [0 = no footprints, 1 = <20% footprints, 2 = 20%-40% footprints, 3 = 40%-60% footprints, 4 = 60%-80% footprints, 5 = >80% footprints].
(b) Baiting period (35 days; 5 day gap post-treatment): One day after the pre-baiting census rolled oats were removed, 100g of treated bait (0.0375% coumatetralyl + 0.01% cholecalciferol) was placed in each of the 20 bait points (bait stations). Quantities consumed were recorded three times a week (bait points with 50% bait take were refilled with 200g of test bait, empty bait stations with 400g of test bait). At the end of the 35 day baiting period, all treated bait was removed and the tracking

Mortality rates of Norway rats: based on feed, sites & tracking census

census day	***1***	***2***	***3***	***4***
census feed uptake (25 bait points)				
Pre-baiting (g)	984	1022	1134	1210
Post-baiting (g)	5	65	135	235
% mortality rate (*feed uptake*)	**99.5**	**93.6**	**88.9**	**80.6**
census feed sites (20 bait points)				
Pre-baiting (activity)	10/20	11/20	11/20	9/20
Post-baiting (activity)	1/20	1/20	1/20	3/20
% mortality rate (*feed sites*)	**90.0**	**92.9**	**92.9**	**66.7**
Tracking activity (13 patches)				
Pre-baiting (activity index)	26	27	23	24
Post-baiting (activity index)	0	0	6	12
% mortality rate (*tracking index*)	**100**	**100**	**73.9**	**50.0**

Consumption (g) during baiting phase & number of dead rats in test area

Day of trial	**2**	**5**	**7**	**10**	**12**	**14**	**16**	**19**	**22**	**26**	**28**	**30**	**33**	**35**	**Total**
Uptake	569	340	244	189	236	335	263	149	94	148	96	34	35	40	**2772**
Uptake/24hr	285	113	122	63	118	168	132	50	31	37	48	17	12	20	-
dead rats		1	3						1	1			1		**7**

Number of bait points with feeding activity during baiting phase

Day of trial	**2**	**5**	**7**	**10**	**12**	**14**	**16**	**19**	**22**	**26**	**28**	**30**	**33**	**35**
No. with feeding activity	9	8	6	4	6	6	4	4	5	5	4	3	2	1
No. empty bait points	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Total No. of bait points	20	20	20	20	20	20	20	20	20	20	20	20	20	20

Tracking activity during the baiting period

Day	**2**	**5**	**7**	**10**	**12**	**14**	**16**	**19**	**22**	**26**	**28**	**30**	**33**	**35**
A I (sum)*	18	15	13	7	9	6	6	6	8	6	7	5	6	6

*based on 12 tracking patches (A I = activity index)

[redacted] (2006)

IIIB5.10-01

<table>
<tr><td></td><td></td><td>patches evaluated to provide an activity index.
(d) Post-baiting census period (5 days): Five days after the treated bait had been removed, the 20 census feed stations were filled with 100g of rolled oats and feeding activities monitored the same as for the pre-baiting census phase. Diet consumption on day 4 was used to determine the size of the surviving rat population At the end of day 5, all census feed was removed.</td><td></td><td></td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus).

Strain: Anticoagulant resistant, homozygous Y139C (WPHR - Westphalia Homozygous Resistant).</td><td>A paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol.

No-choice feeding test: Norway rats (Rattus norvegicus).

Strain: Anticoagulant resistant, homozygous Y139C (WPHR - Westphalia Homozygous Resistant).

Four female and two male rats were caged singly, in suitable stainless steel cages under ambient conditions. There was a 7-day acclimatisation period prior to testing where rat and mouse standard lab diet (Höveler) plus tap water was provided ad libitum, followed by a 4-day test period, where the bait treatment and tap water were offered, followed by a period of up to 21 days (post-treatment observation) where feed and water were provided, same as for the acclimatisation period.

Consumption of bait and mortality were determined; individually ingested doses of both compounds were calculated.</td><td>Consumption of bait (g) and mortality periods
<table><tr><th>Sex</th><th>Day 1</th><th>Day 2</th><th>Day 3</th><th>Day 4</th><th>Day 1 to 4</th><th>Mortality Period (days)</th></tr><tr><td>m</td><td>23.9</td><td>24.6</td><td>3.9</td><td>0.1</td><td>52.5</td><td>5</td></tr><tr><td>m</td><td>29.7</td><td>22.5</td><td>0.8</td><td>0</td><td>53.0</td><td>5</td></tr><tr><td>f</td><td>14.2</td><td>16.4</td><td>6.2</td><td>0.3</td><td>37.1</td><td>5</td></tr><tr><td>f</td><td>27.6</td><td>17.7</td><td>5.0</td><td>0</td><td>50.3</td><td>6</td></tr><tr><td>f</td><td>19.2</td><td>13.7</td><td>5.6</td><td>0</td><td>38.5</td><td>7</td></tr><tr><td>f</td><td>26.3</td><td>21.7</td><td>5.6</td><td>0</td><td>53.6</td><td>5</td></tr><tr><td>Total</td><td>140.9</td><td>116.6</td><td>27.1</td><td>0.4</td><td>285.0</td><td></td></tr></table>Bodyweight of experimental animals and calculated consumed doses
<table><tr><th>Sex</th><th>Bodyweight (g)</th><th>Coumatetralyl (mg/kg)</th><th>Cholecalciferol (mg/kg)</th></tr><tr><td>m</td><td>420</td><td>46.9</td><td>12.5</td></tr><tr><td>m</td><td>420</td><td>47.3</td><td>12.6</td></tr><tr><td>f</td><td>280</td><td>49.7</td><td>13.3</td></tr><tr><td>f</td><td>240</td><td>78.6</td><td>21.0</td></tr><tr><td>f</td><td>230</td><td>62.8</td><td>16.7</td></tr><tr><td>f</td><td>280</td><td>71.8</td><td>19.1</td></tr></table></td><td>[redacted] (2013b)

IIIB5.10-05</td></tr>
</table>

<table>
<tr>
<td>Racumin 3D

(Paste Bait, 10g sachets containing 0.0375% coumatetralyl and 0.01% cholecalciferol)</td>
<td>Anticoagulant-resistant strain Tyr139Cys Norway rats (Rattus norvegicus). Wild population – [redacted] Germany.</td>
<td>The aim of this study was to assess the efficacy of a rodenticide paste formulation, containing 375ppm coumatetralyl and 100ppm cholecalciferol, against Norway rats (Rattus norvegicus), in particular of the anticoagulant-resistant strain Tyr139Cys under practical conditions. Prior to the study, 8 of 13 trapped rats were identified of the resistant genotype Tyr139Cys.

The protocol and time line were fixed according to a standard protocol.

The field test was carried out in three phases:
• Pre- treatment census (3 days, 2 days gap)
• Baiting period (11 days; 2 days gap)
• Post- treatment census (3 days)

a) Pre-treatment census

Ten bait stations were installed. Rolled oats were presented for census (ca. 100g at each point). Consumption of census feed was recorded every 24 hours for each census point. Mean consumption during the census period was considered for pre-treatment census of the rat population. All</td>
<td>Table 1: Survival rates defined by census feed and tracking activity
<table>
<tr><th>Census day</th><th>1</th><th>2</th><th>3</th><th>mean</th></tr>
<tr><td colspan="5">Census feed uptake</td></tr>
<tr><td>Pre-baiting (g/24h)</td><td>162</td><td>351</td><td>370</td><td>294</td></tr>
<tr><td>Post-baiting (g/24h)</td><td>10</td><td>14</td><td>30</td><td>18</td></tr>
<tr><td>% survival rate (feed uptake)</td><td>6</td><td>4</td><td>8</td><td>6</td></tr>
<tr><td colspan="5">Tracking activity</td></tr>
<tr><td>Pre-baiting (activity index)</td><td>22</td><td>121</td><td>22</td><td>22</td></tr>
<tr><td>Post-baiting (activity index)</td><td>2</td><td>2</td><td>4</td><td>3</td></tr>
<tr><td>% survival rate</td><td>9</td><td>10</td><td>18</td><td>12</td></tr>
</table>
Table 2: Consumption during the baiting period in the field trial
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>5</th><th>9</th><th>11</th><th>Total</th></tr>
<tr><td>Uptake (g)</td><td>167</td><td>200</td><td>93</td><td>29</td><td>5</td><td>0</td><td>494</td></tr>
<tr><td>Uptake/24h (g)</td><td>167</td><td>200</td><td>93</td><td>14</td><td>1</td><td>0</td><td></td></tr>
</table>
Table 3: Number of stations with feeding activity during the baiting period.
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>5</th><th>9</th><th>11</th></tr>
<tr><td>Bait stations with uptake (n=10 stations)</td><td>6</td><td>6</td><td>6</td><td>4</td><td>1</td><td>0</td></tr>
<tr><td>n empty stations</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>n stations (total)</td><td>10</td><td>10</td><td>10</td><td>10</td><td>10</td><td>10</td></tr>
</table>
Table 4: Tracking activity during the baiting period
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>5</th><th>9</th><th>11</th></tr>
<tr><td>Index (sum)</td><td>21</td><td>21</td><td>21</td><td>13</td><td>5</td><td>2</td></tr>
</table>
The observed level of control is an excellent proof of efficacy of the test bait Racumin RB 0.0375 (containing 0.0375% coumatetralyl, 0.01% cholecalciferol) in controlling anticoagulant-resistant Norway rats of the strain Tyr139Cys under practical conditions, in particular when only small or</td>
<td>[redacted] (2017).

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</tr>
</table>

		census baits were removed on the last day of the census assay. For a second census method, ten tracking patches (ca. 10cm x 20cm silver sand) were installed. The scoring weighted the density of tracks in relation to the percentage coverage of the tracking plates in five classes: 0% (index 0), 1-5% (index 1), 5-33% (index 2), 34-66% (index 3) and <66% (index 4) of the tracking plate covered with tracks. b) Baiting period Two days after the pre-census feed had been removed, ca. 100g paste bait was placed in the bait stations. Bait stations and census feed points were not in the same positions (distance >1m). The quantities consumed were evaluated and recorded four times during the first week of the treatment and twice during the second week. The bait stations were refilled with ca. 100g of bait. On the last day of the baiting period, the bait was removed. Tracking patches were checked according to the pre-treatment census. Duration of baiting: 11 days. c) Post- treatment census Two days after the bait had been removed, the census feed stations were filled with ca. 100g rolled oats. The feeding activities were evaluated according to phase a). All census feed was removed on the last day of the census assay.	medium infestations are concerned, such as on private grounds in urban and rural areas. The bait was well taken from the first day on, and continued consumption over a period of five days caused over 90% control effect.	

<table>
<tr>
<td>Racumin 3D</td>
<td>Norway rats (Rattus norvegicus)

[Wild population resistance status unknown, in and around a dogs home, [redacted], Germany].</td>
<td>A paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol. Study conditions: Ambient (as encountered in and around animal buildings in May and June). The field test was conducted in and around an animal home (dogs). No rat control measures had been conducted for at least one year prior to the trial in the experimental site.

The field test was conducted in three phases:

a) Pre-baiting census

b) Baiting

c) Post-baiting census.

The size of the study area was approximately 5000 square metres. The type of bait-station used was Protecta rat bait station, black with two holes at either end. Bait was fixed in dishes being part of the bait stations. Baiting-points were established 5 days prior to the pre-baiting census so as to get the rats accustomed to them and to gauge the level of infestation. The pre-baiting census was conducted using rolled oats, weighing consumption daily (100-200g of rolled oats per baiting point, 7 pre-baiting sites). The mean daily consumption over the two days of the pre-baiting census period was considered as 24 hours census consumption. In addition, a tracking census was performed</td>
<td>Daily bait consumption
<table>
<tr><th>Treatment Day #</th><th>Consumption (g)</th><th>Consumption/24 hours (g)</th></tr>
<tr><td>2</td><td>400</td><td>200</td></tr>
<tr><td>4</td><td>118</td><td>59</td></tr>
<tr><td>7</td><td>44</td><td>15</td></tr>
<tr><td>9</td><td>0</td><td>0</td></tr>
<tr><td>Total over 9 days</td><td>562</td><td></td></tr>
</table>
According to the census consumption in the range of 300 g/day, a rat pack of approximately 20 rats was supposed. Based on the data obtained during the census feeding and the baiting, the infestation was fully eradicated (100% control) within one week, which is considered a short period.</td>
<td>[redacted] (2013a)

IIIB5.10-03</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td>using tracking patches with silver sand. Tracking activity was recorded for every tracking patch (0 = no traces; 1 = <1/3 covered with foot prints; 2 = 1/3 to 2/3 covered; 3 = >2/3 covered). Tracking activity was recorded daily during the census periods, but with larger intervals during the baiting period. The sum of tracking values per day was used for the census.

Five days after completion of the pre-baiting census, the treatment began using five Protecta bait stations for rats and one open bait tray on the ceiling inside the building. Initially, 100g of bait per station was laid out; when the station was emptied, 200g of bait was used per station. The baiting period was scheduled for 14 days. Bait remains were replenished when approximately 75% had been consumed. The tracking patches were observed during the treatment as well, although the tracking scores were not considered valid due to different periods of controls.

The post-baiting census was conducted four days after the bait was removed, using rolled oats in the same places as during the pre-treatment census, including the tracking census.</td><td></td><td></td></tr>
<tr><td>Racumin 3D</td><td>Norway rats (Rattus norvegicus)

[Wild population of</td><td>A paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol. Study conditions: Ambient (as encountered in and around agricultural buildings in</td><td>Survival rates defined by feed, electronic & tracking census
<table>
<tr><td>Census day</td><td>1</td><td>2</td><td>3</td><td>Total</td></tr>
<tr><td colspan="5">Census feed uptake (26 bait points)</td></tr>
<tr><td>Pre-baiting (g)</td><td>410</td><td>465</td><td>518</td><td>1393</td></tr>
</table></td><td>[redacted] (2013)

IIIB5.10-06</td></tr>
</table>

	Norway rats on a mixed livestock farm [redacted], *Germany)].*	December and January). The field test was conducted in and around buildings of an old pig farm. No baiting had occurred at the site in the previous 6 months. A total of 26 census/bait points were used distributed throughout the trial area and 13 tracking patches. The positions of the census feed points differed from the treatment bait positions. The bait points consisted of black plastic bait stations (24 x 18 x 15 cm) with 2 entrances (Ø 6.5 cm) or plastic bait trays: Ø 12cm. Tracking patches (ca. 20 x 20cm) consisted of silver sand. The field trial was in four phases: a) Implementation of the trial, b) Pre-baiting census (4 days; then a 3 day break), c) Baiting period (15 days; then a 2 day break), d) Post-baiting census (4 days). a) Implementation of the trial: Infestation assessment, based on excrement, rat damage and footprints, then installing census feed points, tracking patches and bait stations, based on the data. Census feed points were placed in areas of high activity. b) Pre-baiting census: Census 1: Census feed was rolled oats. The census feed points were checked on a daily basis and the number of feed sites visited and the amount of the census feed consumed was recorded daily. All census feed was removed on the last day of the census assay. Census feed was laid for four days, which as far as possible exceeded the maximum daily	

Post-baiting (g)	22	21	31	74
% survival rate (*feed uptake*)	5.4	4.5	6.0	5.3
Tracking activity (13 tr. patches)				
Pre-baiting (activity index)	23	21	22	66
Post-baiting (activity index)	4	4	4	12
% survival rate	17.4	19.0	18.2	18.2

Consumption (g) during baiting phase & number of dead rats found

Day of trial	1	2	3	4	5	6	8	11	13	15	Total
Uptake	276	288	76	178	281	140	123	60	0	0	1422
Uptake/24hr	276	288	76	178	281	140	61.5	20	0.0	0.0	-
Dead rats	0	0	0	0	0	0*	0*	0*	0	0	

*Strong smell of dead animals, associated with a rat corpse in an inaccessible area.

Number of bait points with feeding activity during baiting phase

Day of trial	1	2	3	4	5	6	8	11	13	15
Feed sites (26 bait points)	11	11	8	7	7	4	3	2	0	0
No. empty stations	1	2	0	0	2	0	1	0	0	0
Total No. of stations	25	25	26	26	26	26	26	26	26	26

Tracking activity during the baiting period

Day of trial	1	2	3	4	5	6	8	11	13	15
[illegible]										

		take by rodents. The total amount of census feed consumed gave an index of the population size. Census 2: Tracking activity was measured over four days, simultaneously with the feeding census, using tracking patches/boards laid around the site in numbers almost similar to the census feed points, but as far as possible not in the same locations. The patches/boards were inspected for signs of activity and resurfaced daily. Scoring per patch/board: summing the individual scores gave a daily activity index (0 = none with tracks; 1 = <1/3 with tracks; 2 = 1/3 to 2/3 with tracks; 3 = >2/3 with tracks). c) Baiting period: Three days after the pre-baiting rolled oats were removed, 100g of treated bait was placed in the 26 bait points (either bait stations or bait trays - covered to protect from the weather or spillage and to avoid non-target organism access). Bait points and tracking patches were checked daily during the first week and three times during week 2. Bait stations were refilled with 100g test bait, when consumption of bait was > 50%. The test bait was applied in accordance with the proposed label, for an appropriate period (15 days). Quantities consumed were recorded. On the last day of the treatment, the bait was removed. Tracking patches (same as in the census baiting)		

<table>
<tr><td></td><td></td><td>were evaluated to provide an activity index.

d) Post-baiting census: After a two day lag period, census feed and tracking patches were laid in exactly the same places as in the pre-treatment census. Census feed stations were filled with rolled oats and the feeding activities were evaluated according to phase b). All census baits were removed on the last day of the census assay.</td><td></td><td></td></tr>
<tr><td colspan="5">Laboratory studies House mouse</td></tr>
<tr><td>Racumin 3D</td><td>House mouse (Mus musculus) of a wild strain.</td><td>Choice feeding trial with paste bait (375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol) in House mice (Mus musculus) wild strain.

The palatability and the efficacy of the bait were tested on 9 male and 11 female mice caged under ambient conditions. There were two connected pens per group, each pen measuring 60 cm x 69 cm, complete with feed-bowls and water available ad libitum. Rat and mouse standard lab diet, Höveler, ad libitum and cereals was available pre- and post-treatment. Tap water was available ad libitum. There was control of consumption for 2 days prior to treatment. Only when a minimum of 2.5g was consumed per mouse per day, was the group released for treatment. Healthy, non-pregnant adult mice were used, all of whom had been acclimatised to the test conditions for a minimum</td><td>Daily consumption of test paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol, and of challenge diet in groups of 9 male and 11 female mice.
<table>
<tr><td></td><td colspan="2">Males</td><td colspan="2">Females</td></tr>
<tr><td>Treatment</td><td>Bait</td><td>Challenge</td><td>Bait</td><td>Challenge</td></tr>
<tr><td>Day 1</td><td>4.0 g</td><td>29.2 g</td><td>14.1 g</td><td>22.4 g</td></tr>
<tr><td>Day 2</td><td>7.1 g</td><td>26.6 g</td><td>1.6 g</td><td>20.8 g</td></tr>
<tr><td>Day 3</td><td>3.6 g</td><td>19.2 g</td><td>9.2 g</td><td>19.6 g</td></tr>
<tr><td>Day 4</td><td>0.7 g</td><td>5.1 g</td><td>2.4 g</td><td>6.6 g</td></tr>
<tr><td>Day 5</td><td>0.1 g</td><td>1.6 g</td><td>0.2 g</td><td>5.8 g</td></tr>
<tr><td>Day 6</td><td>0 g</td><td>1.0 g</td><td>0 g</td><td>3.6 g</td></tr>
<tr><td>Day 7</td><td>0 g</td><td>0.7 g</td><td>0 g</td><td>3.0 g</td></tr>
<tr><td>Total</td><td>15.5 g</td><td>83.4 g</td><td>25.2 g</td><td>74.8 g</td></tr>
</table>
Time to death in two groups of house mice after start of consumption of test paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol.
<table>
<tr><td>Day:</td><td></td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr>
<tr><td>No. of Males</td><td></td><td>-</td><td>3</td><td>3</td><td>-</td><td>2</td><td>1</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>No. of Females</td><td></td><td>-</td><td>1</td><td>-</td><td>3</td><td>2</td><td>4</td><td>1</td><td>-</td><td>-</td></tr>
</table></td><td>[redacted] (2013e)

IIIB5.10-09</td></tr>
</table>

<table>
<tr><td></td><td></td><td>of 7 days. A challenge diet of EPPO standard broken wheat preparation (broken wheat, flour, maize oil), was available as an alternative to the bait paste. The number of dead mice was also undertaken. Two bowls of bait were available per group, 30 g of bait/challenge per bowl per day, available as part of the choice diet for 4 days, followed by a 14 day observation period.</td><td></td><td></td></tr>
<tr><td>Racumin 3D</td><td>House mouse (Mus musculus) of a wild strain.</td><td>No-Choice feeding trial with paste bait (375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol) in House mice (Mus musculus) wild strain.

The palatability and the efficacy of the bait were tested on 11 male and 11 females house mice (Mus musculus) wild strain, caged in adjoining connecting pens, under ambient conditions. There was a 7-day acclimatisation period prior to testing where rat and mouse standard lab diet (Höveler) and cereals plus tap water was provided ad libitum, followed by a 4-day test period.</td><td>Daily consumption of test paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol, in groups of 11 male and 11 female mice.
<table>
<tr><td>Treatment</td><td>Males bait consumption</td><td>Females bait consumption</td></tr>
<tr><td>Day 1</td><td>25.7 g</td><td>33.9 g</td></tr>
<tr><td>Day 2</td><td>23.7 g</td><td>18.9 g</td></tr>
<tr><td>Day 3</td><td>19.3 g</td><td>13.0 g</td></tr>
<tr><td>Day 4</td><td>0.3 g</td><td>3.5 g</td></tr>
<tr><td>Total</td><td>69.0 g</td><td>69.3 g</td></tr>
</table>
Time to death in two groups of house mice after start of consumption of test paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol.
<table>
<tr><td>Day:</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr>
</table></td><td>[redacted] (2013d)

IIIB5.10-08</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>During the exposure period, the test animals were provided with 30g test bait per bowl per day for 4 days, plus tap water.

Amount of bait consumed and period to mortality after first consumption of bait was determined for both male and female mice. Weighing the amount of bait remaining was done in order to determine consumption by the male and female mice. Counting the number of dead mice was also undertaken.

Note: all mice except one died within the 10 day testing/ observation period, the one male who survived, probably had already acquired an aversion to baits in general.</td>
<td>
<table>
<tr><td>No. of Males</td><td>2</td><td>-</td><td>-</td><td>3</td><td>3</td><td>1</td><td>-</td><td>-</td><td>1</td></tr>
<tr><td>No. of Females</td><td>-</td><td>1</td><td>4</td><td>2</td><td>2</td><td>2</td><td>-</td><td>-</td><td>-</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td colspan="5">Field studies house mouse</td>
</tr>
<tr>
<td>Racumin 3D</td>
<td>House mouse, (Mus musculus domesticus):

Wild population located on a mixed livestock farm, [redacted] Germany.

(resistance status unknown)</td>
<td>A paste bait containing 375 mg/kg coumatetralyl + 100 mg/kg cholecalciferol. Study conditions: Ambient (as encountered in and around agricultural buildings in December and January). The field test was conducted in and around old pig buildings. No previous baiting had occurred at the site in the previous 6 months. The test site consisted of 29-30 bait stations and 10 tracking patches. All bait stations were made of black plastic (24 x 18 x 15 cm) with 2 entrances (diameter 6.5 cm). Tracking</td>
<td>Survival rates of house mouse: based on feed, sensor & tracking census
<table>
<tr><td>census day</td><td>1</td><td>2+3</td><td>4</td><td>Total</td></tr>
<tr><td></td><td colspan="4">census feed uptake (11 bait points)</td></tr>
<tr><td>Pre-baiting (g)</td><td>84</td><td>173</td><td>100</td><td>357</td></tr>
<tr><td>Post-baiting (g)</td><td>6</td><td>20</td><td>9</td><td>35</td></tr>
<tr><td>% survival rate (feed uptake)</td><td>7.1</td><td>11.6</td><td>9.0</td><td>9.8</td></tr>
<tr><td></td><td colspan="4">tracking activity (7 tracking patches)</td></tr>
<tr><td>Pre-baiting (activity index)</td><td>12</td><td>15</td><td>10</td><td>37</td></tr>
<tr><td>Post-baiting (activity index)</td><td>2</td><td>2</td><td>1</td><td>5</td></tr>
<tr><td>% survival rate (activity)</td><td>16.7</td><td>13.3</td><td>10.0</td><td>11.0</td></tr>
</table>
</td>
<td>[redacted] (2012)

IIIB5.10-04</td>
</tr>
</table>

patches were a 20cm² pad of silver sand.

The field test was carried out in three phases: Pre-baiting census (5 days, 4 day gap), Baiting period (27 days; 3 day gap), Post-baiting census (5 days).

a) Pre-baiting census: Broken wheat was presented (30g at each point). The high amount of census feed was chosen to make sure that some feed was left over to determine consumption (after 24h). Consumption of census feed was recorded daily or every 48h for each census point. Consumption during the last 24h period was considered for pre-baiting census of the mouse population. All census baits were removed on the last day of the census assay. For a second census method, 14 tracking patches (20 cm x 20 cm silver sand) were installed.

b) Baiting period: Four days after the census feed had been removed, 20 g of bait was placed in bait stations. 29 bait stations were installed according to the interactive rodent control program Baytool. Bait stations and census feed points were in the same positions. The quantities consumed were evaluated and recorded two to three times per week. If the bait station was empty, the box was re-filled with 30g of bait. On the

Consumption (g) during baiting phase & number of dead mice in test area

Day of trial	2	5	9	12	16	18	20	23	27	Total
Uptake (g)	3	13	78	35	35	13	4	7	3	191 g
Uptake/24hr (g)	1.5	4.3	19.5	11.7	8.8	6.5	2.0	2.3	0.8	-
dead mice	0	0	2	2	0	1*	0	1	1	7

* No sample taken for genotype

Number of bait points with feeding activity during baiting phase

Day of trial	2	5	9	12	16	18	20	23	27
Bait points with feeding activity	3	4	10	6	7	6	2	2	1
No. empty bait points	0	0	3	0	0	0	0	0	0
Total number of bait points	29	29	29	29	29	29	29	29	29

Tracking activity during the baiting period

Day of trial	2	5	9	12	16	18	20	23	27
Activity index (sum)*	11	13	9	6	4	3	2	2	2

*based on 14 tracking patches

		last day of the baiting period, the bait was removed. The tracking patches were checked and re-freshed throughout the treatment. Bait Duration: 27 days. c) Post-baiting census Three days after the bait had been removed, the census feed stations were filled with 20 g broken wheat. The feeding activities were evaluated according to phase a). All census feed was removed on the last day of the census assay. Genotyping: Tissue-samples (5mm of the tail) of four mice found dead during the course of the treatment were stored in ethanol 80%, in small plastic vessels (Eppendorf 2.5ml). Every sample was marked with an ID, and a data sheet was filled in immediately after each sampling, containing the following information: ID, date of sampling. Samples were genotyped by the laboratory of [redacted] After four weeks of baiting, the survival rate as determined by pre versus post-census feed uptake was 9.8 % (90.2% control). Tracking activity was reduced to 11.0 % (89% control). 191g of bait was consumed during the course of treatment.		

<table>
<tr>
<td>Coumatetralyl Racumin RB 0.0375 (containing 375 mg/kg coumatetralyl)</td>
<td>House mouse, (Mus musculus domesticus):

Wild population located on a pig farm, Muensterland, in north-western

Germany [redacted]</td>
<td>Field trial to determine the efficacy of a paste bait containing coumatetralyl (0.0375%) against house mice (Mus musculus domesticus).

a) Pre-baiting census

Broken wheat was presented for census (40g at each point). The amount of 40g was chosen to make sure that some feed was left over to determine consumption (after 24h). Consumption of census feed was recorded daily for each census point. Consumption during the last 24h period was considered for pre-baiting census of the mouse population. All census baits were removed on the last day of the census assay.

b) Baiting period (28 days)

Two days after census feed was removed, 20g of bait were placed in bait stations. 15 bait stations were installed according to the interactive rodent control program Baytool which is available at www.baytool.de and www.baytool.info. Bait stations were different from census feed points. The quantities consumed were evaluated two times a week and recorded. If the bait station was empty, the box was refilled with 40g of bait. This increased amount of bait was required, because no bait stations could be applied inside the pig-boxes. On the last day of the baiting period, the bait was removed. Due to suspected mouse activity one</td>
<td>Table 1: Survival rates defined by census feed, feed sites and tracking census.
<table>
<tr><td>Census day</td><td>1</td><td>2</td><td>3</td><td>3</td></tr>
<tr><td>Census feed uptake (15 bait points)</td><td></td><td></td><td></td></tr>
<tr><td>pre-baiting (g)</td><td>103</td><td>117</td><td>119</td></tr>
<tr><td>post-baiting (g)</td><td></td><td>6</td><td>8</td></tr>
<tr><td>% survival rate (feed uptake)</td><td></td><td>5.1</td><td>6.7</td></tr>
<tr><td>Census feed sites (15 bait p.)</td><td colspan="3"></td></tr>
<tr><td>pre-baiting (n)</td><td>12</td><td>14</td><td>14</td></tr>
<tr><td>post-baiting (n)</td><td></td><td>2</td><td>3</td></tr>
<tr><td>% survival rate (feed sites)</td><td></td><td>14.3</td><td>21.4</td></tr>
<tr><td>Tracking activity (10 tr. patches)</td><td></td><td></td><td></td></tr>
<tr><td>Pre-baiting (activity index)</td><td>12</td><td>12</td><td>13</td></tr>
<tr><td>Post-baiting (activity index)</td><td></td><td>3</td><td>3</td></tr>
<tr><td>% survival rate</td><td></td><td>25.0</td><td>23.1</td></tr>
</table>
Table 2: Consumption during the baiting period and number of mice found dead during the treatment.
<table>
<tr><td>Day of trial</td><td>2</td><td>4</td><td>6</td><td>9</td><td>12</td><td>15</td><td>18</td><td>21</td><td>23</td><td>28</td><td>Total</td></tr>
<tr><td>uptake (g)</td><td>45</td><td>63</td><td>45</td><td>30</td><td>32</td><td>21</td><td>18</td><td>18</td><td>13</td><td>12</td><td>297</td></tr>
<tr><td>uptake/24 h (g)</td><td>22.5</td><td>31.5</td><td>22.5</td><td>10</td><td>10.7</td><td>7</td><td>6</td><td>6</td><td>6.5</td><td>2.4</td><td></td></tr>
<tr><td>dead mice</td><td>0</td><td>1</td><td>0</td><td>2</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>4</td></tr>
</table>
</td>
<td>[redacted]

IIIB5.10-18</td>
</tr>
</table>

additional bait station was established (Day 12; No. 16).

c) Post-baiting census

48 hours after the bait was removed, the census feed stations were filled with 40g broken wheat. The feeding activities were evaluated according to phase a). All census feed was removed on the last day of the census assay. For field trial schedule see Appendix 5.1. During the field trial 10 tracking patches (ca. 20 cm x 20 cm silver sand) were installed. Tracking activity was measured during census baiting and during treatment).

Genotyping for SNPs coding for resistance on VKOR gene:

Samples were taken from four mice found dead during the course of the treatment, provided that they were found fresh dead (<72h at low environmental temperature). Tissue-samples (5mm of the tail) were stored in ethanol 80%, in small plastic vessels (Eppendorf 2.5ml). Every sample was marked with an ID, and a data sheet was filled in immediately after each sampling, containing the following information: ID, juvenile/adult, trapped or found dead, gender, date of sampling. Samples will be genotyped by [redacted]. The results of the genotyping were not available when the present report was filed (list

Table 3: Number of bait stations with activity out of 16 stations during the baiting period

Day of trial	2	4	6	9	12	15	18	21	23	28
feed sites	6	7	5	6	6	6	4	4	4	2
n empty stations	2	1	0	0	0	0	0	0	0	0
n stations (total)	15	15	15	15	15	16	16	16	16	16

Table 4: Tracking activities during the baiting period.

Day of trial	2	4	6	9	12	15	18	21	23	28
index (sum)	13	13	11	7	8	7	5	5	5	4

		[redacted] The size of the initial infestation on the test farm was according to the consumption of 119g/24h). After four weeks of baiting the survival rate as determined by census-feed uptake was 6.7%. Number of feed sites was reduced from 14 in pre-baiting to 3 feed sites in post-baiting. Index values of the tracking patches were lower by 77.0% in post-baiting compared to pre-baiting .297g bait was consumed during the course of treatment		

Section	Author	Year	Title, Origin, Report No, Date
IVB5.10.01	[redacted]	2006	[redacted] (2006). Field trial to determine the efficacy of bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling bromadiolone-resistant Norway rats (*Rattus norvegicus*) on a farm in Muensterland, Germany. [redacted]. Study ID: KLN/BCS/2006-1, Bayer ID: BES01661. Not GLP, Unpublished. Trial period: 5/5/2006-23/6//2006.
IVB5.10.03	[redacted]	2013a	Field Trial with Bait Containing Coumatetralyl (375 mg/kg) and Vitamin D3 (100 mg/kg): Control of Norway Rats (*Rattus norvegicus*) in an Animal Home. [redacted]. Study ID: 04892. Bayer ID: ES 04892. Not GLP, Unpublished. Trial period: 16/5/2011-8/6//2011.
IVB5.10.04	[redacted]	2012	Field trial to determine the efficacy of paste bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling house mice (*Mus musculus domesticus*). [redacted] S., BCS-ESI/WBR. Study ID: KLN/BCS/2012-3. Bayer ID: ES 05510. Not to GLP, unpublished.
IVB5.10.05	[redacted]	2013b	Feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) in anticoagulant-resistant Norway rats (*Rattus norvegicus*). [redacted] Study ID: BES-09-12 Bayer ID: ES 05712. Not GLP, Unpublished.
IVB5.10.06	[redacted]	2013	Field trial to determine the efficacy of a paste bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling Norway rats (*Rattus norvegicus*). [redacted] Study ID: KLN/BCS/2012-06, Bayer ID: ES05713. Not GLP, Unpublished. Trial period: 9/10/2012-4/11//2012.
IVB5.10.07	[redacted]	2013c	Choice feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) in Norway rats (*Rattus norvegicus*) of a wild strain. [redacted]. Study ID: BES-13-002 Bayer ID: ES 05745. Not GLP, Unpublished.
IVB5.10.08	[redacted]	2013d	Feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) to prove the efficacy in the house mouse (*Mus musculus*) of a wild strain. [redacted]. Study ID: FRM-13-003. Bayer ID: ES 05748. Not to GLP, unpublished.
IVB5.10.09	[redacted]	2013e	Feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) to prove the efficacy in the house mouse (*Mus musculus*) of a wild strain. [redacted] Study ID: FRM-13-004. Bayer ID: ES 05749. Not to GLP, unpublished.
IVB5.10-13	[redacted]	2014a	Efficacy trial of Racumin Paste Bait (Coumatetralyl 0.0375% w/w) in Brown Rat (*Rattus norvegicus*). [redacted] Study ID: 14TOX006. Not GLP, Unpublished.
IVB5.10-14	[redacted]	2014b	Efficacy trial of a paste bait (0.0375% w/w Coumatetralyl + 0.010% w/w cholecalciferol) in Brown Rat (*Rattus norvegicus*). [redacted]. Study ID: 14TOX007. Not GLP, Unpublished.
IVB5.10-15	[redacted]	2012	Expert Opinion: Stop-Feeding Effect and Conditioned Taste Aversion Induced by Vitamin D3 (Cholecalciferol) in the Norway Rat, [redacted], 25 July 2012. Doc ID: ES 05454. Non-GLP, unpublished.

IVB5.10-17	[redacted]	2015	Efficacy of a Batch of Paste Bait Containing Coumatetralyl 375 mg/kg+ Vit. D3 100 mg/kg (batch ID 2012-004743), after 24 months storage. [redacted]. Study ID: FRM-15-001. Bayer ID: ES 06197. GLP, unpublished.
IVB5.10-18	[redacted]	2010	Field trial to determine the efficacy of a paste bait containing coumatetralyl (0.0375%) in controlling house mice *(Mus musculus domesticus)*. [redacted] Study ID No: KLN/BCS/2010-4A. Bayer ID No.: ES04389
IVB5.10-20	[redacted]	2017	Field trial to determine the efficacy of a rodenticide paste formulation, containing 375ppm coumatetralyl and 100ppm cholecalciferol, in controlling an infestation with Norway rats (*Rattus norvegicus*) comprising anticoagulant-resistant animals on a farm in Muensterland. [redacted]. Study No.: KLN/BCS/2016-5. Signed on 12th September 2017. Non-GLP, Unpublished.

2.4 HUMAN EXPOSURE ASSESSMENT

2.4.1 Introduction

Racumin 3D is a product intended for professional use by pest control operators. The exposure scenarios identified are direct exposure of professional users and indirect exposure of general public.

With regard to direct exposure it has to be noted that no specific model exists to estimate direct exposure during application and disposal of rodenticides for such a formulation type as Racumin 3D. The assessment of professional exposure has been performed using two different approaches. The first assessment (Tier 1) is based on HEEG opinion (wax block formulation) and is presented in section 2.4.2.4 and the second assessment (Tier 2) is based on formulation specific data which was used and accepted in the Annex I inclusion process of coumatetralyl. This assessment is presented in section 2.4.2.5.

Table 2.4.1-1 Identification of main paths of human exposure towards active substances from its use in biocidal products

Exposure path	Industrial use[1)]	Professional use	General public[2)]	Via the environment[3)]
Inhalation[4)]	Not appropriate	Negligible	Negligible	No
Dermal	Not appropriate	Yes	Yes	No
Oral[5)]	Not appropriate	No	Yes	No

[1)] Industrial use (manufacture of active substance and formulation of products) is not covered by BPR.

[2)] Indirect exposure due to handling of dead rodents or transient mouthing of bait by toddlers is included in the scenarios for general public.

[3)] According to the TNsG, indirect exposure via the environment is considered to be of minor importance as the release of rodenticides to the environment is limited.

[4)] CEFIC data (pilot study)[2] showed levels of inhalation exposure for pest control operators using wax block baits were negligible. The vapour pressure for coumatetralyl and cholecalciferol is also very low, i.e. 1×10^{-5} Pa at 20°C and 6×10^{-5} at 25 °C respectively.

[5)] As a major path of exposure the oral route is realistic only for toddlers accidentally ingesting the product. The User Guidance states that oral exposure during handling of baits is also possible for operators, if insufficient hygiene measures are followed.

[2] Snowden, P.J. Pilot study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide "baits". Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1301,27 November 2003, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

2.4.2 Professional exposure

2.4.2.1 Description of tasks

Racumin 3D is a ready-to-use bait paste which is formulated as a paste based on vegetable oils and is sealed in paper bags as ready to use bait sachets containing 10 g of paste per sachet. The product is applied at covered bait points or in bait boxes for use by professionals in and around buildings for the control of rats and mice. For rats, it is intended that up to 200 g paste are used per bait point 3-10 m apart in heavy infestations and 100 g paste per bait 5-20 m apart in light infestations. For mice, it is intended that 20 g paste are used per bait point 2-10 m apart in heavy infestations and 10 g, 5-20 m apart in light infestations.

The bait is placed in discrete locations within the infested area. Bait points are inspected frequently and the bait point is replenished when bait take is observed. When no further take is observed it is considered that control has been achieved and bait and bait points are removed from the site.

The label clearly instructs the user that bait sachets are to be secured and placed out of reach of children as well as inaccessible to uninvolved people and non-target animals. For professionals, only use in tamper resistant bait stations is authorised. For trained professional use in covered and protected bait points can also be used, however only in such a way that they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. In line with EU recommendations[3] the product contains further risk mitigation measures, i.e. the aversion agent Bitrex and a blue dye.

The Technical Notes for Guidance on Human Exposure to Biocidal Products, Part 2, June 2002 (pages 106 to 107) provides the following information for rodenticide wax block products.

- Application is by placing bait in bait stations. Solid baits are placed manually. Bait boxes are fixed in place.
- Outdoor treatments are seasonal. Highest usage outdoors is generally in the autumn months. Indoor treatments occur all year round.
- Post application tasks include checking bait boxes and the collection of uneaten bait and dead animals to minimize the risk to non-target animals.
- Much of the workers time is spent travelling to treatment sites and surveying. Rodenticide use is expected to occur on a daily basis.

2.4.2.2 Inhalation exposure

Inhalation exposure is considered not appropriate or negligible. Due to the non-volatile nature of coumatetralyl and cholecalciferol (vapour pressure: 1×10^{-5} Pa at 20 °C and 6×10^{-5} at 25 °C respectively) and the nature of the paste formulation it is reasonable to assume that inhalation is negligible and needs no further assessment.

2.4.2.3 Oral Exposure

Oral exposure during handling of baits is possible for operators, if insufficient hygiene measures are followed. However, for professional pest control operators this route is considered not appropriate or

[3] European Commission; Risk mitigation measures for anti-coagulants used as rodenticides; Version dated 28/02/2007; ENV B.3/PC D (2007)

negligible. The oral route is realistic only for toddlers accidentally ingesting the product. This scenario is further considered in the section for General public.

2.4.2.4 Dermal exposure - Tier 1 - according to HEEG approach

The approach used for the exposure assessment for rodenticide products, as proposed by HEEG (TM II 2011) is based on three exposure studies. The first, reported by Vetter and Sendor[4] established the number of manipulations associated with the application of rodenticide bait and bait station cleaning operations. A HEEG opinion, which harmonised the number of manipulations for these activities, was issued on 13 August 2010. For wax block and units of paste bait the agreed number of manipulations for professional use are:

- Number of individual bait stations loaded per day (application phase) = 60
- Number of individual bait station cleaning operations per day (post application phase) = 15

Further to this, an exposure study was commissioned by a consortium of rodenticide manufacturers under the auspices of CEFIC, in which exposures associated with all activities involved in using a grain bait and wax block bait product were monitored. These data[5,6] are used to derive indicative exposure values for dermal and inhalation exposure which, when combined with the findings from the Vetter and Sendor study, provide an exposure model for quantifying the exposure for pest control operators and non-professional users using rodenticide bait products.

The study reported by Chambers and Snowden took place in two small outbuildings of approximate floor areas 3.5 m^2 and 30 m^2. Each building was emptied of all temporary fixtures and fittings prior to beginning the study. It was noted from the pilot study that inhalation exposure was shown to be negligible for all tasks, apart from an indication of low, but measureable air concentrations when decanting grain bait in a confined space. The tasks monitored for the wax block product were securing the wax blocks in bait stations and the clean-up and disposal of wax blocks. Securing the wax blocks in bait stations was achieved by pushing the bait mounting pegs in the stations through the holes in the wax blocks. Five blocks were secured for each bait station. For the clean-up task, the loaded bait station was emptied by sliding each of the wax blocks off the steel mounting rod into a bucket and sweeping any remaining material from the bait station directly into the same bucket.

Racumin 3D is formulated as a paste based on vegetable oils and is sealed in paper bags as ready-to-use bait sachets containing 10 g of paste per sachet. Data determined for wax blocks may be used to predict exposure for these bait unit type products, as the handling and characteristics of these products are comparable. This principle was agreed at TM III 2006. The harmonised approach for exposure assessment, as proposed by HEEG, is to use the indicative 75th percentile values derived from the CEFIC

[4] Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFIC Rodenticides Working Group, report and addendum 2006.

[5] Snowden, P.J. Pilot study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide “baits”. Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1301,27 November 2003, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

[6] Chambers, J.G and Snowden, P.J. Study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide “baits”. Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1302, 8 March 2004, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

study for the various work tasks. The indicative 75th percentile values taken from the CEFIC data for the various activities associated with using wax block products are summarised below:

	Dermal **75th percentile mg b.p. per manipulation**
Loading bait boxes – placing of 5 blocks into a bait station = 1 manipulation	27.79
Cleaning up – emptying of loaded bait stations, sliding blocks off into a bucket	5.7

The CEFIC study monitored the exposure of subjects securing 5 compressed wax blocks (each 20 g, in total 100 g bait per box) into a bait station. One manipulation therefore involves handling five 20 g blocks of bait. HEEG recommends taking into account the number of contacts during one manipulation. For Racumin 3D the indicative values for rat and mouse control are as follows:

Application phase - Loading bait boxes

Rat control - up to 20 units of 10 g paste bait are used per bait point. So for each manipulation (bait point) the indicative dermal exposure value is 27.79/5 contacts x 20 contacts = 111.16 mg b.p./manipulation.

Mouse control – 2 units of 10 g paste bait are used per bait point. So for each manipulation the indicative dermal exposure value is 27.79 / 5 contacts x 2 contacts = 11.116 mg b.p./manipulation.

Post application - Cleaning up loaded bait

The indicative dermal exposure value (5.7 mg b.p.) is potential hand exposure for cleaning one bait point. This value is valid for different sized blocks.

Based upon the 75th percentile indicative values for wax blocks from the CEFIC data, exposure is predicted for professional pest control operators using Racumin 3D in the manner proposed as follows:

Table 2.4.2-1 Predicted exposure for loading 20 bait units (200 g) per rat bait point

	No PPE	**PPE (gloves)**
Coumatetralyl		
Amount of exposure to product (75th percentile overall) during loading 20 bait units per manipulation	27.79 mg b.p./5 contacts x 20 contacts = **111.16 mg b.p.**	27.79 mg b.p./5 contacts x 20 contacts = **111.16 mg b.p.**
Potential dermal exposure for 60 manipulations	111.2 mg b.p. x 60 = **6669.60 mg b.p.**	111.2 mg b.p. x 60 = **6669.60 mg b.p.**
Actual dermal exposure	**6669.60 mg b.p.**	6669.60 mg b.p. x 0.05 (glove protection) = **333.48 mg b.p.**
Amount of a.s. (0.0375% w/w)	6669.6 mg x 0.000375 = **2.50 mg a.s.**	333.48 mg x 0.000375 = **0.13 mg a.s.**

Systemic dose (dermal absorption 1.14%, bw 60 kg)	**4.8 x 10^{-4} mg/kg bw/d**	**2.4 x 10^{-5} mg/kg bw/d**
Cholecalciferol		
Amount of exposure to product (75th percentile overall) during loading 20 bait units per manipulation	27.79 mg b.p / 5 contacts x 20 contacts = **111.16 mg b.p.**	27.79 mg b.p / 5 contacts x 20 contacts = **111.16 mg b.p.**
Potential dermal exposure for 60 manipulations	111.2 mg b.p. x 60 = **6669.60 mg b.p.**	111.2 mg b.p. x 60 = **6669.60 mg b.p.**
Actual dermal exposure	**6669.60 mg b.p.**	6669.60 mg b.p. x 0.05 (glove protection) = **333.48 mg b.p.**
Amount of a.s. (0.01% w/w)	6669.6 mg x 0.0001 = **0.67 mg a.s.**	333.48 mg x 0.0001 = **0.033 mg a.s.**
Systemic dose (dermal absorption 0.16%, bw 60 kg)	**1.8 x 10^{-5} mg/kg bw/d**	**8.9 x 10^{-7} mg/kg bw/d**

Table 2.4.2-2-Predicted exposure for loading 2 bait units (20 g) per mouse bait point

	No PPE	PPE (gloves)
Coumatetralyl		
Amount of exposure to product (75th percentile overall) during loading 2 bait units per manipulation	27.79 mg b.p./5 contacts x 2 contacts = **11.12 mg b.p.**	27.79 mg b.p./5 contacts x 2 contacts = **11.12 mg b.p.**
Potential dermal exposure for 60 manipulations	11.12 mg b.p. x 60 = **666.96 mg b.p.**	11.12 mg b.p. x 60 = **666.96 mg b.p.**
Actual dermal exposure	**666.96 mg b.p.**	666.96 mg b.p. x 0.05 (glove protection) = **33.35 mg b.p.**
Amount of a.s. (0.0375% w/w)	666.96 mg b.p. x 0.000375 = **0.25 mg a.s.**	33.35 mg b.p. x 0.000375 = **0.013 mg a.s.**
Systemic dose (dermal absorption 1.14%, bw 60 kg)	**4.8×10^{-5} mg/kg bw/d**	**2.4×10^{-6} mg/kg bw/d**
Cholecalciferol		
Amount of exposure to product (75th percentile overall) during loading 2 bait units per manipulation	27.79 mg b.p. / 5 contacts x 2 contacts = **11.12 mg b.p.**	27.79 mg b.p. / 5 contacts x 2 contacts = **11.12 mg b.p.**
Potential dermal exposure for 60 manipulations	11.12 mg b.p. x 60 = **666.96 mg b.p**	11.12 mg b.p. x 60 = **666.96 mg b.p**
Actual dermal exposure	**666.96 mg b.p.**	666.96 mg b.p. x 0.05 (glove protection) = **33.35 mg b.p.**
Amount of a.s. (0.01% w/w)	666.96 mg b.p. x 0.0001 = **0.07 mg a.s**	33.35 mg b.p. x 0.0001 = **0.0033 mg a.s**
Systemic dose (dermal absorption 0.16%, bw 60 kg)	**1.8×10^{-6} mg/kg bw/d**	**8.9×10^{-8} mg/kg bw/d**

The indicative exposure for clean-up operations is 5.70 mg per manipulation, regardless of the number of bait units. Predicted exposure can be calculated as follows:

Table 2.4.2-3- Predicted exposure for clean-up operations

	No PPE	**PPE (gloves)**
Coumatetralyl		
Potential dermal exposure for 15 manipulations	5.70 mg b.p. x 15 = **85.50 mg b.p.**	5.70 mg b.p. x 15 = **85.50 mg b.p.**
Actual dermal exposure	**85.50 mg b.p.**	85.50 mg b.p. x 0.05 (glove protection) = **4.28 mg b.p.**
Amount of a.s. (0.0375% w/w)	85.5 mg b.p. x 0.000375 = **0.03 mg a.s.**	4.28 mg b.p. x 0.000375 = **0.0016 mg a.s.**
Systemic dose (dermal absorption 1.14%, bw 60 kg)	**6.1×10^{-6} mg/kg bw/d**	**3.0×10^{-7} mg/kg bw/d**
Cholecalciferol		
Potential dermal exposure for 15 manipulations	5.70 mg b.p. x 15 = **85.50 mg b.p.**	5.70 mg b.p. x 15 = **85.50 mg b.p.**
Actual dermal exposure	**85.50 mg b.p.**	85.50 mg b.p. x 0.05 (glove protection) = **4.28 mg b.p.**
Amount of a.s. (0.01% w/w)	85.5 mg x 0.0001 = **0.009 mg a.s.**	4.28 mg x 0.0001 = **0.00043 mg a.s.**
Systemic dose (dermal absorption 0.16%, bw 60 kg)	**2.3×10^{-7} mg/kg bw/d**	**1.1×10^{-8} mg/kg bw/d**

Table 2.4.2-4 – Summary of predicted dermal exposures for professional pest control operators – HEEG approach

Workplace operation	PPE	Exposure Path	Body dose (mg/kg bw/d)
Coumatetralyl			
Placing of bait units and clean up, trained professional – Rat control	None	Dermal, hands	4.8×10^{-4}
	Gloves	Dermal, hands	2.4×10^{-5}
Placing of bait units and clean up, trained professional – Mouse control	None	Dermal, hands	5.4×10^{-5}
	Gloves	Dermal, hands	2.7×10^{-6}
Cholecalciferol			
Placing of bait units and clean up, trained professional – Rat control	None	Dermal, hands	1.8×10^{-5}
	Gloves	Dermal, hands	9.0×10^{-7}
Placing of bait units and clean up, trained professional – Mouse control	None	Dermal, hands	2.0×10^{-6}
	Gloves	Dermal, hands	1.0×10^{-7}

Table 2.4.2-5 - Summary of direct exposure Professional Use (Tier 1)

Scenario		Exposure (µg/kg bw/day)	
		Coumatetralyl	**Cholecalciferol**
Inhalation exposure		Negligible	Negligible
Oral exposure		Negligible	Negligible
Dermal exposure			
DIRECT EXPOSURE – PROFESSIONAL USE			
Professional pest control operator – Rat control	no PPE	**0.481**	**0.018**
	PPE	**0.024**	**0.001**
Professional pest control operator – Mouse control	no PPE	**0.054**	**0.002**
	PPE	**0.003**	**0.0001**

The predicted exposures for professional pest control operators summarised above are based on a generic exposure model which provides a first tier assessment, and a worst case scenario. In the next section a higher tier assessment for this product has been made based on exposure figures generated in a formulation specific exposure study

2.4.2.5 Dermal exposure - Tier 2 - based on a formulation specific exposure study

Since no model is available specifically for assessment of exposure to paste baits in sachets, a second (Tier 2) assessment of the direct exposure of professional pest control operators were done base on a formulation specific study. The study : *"Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin Paste by Professionals and Amateurs (W. Maasfeld and G. Müller; MR-203/03, Jan. 16, 2004)"*, has been accepted by the RMS (Denmark) in the Annex I inclusion process of coumatetralyl (product-type PT14)[7] for evaluating direct exposure to coumatetralyl formulated as Racumin Paste. In this context it has to be noted that Racumin 3D is the same type of formulation, i.e. rodenticide paste based on vegetable oil. Hence, the results of this formulation specific study are considered to be appropriate to be used for estimating direct exposure of the professional user during the intended use of Racumin 3D.

During the Annex I procedure direct exposure of the professional user to coumatetralyl when using Racumin® Paste was assessed considering a work rate of 75 manipulations per day, i.e. loading of 60 bait stations and cleaning-up/disposal of 15 bait stations[8], which is in line with the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)[9]. However, it has to be noted that for Racumin Paste the size of the sachets amounted to 100 g paste/sachet whereas for Racumin 3D the size per sachet amounts to 10 g/sachet only. Thus taking into account that for both products the maximum application rate is the same, i.e. 200 g bait per baiting point for the control of rats, ten times the number of Racumin 3D sachets have to be handled compared to Racumin Paste to achieve the same application rate. Therefore the number of manipulations is adjusted accordingly, i.e. **600 loadings** and **150 disposals** are considered for Racumin 3D. Use of the data in this manner should be regarded as a precautionary approach and is expected to give a high estimate of exposure.

Furthermore the assessment for Racumin Paste was made for two scenarios:

- Considering exposure over a medium time period (corresponding to average exposure = geometric mean values were taken into account).
- Considering acute exposure (= maximum values were taken into account).

Accordingly, the same approach as proposed by the EU for Racumin Paste is used in this evaluation to assess direct exposure of the professional user to Racumin 3D.

2.4.2.5.1 Assessment of direct exposure through use – Dermal contract

The exposure figures used during EU review of coumatetralyl to assess direct exposure of the professional user are summarised in Table 2.4.1.2.3-1. In this context, the exposure assessment conducted by the EU for coumatetralyl considered specific exposure values normalised to µg coumatetralyl per event, as the exposure study was done with the representative formulation. However, to allow a generic use of the data corresponding exposure figures normalised to µg paste per event are presented as well and will be used in this evaluation together with the concentration of the active substance, i.e. 0.375 g coumatetralyl/kg and 0.1 g cholecalciferol/kg.

[7] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

[8] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

[9] HEEG opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants); Agreed at TM III 2010; Ispra, 13/08/2010

Table 2.4.2-6: Specific exposure figures used during the EU evaluation of coumatetralyl to assess direct exposure of the professional user to the representative formulation Racumin® Paste

Exposure conditions	PPE	Task	Specific Exposure	
			[µg coumatetralyl/event]	[mg paste/event]*
Sub chronic	No gloves	Application	0.845	2.25
		Disposal	0.502	1.34
	With gloves	Application	0.00439	0.0117
		Disposal	0.00606	0.0162
Acute	No gloves	Application	1.035	2.76
		Disposal	1.09	2.91
	With gloves	Application	0.0350	0.0933
		Disposal	0.0158	0.0421

*: Calculated figures consider coumatetralyl content of 0.375 µg coumatetralyl/mg present in the Racumin® Paste formulation.

Further assumptions used for the exposure assessment are as follows:

Concentration of the a.s.
- coumatetralyl: 0.375 µg/mg
- cholecalciferol: 0.1 µg/mg

Dermal absorption:
- cholecalciferol: 0.16%
- coumatetralyl: 1.14%

Body weight: 60 kg

Personal protective equipment (PPE):
No PPE: no gloves are worn when handling the sachets
With PPE: protective gloves are worn when handling the sachets.

It should be noted that this selection of protective measures is not intended to be a recommendation for the minimum PPE necessary when handling Racumin 3D. It does not consider specific requirements, which may exist in individual member states. Additional PPE can be used to further reduce the exposure of the operator.

Corresponding exposure estimates are presented in Table 2.4.2-7

Table 2.4.2-7: Estimated systemic direct exposure to cholecalciferol

Task	**Specific Exposure** [mg/event]		**Content of a.s.** [µg/mg]		**Events** [no./day]		**Dermal exposure** [µg a.s./day]		**Dermal absorption** [fraction]		**Systemic exposure**
Subchronic exposure situation											
No PPE											
Application	2.25	x	0.1	x	600	=	135	x	0.0016	=	0.216
Disposal	1.34	x	0.1	x	150	=	20.1	x	0.0016	=	0.0322
							Total [µg a.s./person/day]:			=	0.248
							Total [µg a.s./kg bw/day]:				**0.00413**
With PPE											

Task	**Specific Exposure** [mg/event]		**Content of a.s.** [µg/mg]		**Events** [no./day]		**Dermal exposure** [µg a.s./day]		**Dermal absorption** [fraction]		**Systemic exposure**
Application	0.0117	x	0.1	x	600	=	0.702	x	0.0016	=	0.00112
Disposal	0.0162	x	0.1	x	150	=	0.243	x	0.0016	=	0.00039
									Total [µg a.s./person/day]:	=	0.00151
									Total [µg a.s./kg bw/day]:		**0.0000252**
Acute exposure situation											
No PPE											
Application	2.76	x	0.1	x	600	=	166	x	0.0016	=	0.265
Disposal	2.91	x	0.1	x	150	=	43.7	x	0.0016	=	0.0699
									Total [µg a.s./person/day]:	=	0.335
									Total [µg a.s./kg bw/day]:		**0.00558**
With PPE											
Application	0.0933	x	0.1	x	600	=	5.60	x	0.0016	=	0.00896
Disposal	0.0421	x	0.1	x	150	=	0.632	x	0.0016	=	0.00101
									Total [µg a.s./person/day]:		0.00997
									Total [µg a.s./kg bw/day]:		**0.000166**

Table 2.4.2-8: Estimated systemic direct exposure to coumatetralyl

Task	**Specific Exposure** [mg/event]		**Content of a.s.** [µg/mg]		**Events** [no./day]		**Dermal exposure** [µg a.s./day]		**Dermal absorption** [fraction]		**Systemic exposure**
Subchronic exposure situation											
No PPE											
Application	2.25	x	0.375	x	600	=	506	x	0.0114	=	5.77
Disposal	1.34	x	0.375	x	150	=	75.4	x	0.0114	=	0.860
									Total [µg a.s./person/day]:	=	6.63
									Total [µg a.s./kg bw/day]:		**0.111**
With PPE											
Application	0.0117	x	0.375	x	600	=	2.63	x	0.0114	=	0.030
Disposal	0.0162	x	0.375	x	150	=	0.911	x	0.0114	=	0.0104
									Total [µg a.s./person/day]:	=	0.0404
									Total [µg a.s./kg bw/day]:		**0.00067**

Table 2.4.2.5-3 continued

Task	Specific Exposure [mg/event]		Content of a.s. [µg/mg]		Events [no./day]		Dermal exposure [µg a.s./day]		Dermal absorption [fraction]		Systemic exposure
Acute exposure situation											
No PPE											
Application	2.76	x	0.375	x	600	=	621	x	0.0114	=	7.08
Disposal	2.91	x	0.375	x	150	=	164	x	0.0114	=	1.87
							Total [µg a.s./person/day]:			=	8.95
							Total [µg a.s./kg bw/day]:				**0.149**
With PPE											
Application	0.0933	x	0.375	x	600	=	21.0	x	0.0114	=	0.239
Disposal	0.0421	x	0.375	x	150	=	2.37	x	0.0114	=	0.0270
							Total [µg a.s./person/day]:				0.266
							Total [µg a.s./kg bw/day]:				**0.00443**

Table 2.4.2-9: Summary of direct exposure Professional use (Tier 2)

Scenario		Exposure (µg/kg bw/day)	
		Coumatetralyl	**Cholecalciferol**
Inhalation exposure		Negligible	Negligible
Oral exposure		Negligible	Negligible
Dermal exposure			
DIRECT EXPOSURE – PROFESSIONAL USE			
Subchronic exposure situation	no PPE	**0.111**	**0.00413**
	PPE	**0.00067**	**0.0000252**
Acute exposure situation	no PPE	**0.149**	**0.00558**
	PPE	**0.00443**	**0.000166**

The predicted direct exposures for professional pest control operators summarised above are based on exposure figures generated in a formulation specific exposure study (Tier 2). This confirms that the actual levels of exposure to coumatetralyl and cholecalciferol are lower than those predicted using the HEEG approach (Tier 1).

2.4.3 Exposure of the general public

The product is not intended for use by non-professionals. Despite this it can not be excluded that the general public come in contact with the product, either while handling dead rodents or small children mouthing bait by mistake.

2.4.3.1.1 Inhalation exposure

Inhalation exposure is considered not appropriate or negligible. Due to the non-volatile nature of coumatetralyl and cholecalciferol (vapour pressure: 1×10^{-5} Pa at 20 °C and 6×10^{-5} at 25 °C respectively) and the nature of the paste formulation it is reasonable to assume that inhalation is negligible and needs no further assessment.

2.4.3.1.2 Dermal – Adults, Handling Dead Rodents (Acute)

Professional pest control operators and non professional users are not anticipated to handle dead rodents directly. Even in the event that rodents are found, handling dead rodents directly is not likely to be a source of exposure to Racumin 3D because (1) the bait works by ingestion, so there is likely to be no active substance on the outer surface of the rodent and thus, there is no source for dermal exposure and (2) professional pest control operators and non professional users are averse to handling dead animals and so will do so carefully and only while wearing gloves to help protect against rodent-borne diseases. Therefore, potential exposure to coumatetralyl and cholecalciferol associated with handling dead rodents is negligible.

2.4.3.1.3 Dermal – Children Handling Dead Rodents (Acute)

The Technical Meeting on Biocides (conclusion of the anti-coagulant expert meeting of May 18th 2006, TM II 2006,) agreed that "children handling dead rodents" is not a relevant exposure scenario.

2.4.3.1.4 Oral – Toddler Ingesting Bait (Acute)

The ingestion of poison bait by toddler was discussed at the Technical Meeting on Biocides (TM III) in 2008 (Ispra 04/07/2008). The scenario was re-defined as "Mouthing of poison bait - an exceptional scenario" and concerns the situation where a toddler manages to access a bait block, despite the preventive measures taken, and then licks the block, or ingests a piece of the block. Exposure is thus acute and is expected to occur only exceptionally.

The competent authority report prepared for coumatetralyl with Racumin Paste being the representative formulation considered this exceptional exposure scenario. In this context two situations were taken into account regarding the amount of bait mouthed, i.e. 10 mg of bait and 5 g of bait. These scenarios are taken from the biocides TNsG, which suggest a toddler could consume up to 5 g of product if no bait box is used for baits without a bittering agent (TNsG 2007, page 94). Where a bittering agent is used, as in the case of Racumin 3D, the amount ingested is assumed to be 10 mg (TNsG, Part 3, June 2002 / Final, Page 58).

Accordingly this exceptional exposure situation is considered when assessing indirect exposure to Racumin 3D even if this product contains 10 ppm of Bitrex for its bittering properties.

Further assumptions:

Concentration of the a.s.

- coumatetralyl: 0.375 µg/mg
- cholecalciferol: 0.1 µg/mg

Oral absorption:

- cholecalciferol: 100%
- coumatetralyl: 75%

Body weight (toddler): 10 kg

The corresponding exposure calculations are presented in the following.

Scenario A: Mouthing of 10 mg bait

With this exceptional scenario it is assumed that a toddler ingests 10 mg of bait. The corresponding systemic dose by the oral route (S_{oral}) is calculated as follows.

S_{oral} = amount bait ingested (mg) × concentration of a.s. × oral absorption

So for <u>cholecalciferol</u>

S_{oral} = 10 mg × 0.1 µg/mg × 1
= 1.0 µg/child
=0.1 µg/kg bw/day (10 kg toddler)

So for <u>coumatetralyl</u>

S_{oral} = 10 mg × 0.375 µg/mg × 0.75

= 2.81 µg/child

= **0.281 µg/kg bw/day** (10 kg toddler)

Scenario B: Mouthing of 5 g bait

With this exceptional scenario it is assumed that a toddler ingests 5 g of bait. The corresponding systemic dose by the oral route S_{oral} is calculated as follows.

S_{oral} = amount bait ingested (mg) × concentration of a.s. × oral absorption

So for <u>cholecalciferol</u>

S_{oral} = 5000 mg × 0.1 µg/mg × 1

= 500 µg/child

= 50 µg/kg bw/day (10 kg toddler)

So for <u>coumatetralyl</u>

S_{oral} = 5000 mg × 0.375 µg/mg × 0.75

= 1406 µg/child

= **141 µg/kg bw/day** (10 kg toddler)

Table 2.4.3-1: Summary of secondary exposure - General public

Scenario	Exposure (µg/kg bw/day)	
	Coumatetralyl	**Cholecalciferol**
SECONDARY EXPOSURE – GENERAL PUBLIC		
Mouthing of 10 mg bait (10 kg toddler)	**0.281**	**0.1**
Mouthing of 5 g bait ol (10 kg toddler)	**141**	**50**

2.4.4 Summary of human exposure assessment

The predicted exposures for professional pest control operators according to the HEEG approach are based on a generic exposure model, referring to handling of wax blocks, and can be considered as a worst case scenario and provides a first tier assessment. A second tier assessment for this product has been made based on exposure figures generated in a formulation specific exposure study: "Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin Paste by Professionals and Amateurs (W. Maasfeld and G. Müller; MR-203/03, Jan. 16, 2004)". This exposure study, accepted by the RMS (Denmark) in the Annex I inclusion process of coumatetralyl (product-type PT14)[10] confirms actual levels of exposure to coumatetralyl and cholecalciferol are lower than those predicted using the HEEG approach.

The predicted exposure of general public is limited to the scenario for mouthing of bait by toddlers. Other exposure scenarios were considered negligible or not relevant.

2.5 ENVIRONMENTAL EXPOSURE ASSESSMENT

2.5.1 Introduction

Racumin 3D containing 0.0375% w/w (375 ppm) coumatetralyl and 0.010% w/w (100 ppm) cholecalciferol is presented as a paste and applied in tamper-resistant bait stations. For trained professional use at covered and protected bait points can also be used, however only in such a way that they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. For rats, it is intended that up to 200g paste are used per bait point 3-10m apart in heavy infestations and 100g paste per bait 5-20m apart in light infestations. For mice, it is intended that up to 20g paste are used per bait point 2-10m apart in heavy infestations and 10g 5-20m apart in light infestations.

The bait is placed in discrete locations within the infested area; it is not dispersed or broadcast within the environment. All bait points are placed in dry locations and are protected to help prevent access by non-target animals. Bait points are inspected frequently and the bait point is replenished when bait take is observed. When no further take is observed it is considered that control has been achieved and bait and bait points are removed from the site.

[10] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

Table 2.5.1-1: Intended use of Racumin 3D

Product name Object and/or situation	Application: ready-to-use product - professional	
	PT	Application rate of active
In and around buildings Racumin 3D	14	Rats: 100-200g: 3-10 m apart for heavy infestations and 5-20 m apart for light infestations Mice: 20g: 2-10 m apart for heavy infestations and 5-20 m apart for and light infestations

2.5.2 Fate and Distribution in the Environment

Cholecalciferol:

No studies on hydrolysis or phototransformation were performed. The waiving of the hydrolysis study can be accepted on the basis that cholecalciferol lacks functional groups that hydrolyse under environmental conditions and is therefore not expected to be an important environmental fate process. With regards to the photolysis study waiver, this is acceptable as the study would be difficult to perform based the low solubility in water (<0.5 µg/l at 20ºC). In addition, the log Kow is >5 indicating low partitioning to the water phase. In addition Cholecalciferol + Coumatetralyl RB 0.0475 (0.1+0.375 g/kg) will be used in and around buildings only. According to the ESD for PT14[11] for this exposure scenario the main exposure of the environment is expected to be soil and other environmental compartments, such as the aquatic compartment, are considered not to be relevant.

Cholecalciferol is not readily biodegradable.

Therefore, due to its high log Kow of >5.0 and poor water solubility it is expected to rapidly partition to sewage sludge/sediment/soil. This is also confirmed by the measured log K_{OC} value of > 5.63 (K_{OC} value > 426580). However because of its impersistence it will be rapidly degraded in the environment. A summary of parameters are given in the table below.

Table 2.5.2-1: Summary of environmental fate parameters

Parameter	Value
Molecular Mass (g/mol)	384.7
Vapour pressure (Pa)	6.0 x 10^{-5} Pascal at 20°C
Water solubility (mg/l)	0.5 µg/L at 20°C.
Log Kow	>5.0 at 20°C
Adsorption K_{OC}	426580 (log K_{OC} > 5.63), OECD 121
Ready biodegradation	Not readily biodegradable
Soil DT_{50}	DT50s between 29.3 and 62.4 days

Coumatetralyl:

[11] Emission Scenario Document for Biocides used as Rodenticides (ESD PT14). CA-June03-Doc.8.2-PT14, J. Larsen, May 2003.

Coumatetralyl has already been reviewed for Annex I inclusion according to Directive 98/8/EC. Therefore in the following environmental exposure assessment agreed endpoints from the Coumatetralyl Assessment Report (CAR, 2009[12]) were used.

In the following a short summary of relevant parameters is presented:

Table 2.5.2-2: Summary of environmental fate parameters – coumatetralyl – CAR, 2009

Parameter	Value
Molecular Mass (g/mol)	292.3
Vapour pressure (Pa)	$<1.0 \times 10^{-3}$ Pa at 20°C
Water solubility (mg/l)	0.46 g/L at 20°C and pH7
Log Kow	>1.5 at 20°C and pH7
Adsorption K_{OC}	Arithmetic mean: K_{OC} is 302 cm^3/g based on 5 soils with 403 cm^3/g (Sand), 185 cm^3/g (Clay loam), 71 cm^3/g (Silt loam), 735 cm^3/g (Sandy loam) and 115 cm^3/g (Clay)
Ready biodegradation	Not readily biodegradable
Soil DT_{50}	No data available

The local predicted environmental concentrations (PECs) have been calculated with reference to the demonstrated use pattern above and the worst case scenarios outlined in the Emission Scenario Document (ESD) for biocides used as rodenticides (ESD for PT14).

According to the intended use and the ESD for PT14[13] one exposure scenario (in and around buildings) is appropriate for this product. The scenario is based on "realistic worst case" principles and was developed on the basis of rodenticide types, methods of application and disposal that are expected to result in the largest emissions to the environment.

The main exposure of the environment is expected to be soil and other environmental compartments, such as the aquatic compartment, are considered not to be relevant.

The label instructs users to search for rodent bodies during treatment and remove all remains of bait and bait containers after treatment using safe disposal methods. Such waste from this professional use must not be disposed of in refuse sacks or on open rubbish tips. Disposal is as controlled waste in accordance with National Regulations.

Taking these disposal methods into account, environmental exposure from disposal is expected to be limited to authorised waste sites.

[12] Assessment Report for Coumatetralyl PT14, Feb. 2009, available via:

[13] Emission Scenario Document for Biocides used as Rodenticides (ESD PT14). CA-June03-Doc.8.2-PT14, J. Larsen, May 2003.

2.6 HUMAN HEALTH EFFECTS ASSESSMENT

2.6.1 Percutaneous absorption

2.6.2 Percutaneous absorption

Test	Method Guideline	Species Strain Sex	% of applied dose	Reference
Coumatetralyl				
In vitro percutaneous absorption	OECD 428	Human (female) Rat (males)	Human: 0.316 Rat: 1.441 Rat-to- Human ratio of 4.6	[redacted], (2003a)
In vivo percutaneous absorption	OECD 427	Rat (males)	4.44%, 5.26%, 3.47%, 4.47% at 8, 24, 72, 168 hours post-application, respectively.	[redacted], (2003b)
Cholecalciferol				
In vitro percutaneous absorption	OECD 428	Human (female)	0.16	[redacted] (2013)

For coumatetralyl a dermal absorption value in humans of 1.14% is therefore used in the risk assessment based on extrapolation taking into consideration the worst case scenario including a dermal absorption of 5.26% in rat skin at 24 hours and a rat-to-human ratio of 4.6. For cholecalciferol a dermal absorption value in humans of 0.16% is used in the risk assessment based on the results of the *in vitro* percutaneous absorption study.

Ref-MS Information:	Although there are some minor differences in the product compositions, Ref-MS accepts the read across between Racumin 3D and Racumin Paste, the representative product in the CAR of coumatetralyl. Ref-MS recognises that if strictly interpreting Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665, the conditions in the guidance is not met since some co-formulants differ more than ±25%. Furthermore, the skin irritancy mean scores are higher for Racumin 3D. Ref-MS accepts the study based on the fact that the ingredients which are believed to drive the dermal absorption does not differ more than ±25% and that the irritancy mean scores are <2, based on very slight erythema. Dermal absorption of 1,14% for coumatetralyl is therefore accepted for the evaluation. The study on dermal absorption of cholecalciferol is considered acceptable and the value of 0.16% should be used for the evaluation of the product.

2.6.3 Acute toxicity

Route	Method Guideline	Species Strain Sex no/group	dose levels duration of exposure	Value LD50/ LC50	Remarks	Reference
Oral	OECD 423 (EC) No 440/2008, B.1tris.	Rat Sprague Dawley (female)	300, 2000 mg/kg 14 days	LD_{50} >2000 mg/kg bw	No classification	IIIB 6.1.1 [redacted] (2013a)
Dermal	OECD 402 (EC) No 440/2008, B.3.	Rat Sprague Dawley (5m/5f)	2000 mg/kg 24 hours	LD_{50} >2000 mg/kg bw	No classification	IIIB 6.1.2 [redacted] (2013b)
Inhalation	Conventional calculation method				No classification	IIIB 6.1.3

Racumin 3D does not require classification for acute oral, dermal or inhalation toxicity.

2.6.4 Irritation and corrosivity

Dermal irritation

Species	Method	Average score 24, 48, 72 h		Reversibility yes/no	Result	Reference
		Erythema	Oedema			
Rabbit (N Zealand white)	OECD 404 (EC) No.440/2008, B4	1.3, 0.3, 1.3	0.0, 0.0, 0.0	yes	Non-irritant No classification	IIIB 6.2s [redacted] (2013d)

Racumin 3D does not require classification for skin irritancy.

2.6.5 Eye irrition

Species	Method	Average Score				Result	Reversibility yes/no	Reference
		Cornea	Iris	Redness Conjunctiva	Chemosis			
Rabbit (N Zealand white)	OECD 405 (EC) No.440/2008, B5	0.0	0.0	0.5	0.5	Slightly irritant No classification	Yes	IIIB 6.2e [redacted] (2013c)

Racumin 3D does not require classification for eye irritancy.

2.6.6 Sensitisation

Species	Method	Concentration (%)	Stimulation index	Result	Reference

Mouse (CBA/J)	OECD 429 (EC) No 440/2008, B42	10%	1 (2.34)*	Not a Sensitiser No Classification	IIIB 6.3 [redacted] (2013e)
		25%	0.94 (2.20)*		
		50%	2.23 (5.21)*		

*Original evaluation

In the original evaluation of the sensitisation study, Racumin 3D fulfils the criteria to be classified as a skin sensitizer (Category 1 and sub-category 1B) and labelled with the signal word 'Warning' and hazard statement H317 (May cause an allergic skin reaction).

However, re-analysis of the results of the LLNA study with Racumin 3D indicated that the stimulation index at the highest dose was overestimated, due to an exceptionally low vehicle control value which was outside the laboratory historical control data. Using the mean value of the laboratory historical vehicle control data, the SI index of Racumin 3D is below 3 at all doses tested.

Ref-MS Information:	Ref-MS agrees with this conclusion. Racumin 3D does not require classification for sensitisation.

2.6.7 'In and around buildings'

For the scenario 'in and around buildings', it is assumed that the bait is placed at intervals 2 to 5 metres apart (depending if rats or mice are at a high and low infestation). The number of application sites was adapted according to the ESD for PT14.

2.6.7.1 PEC in air - 'In and around buildings'

The exposure of air is considered negligible in the scenario 'in and around buildings' according to the ESD and in addition cholecalciferol and coumatetralyl have a low vapour pressures (cholecalciferol: 6.0×10^{-5} Pa at 20°C; coumatetralyl $<1.0 \times 10^{-3}$ Pa at 20°C). Consequently, exposure of air will be negligible.

2.6.7.2 PEC in surface water, sewage treatment plant, ground water and sediment - 'In and around buildings'

The product is intended to be used within enclosed bait stations in and around buildings, only. According to the ESD for PT14 for this exposure scenario the main exposure of the environment is expected to be soil, and other environmental compartments, such as the aquatic compartment, are considered not to be relevant. However, since rodenticide active substances might be vertically transported to aquifers or even groundwater when entering the soil compartment a groundwater assessment should always be performed according to the ESD for PT14. Therefore, a quantitative assessment was carried out according to section 2.3.8.6 of the ECHA BPR Guidance, Volume IV Environment - Part B Risk Assessment.

$$PEClocal_{soil,porew} = \frac{PEClocal_{soil} \cdot RHO_{soil}}{K_{soil\text{-}water} \cdot 1000}$$

$$PEClocal_{grw} = PEClocal_{agr.soil,porew}$$

Table 2.6.7-1 Summary of PECs for groundwater – coumatetralyl and cholecalciferol

'in and around buildings'		
Coumatetralyl; Rats		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 2,52E-03 7,547E-04
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 5,38E-03 1,62E-03
Coumatetralyl; Mice		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 2,57E-04 7,35E-05
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case]	 5,88E-04 1,65E-04
Coumatetralyl Metabolite; Rats		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 2,68E-03 8,09E-04
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 9,13E-03 2,74E-03
Coumatetralyl metabolite; Mice		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 2,76E-04 7,35E-05
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case]	1,34E-03 4,04E-04
Cholecalciferol; Rats		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 4.91 E-06 1.59E-06
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 1.09E-05 3,32E-06
Cholecalciferol; Mice		
Low infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case	 5,31E-07 1.33E-07
High infestation	$PEC_{local,soil}$ [mg/L] -realistic worst case -normal case]	 1.20E-06 3,99E-07

2.6.7.3 PEC in soil - 'In and around buildings'

Estimation of direct and indirect environmental release

According to the ESD for PT14 exposure to the terrestrial environment is via direct release during application (1%) and indirect release via ingestion of bait and return to the soil as urine and faeces (90%). The area affected by indirect release during application is assumed to be 55m long by 10m wide.

In the Doc IIB Appendix II of the final Competent Authority Report for Coumatetralyl (2009) the fractions released to soil indirectly were refined based on guideline metabolism study of Anderson (1999).

The animals of the single-dose group received an oral dose of 0.1 mg/kg bw. The animals of the repeated-dose group (5 males) received 0.1 mg/kg bw of the non-labelled coumatetralyl on 14 consecutive days and the radiolabelled compound (0.1 mg/kg bw) on day 15. Chromatographic analysis of urine and faeces showed that coumatetralyl was extensively metabolized by rats after single or multiple dose administration.

The fraction of coumatetralyl which remained unchanged within the 7-day observation period ranged from 4.5 and 6.3 % of the applied dose in single and multiple-dose animals. Based on these data, the fraction of coumatetralyl potentially released in soil via urine and faeces of treated animals is estimated to be of 7% of the applied dose in following refinements. Therefore the fraction of coumatetralyl released indirectly to soil as parent is considered to be of 0.07 (coumatetralyl $F_{release\text{-}ID,soil}$ = 0.07). This value is used in PEC soil calculation for coumatetralyl.

A total of 77.2% of the applied dose was retrieved in excreta of multiple-dose animals. A fraction of 4.7% of this dose corresponded to unchanged coumatetralyl, whereas a total of 37.2% of the applied dose remained unidentified. As a worst case approach, the fraction of metabolites potentially released in soil via urine and faeces of treated animals is estimated to be of 77.2 – 4.7 = 72.5% = 73% of the applied dose. Therefore the fraction of coumatetralyl released indirectly to soil as metabolites is considered to be of 0.73 (Metabolites $F_{release\text{-}ID,soil}$ = 0.73). This value is used in PEC soil calculation for coumatetralyl.

For cholecalciferol, the default value is used for the fraction released indirectly to soil as parent.

Table 2.6.7-2: Quantitative evaluation of phenyl-UL-^{14}C]coumatetralyl and metabolites in rat urine and faeces (mean values in percent of the administered radioactivity) (see CAR, 2009)

Parameter	Males 0.1 mg/kg bw One single dose			Females 0.1 mg/kg bw One single dose			Males 15 x 0.1 mg/kg bw **Repeated dose**		
	% of the radioactive dose								
component	Urine	faeces	total	urine	faeces	total	urine	faeces	total
13-hydroxy-coumatetralyl (MT0315A)	11.4	4.5	15.9	13.2	1.3	14.5	19.5	7.2	26.7
12-hydroxy-coumatetralyl (MT0315C) + dihydroxy-coumatetralyl (MT0315D)	0.4	nd	0.4+	7.1	nd	7.1+	0.7	nd	0.7+
unidentified 306Da (MT0315B+E)	1.4	nd	1.4+	1.6	nd	1.6+	2.3	nd	2.3+
dihydroxy-coumatetralyl (MT0315F)	0.6	nd	0.6+	3.3	nd	3.3+	2.8	nd	2.8+
Coumatetralyl	0.9	3.6	**4.5**	4.2	2.1	**6.3**	0.9	3.8	**4.7**
Total identified	14.7	8.1	22.8	29.4	3.4	32.8	26.2	11.0	**37.2**
Total excreted	20.6	21.4	42.0	32.7	11.5	48.7	43.8	33.4	**77.2**

In the Doc IIB Appendix II of the final Competent Authority Report for Coumatetralyl (2009) the fractions released to soil directly were refined based on recommendations of ESD PT 14 (2003). The direct release during application and use in the environment is estimated by default at 1%. However this estimation is primarily based on grains and wax blocks. The formulation Racumin 3D is a ready bait paste which does not strictly fit any of the product types for which emissions scenarios have been detailed in ESD PT14. In addition Racumin 3D is enclosed in a paper sachet which minimizes the environment release as the product is never handled in a loose form. For these reasons the direct release during application and use in the environment is assumed to be at least 10 times lower than the default value of 1% proposed in ESD PT14. Therefore a value of 0.1% is used in PEC soil calculations. This refinement was accepted and used by the Rapporteur Member State (DK) for coumatetralyl.

Calculation of PEC soil

The following equations to calculate $E_{localsoil\text{-}campaign}$, $C_{localsoil\text{-}D}$, $C_{localsoil\text{-}ID}$ and $PEC_{local,soil}$ according to the ESD for PT14 were used:

$$E_{local,soil-D-campaign} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times F_{release,soil}$$

$$Clocal\_soil_{direct} = \frac{Qprod \cdot Fsubst \cdot Nsites \cdot Nrefill \cdot Fdirect_{soil}}{AREA_{expo,direct} \cdot DEPTHsoil \cdot RHOsoil \cdot Nsites}$$

$$Clocal\_soil_{indirect} = \frac{Qprod \cdot Fsubst \cdot Nsites \cdot Nrefill \cdot Fexcrete_{soil} \cdot (1 - Fdirect_{soil})}{AREA_{expo,indirect} \cdot DEPTHsoil \cdot RHOsoil}$$

$$Clocal_{soil} = Clocal\_soil_{direct} + Clocal\_soil_{indirect}$$

According to the intended use for rats up to 200g per bait point up to 3m apart in heavy infestations and up to100g up to 5m apart in light infestations are used[14].

Table 2.6.7-3: PEC in soil - rats - 'In and around buildings' - coumatetralyl

Exposure	
	coumatetralyl (0.375 g/kg)
amount of product used in control operation for each bait box	100-200 g
fraction of active substance in product	0.000375
number of application sites – low infestation (5m apart) [15]	10
number of application sites – high infestation (3m apart)	17
number of refilling times (default ESD)	
- realistic worst case	5
- normal case	1.5
fraction of product released directly to soil	0.001[a)]
fraction released indirectly to soil as parent	0.07[a)]
fraction released indirectly to soil as metabolite	0.73[a)]
Soil – low infestation – realistic worst case*	
Local direct emission rate of active substance to soil from a campaign:	
$E_{localsoil\text{-}campaign}$	**0.0019 g/campaign wwt**
Local concentration in soil due to direct release after a campaign:	
$C_{localsoil\text{-}D,parent}$	**0.0123 mg/kg wwt**
PARENT:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID\text{-}parent}$	**0.0014 mg/kg** wwt
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.0137 mg/kg wwt**
- normal case	**0.0041 mg/kg wwt**
METABOLITE:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID\text{-}metabolite}$	
- realistic worst case	**0.0146 mg/kg wwt**
- normal case	**0.0044 mg/kg wwt**
Soil – high infestation – realistic worst case*	
Local direct emission rate of active substance to soil from a campaign:	
$E_{localsoil\text{-}campaign}$	**0.0064 g/campaign** wwt
Local concentration in soil due to direct release after a campaign:	
$C_{localsoil\text{-}D,\ parent}$	**0.0245 mg/kg** wwt
PARENT:	
Concentration in soil due to indirect (disperse) release after a campaign:	**0.0048 mg/kg** wwt
$C_{localsoil\text{-}ID,\ parent}$	
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.0293 mg/kg wwt**
- normal case	**0.0088 mg/kg wwt**
METABOLITE:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID,\ metabolite}$	
- realistic worst case	**0.0497 mg/kg wwt**

[14] The lowest distance is used for the risk assessment to cover the worst case.

[15] 10 sites is the default value according to the ESD for a 5m distance between the baits (=55/5=11, but first bait stations is placed after the first 5m, see ESD for PT14), for 3m this results in ca. 17 sites (55/3=18.3), if first bait stations is placed after the first 3m.

- normal case	**0.0149 mg/kg wwt**
*Please note that values presented above were calculated and rounded in Excel and therefore minimal differences might occur if the values above are used in a manual calculation.	

a) justification on previous page

For mice, up to 20g per bait point up to 2m apart in heavy infestations and up to 10g with 5m distance in light infestations are used[16].

Table 2.6.7-4: PEC in soil – mice - 'In and around buildings' - coumatetralyl

Exposure	
	coumatetralyl (0.375 g/kg)
amount of product used in control operation for each bait box	10-20 g
fraction of active substance in product	0.000375
number of application sites – low infestation (5m apart)	10
number of application sites – high infestation (2m apart)	25
number of refilling times (default ESD)	
- realistic worst case	5
- normal case	1.5
fraction of product released directly to soil	0.001[a)]
fraction released indirectly to soil as parent	0.07[a)]
fraction released indirectly to soil as metabolite	0.73[a)]
Soil – low infestation–realistic worst case*	
Local direct emission rate of active substance to soil from a campaign:	
$E_{localsoil\text{-}campaign}$	**0.0002 g/**campaign
Local concentration in soil due to direct release after a campaign:	
$C_{localsoil\text{-}D}$	**0.0012 mg/kg** wwt
PARENT:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID\text{-}parent}$	**0.0001 mg/kg** wwt
Total concentration in soil: $PEClocal_{soil}$-	
- realistic worst case	**0.0014 mg/kg wwt**
- normal case	**0.0004 mg/kg wwt**
METABOLITE:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID\text{-}metabolite}$	
- realistic worst case	**0.0015 mg/kg wwt**
- normal case	**0.0004 mg/kg wwt**
Soil – high infestation–realistic worst case*	
Local direct emission rate of active substance to soil from a campaign:	
$E_{localsoil\text{-}campaign}$	**0.0009 g**/campaign
Local concentration in soil due to direct release after a campaign:	
$C_{localsoil\text{-}D,\ parent}$	**0.002 mg/kg** wwt
PARENT:	
Concentration in soil due to indirect (disperse) release after a campaign:	
$C_{localsoil\text{-}ID,\ parent}$	**0.0007 mg/kg** wwt
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.0032 mg/kg wwt**
- normal case	**0.0009 mg/kg wwt**
METABOLITE:	

[16] The lowest distance is used for the risk assessment to cover the worst case.

Concentration in soil due to indirect (disperse) release after a campaign: $C_{localsoil\text{-}ID,\ metabolite}$	
- realistic worst case	**0.0073 mg/kg wwt**
- normal case	**0.0022 mg/kg wwt**
*Please note that values presented above were calculated and rounded in Excel and therefore minimal differences might occur if the values above are used in a manual calculation.	

a) justification above

Table 2.6.7-5: PEC in soil - rats - 'In and around buildings' - cholecalciferol

Exposure	
	Cholecalciferol (0.10 g/kg)
amount of product used in control operation for each bait box	100-200 g
fraction of active substance in product	0.00010
number of application sites – low infestation (5m apart)	10
number of application sites – high infestation (3m apart)	17
number of refilling times (default ESD)	
- realistic worst case	5
- normal case	1.5
fraction of product released directly to soil	0.01[a]
fraction released indirectly to soil as parent	0.9
<u>Soil – low infestation–realistic worst case</u>	
Local direct emission rate of active substance to soil from a campaign: $E_{localsoil\text{-}campaign}$	0.0050 g/campaign
Local concentration in soil due to direct release after a campaign: $C_{localsoil\text{-}D}$	0.0327 mg/kg
Concentration in soil due to indirect (disperse) release after a campaign: $C_{localsoil\text{-}ID}$	0.0048 mg/kg
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.037 mg/kg wwt**
- normal case	**0.012 mg/kg wwt**
<u>Soil – high infestation–realistic worst case</u>	
Local direct emission rate of active substance to soil from a campaign: $E_{localsoil\text{-}campaign}$	0.0170 g/campaign
Local concentration in soil due to direct release after a campaign: $C_{localsoil\text{-}D}$	0.0654 mg/kg
Concentration in soil due to indirect (disperse) release after a campaign: $C_{localsoil\text{-}ID}$	0.0162 mg/kg
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.082 mg/kg wwt**
- normal case	**0.025 mg/kg wwt**

a) justification above

Table 2.6.7-6: PEC in soil – mice - 'In and around buildings' - cholecalciferol

Exposure	
	Cholecalciferol (0.10 g/kg)
amount of product used in control operation for each bait box	10-20 g
fraction of active substance in product	0.00010
number of application sites – low infestation (5m apart)	10
number of application sites – high infestation (2m apart)	25
number of refilling times (default ESD)	
- realistic worst case	5
- normal case	1.5
fraction of product released directly to soil	0.01[a]
fraction released indirectly to soil as parent	0.9
Soil – low infestation	
Local direct emission rate of active substance to soil from a campaign: $E_{localsoil\text{-}campaign}$	0.0005 g/campaign
Local concentration in soil due to direct release after a campaign: $C_{localsoil\text{-}D}$	0.0033 mg/kg
Concentration in soil due to indirect (disperse) release after a campaign: $C_{localsoil\text{-}ID}$	0.0005 mg/kg
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.004 mg/kg wwt**
- normal case	**0.001 mg/kg wwt**
Soil – high infestation	
Local direct emission rate of active substance to soil from a campaign: $E_{localsoil\text{-}campaign}$	0.0025 g/campaign
Local concentration in soil due to direct release after a campaign: $C_{localsoil\text{-}D}$	0.007 mg/kg
Concentration in soil due to indirect (disperse) release after a campaign: $C_{localsoil\text{-}ID}$	0.002 mg/kg
Total concentration in soil: $PEClocal_{soil}$	
- realistic worst case	**0.009 mg/kg wwt**
- normal case	**0.003 mg/kg wwt**

a) justification above

2.6.7.4 Summary PECs

The PECs in soil are calculated for 'in and around buildings' according to the ESD for PT14 and are presented in the table below. It should be noted that at Tier I these values are based on worst case assumptions and without any further consideration of degradation. In addition they are related to a localised area around the bait stations or bait points. According to the ESD for PT14 it is assumed that exposure of air and surface water from the use 'in and around buildings' is negligible.

Table 2.6.7-7: Summary of PECs for soil - coumatetralyl

'in and around buildings'		
Parent		
Rats		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0137 0.0041
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0293 0.0088
Mice		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0014 0.0004
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0032 0.0009
Metabolite		
Rats		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0146 0.0044
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0497 0.0149
Mice		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0015 0.0004
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.0073 0.0022

Table 2.6.7-8: Summary of PECs for soil - cholecalciferol

'in and around buildings'		
Rats		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.037 0.012
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.082 0.025
Mice		
Low infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case	 0.004 0.001
High infestation	$PEC_{local,soil}$ [mg/kg wwt] -realistic worst case -normal case]	 0.009 0.003

Regarding predicted concentrations in porewater (surrogate for groundwater):

PECs for coumatetralyl range between 2.57E-04 – 5.38E-03 mg/L (realistic worst case) and 7,35E-05 - 1,62E-03 mg/L (normal case).

PECs for coumatetralyl metabolite range between 2,76E-04 - 9,13E-03 mg/L (realistic worst case) and 7.35E-05 – 2.74E-03 mg/L (normal case).

PECs for cholecalciferol range between 5.31E-07- 1.09E-05 mg/L (realistic worst case) and 1.33E-07 – 3.32E-06 mg/L (normal case).

2.6.8 Non compartment specific exposure relevant to the food chain

2.6.8.1 Primary poisoning of non-target organisms

Normal use

In use scenarios where the bait is placed in protected bait points, there is the risk of primary poisoning mainly for birds and mammals of equal size or smaller than the target rodents, which may be able to enter the bait stations. Also when tamper-resistant bait boxes are used, there is the risk of primary poisoning mainly for birds and mammals of equal size or smaller than the target rodents, which may be able to enter the bait stations. Furthermore, when target animals carry bait away from e.g. bait stations, non-target animals may be exposed. However, primary poisoning hazard to mammals and birds (both wild and domestic) from use in and around buildings is expected to be small due to the use of specific risk mitigation measures (the use of protected bait stations, stringent use of careful baiting practises, for example the cleaning up of spillage afterwards).

Realistic Worst case (Tier 1 and Tier 2)

Worst case exposure estimations are based on the formulae and default values proposed by the ESD for PT14. The estimation of primary poisoning is based on the estimated daily uptake of a compound (ETE)

and relevant parameters are presented below. The results, including a second tier refinement according to the ESD for PT14 defaults, are presented in the following tables.

Table 2.6.8-1: Explanation of parameters used to estimate hazard of non-target mammals and birds

Variable/parameter	Symbol	Unit	Default
Input			
Food intake rate of indicator species (fresh weight)	FIR	g/d	See table below
Body weight	BW	g	See table below
Concentration of active compound in fresh diet (bait)	C	ppm	375ppm for coumatetralyl
Avoidance factor (1 = no avoidance, 0 = complete avoidance)	AV	–	1
Fraction of diet obtained in treated area (value between 0 and 1)	PT	–	1
Fraction of food type in diet (number between 0 and 1; one type or more types)	PD	–	1
Output			
Estimated daily uptake of active substance	ETE	mg/kg/bw/day	

The Tier 1 realistic-worst-case assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100 % of their diet in the treated area.

Birds: A hypothetical hazard of primary exposure to rodenticide bait material is given for any seed-eating bird. The worst case scenario for such a situation as set out by the ESD for PT14 was calculated.

Livestock and Pets: The maximum figure of 600g bait consumption (equivalent to the default amount of bait available on a treated site) is adopted by default from the ESD for PT14.

Table 2.6.8-2: Body weight and daily mean food intake and resulting bait consumption in non-target animals in the worst case situation

Species	Body weight [g]*	Daily mean food intake [g]*	Bait consumption [g]
Canis familiaris	10000	**	600.0
Sus scrofa	80000	**	600.0
Sus scrofa	25000	**	600.0
Passer montanus	22	7.6	7.6
Fringilla coelebs	21.4	6.42	6.42
Phasianus colchicus	953	102.7	102.7
*) Body weight and food intake values as given in the ESD for PT14 by default **) Not stated in ESD for PT14; therefore, a maximum bait consumption of 600 g is assumed.			

The Tier 1 realistic-worst-case assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100 % of their diet in the treated area.

Coumatetralyl:

The Tier 2 realistic-worst-case exposure estimates are based on adapted default values of AV=0.5 for birds and 0.9 for mammals (instead of 1 as suggested in the CAR for Coumatetralyl based on formulation

type (paste)[17]), PT=0.8 (instead of 1) as recommended in the ESD for PT14. An elimination factor of 0.3 per day was used, which is recommended in the ESD for PT14 as a reasonable average default value for elimination, as anticoagulant rodenticides are eliminated from the body mainly through faeces.

Table 2.6.8-3: Expected concentrations of coumatetralyl in selected non-target animals in primary poisoning scenarios after one meal followed by a 24 hour elimination period (concentration of coumatetralyl in rodenticide bait 0.0375%)

	Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
				mg/kg BW	mg/kg BW
OUTPUT	ETE dog	estimated daily uptake of a compound	≅ 0	22.5	16.2
	EC	estimated conc. of a.i. in indicator species	≅ 0	20.3	11.3
	ETE pig	estimated daily uptake of a compound	≅ 0	2.8	2.0
	EC	estimated conc. of a.i. in indicator species	≅ 0	2.5	1.4
	ETE young pig	estimated daily uptake of a compound	≅ 0	9.0	6.5
	EC	estimated conc. of a.i. in indicator species	≅ 0	8.1	4.5
	ETE tree sparrow	estimated daily uptake of a compound	≅ 0	129.5	51.8
	EC	estimated conc. of a.i. in indicator species	≅ 0	116.5	36.3
	ETE chaffinch	estimated daily uptake of a compound	≅ 0	112.5	45.0
	EC	estimated conc. of a.i. in indicator species	≅ 0	101.3	31.5
	ETE wood pigeon	estimated daily uptake of a compound	≅ 0	40.6	16.3
	EC	estimated conc. of a.i. in indicator species	≅ 0	36.6	11.4
	ETE pheasant	estimated daily uptake of a compound	≅ 0	40.4	16.2
	EC	estimated conc. of a.i. in indicator species	≅ 0	36.4	11.3

*If label instructions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. **The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.9 for mammals and AV=0.5 for birds (instead of 1), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).

Cholecalciferol:

The Tier 2 realistic-worst-case exposure estimates are based on adapted default values of AV=0.9 (instead of 1), PT=0.8 (instead of 1) as recommended in the ESD for PT14. An elimination factor of 0.3 per day was used, which is recommended in the ESD for PT14 as a reasonable average default value for elimination, as anticoagulant rodenticides are eliminated from the body mainly through faeces.

Table 2.6.8-4: Expected concentrations of cholecalciferol in selected non-target animals in primary poisoning scenarios after one meal followed by a 24 hour elimination period (concentration of cholecalciferol in rodenticide bait 0.010%)

	Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
				mg/kg BW	mg/kg BW
OUTPUT					

[17] AV can be set to 0.5 for birds product is a paste (agreed at Ca-Nov 2006, Doc. 4.3)

	ETE dog	estimated daily uptake of a compound	≅ 0	6.0	4.3
	EC	estimated conc. of a.i. in indicator species	≅ 0	5.4	3.0
	ETE pig	estimated daily uptake of a compound	≅ 0	0.8	0.5
	EC	estimated conc. of a.i. in indicator species	≅ 0	0.7	0.4
	ETE young pig	estimated daily uptake of a compound	≅ 0	2.4	1.7
	EC	estimated conc. of a.i. in indicator species	≅ 0	2.2	1.2
	ETE tree sparrow	estimated daily uptake of a compound	≅ 0	34.5	13.8
	EC	estimated conc. of a.i. in indicator species	≅ 0	31.1	9.7
	ETE chaffinch	estimated daily uptake of a compound	≅ 0	30.0	12.0
	EC	estimated conc. of a.i. in indicator species	≅ 0	27.0	8.4
	ETE wood pigeon	estimated daily uptake of a compound	≅ 0	10.8	4.3
	EC	estimated conc. of a.i. in indicator species	≅ 0	9.8	3.0
	ETE pheasant	estimated daily uptake of a compound	≅ 0	10.8	4.3
	EC	estimated conc. of a.i. in indicator species	≅ 0	9.7	3.0
*If label instructions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. ** The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.9 for mammals and AV=0.5 for birds (instead of 1), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).					

2.6.8.2 Secondary poisoning

Owing to their nature and use patterns, the only relevant pathway by which rodenticides may enter the food chain is via poisoned rodents (target or non-target) captured by predatory birds and mammals. Accordingly, secondary poisoning hazards are assessed following the scenarios set out in the ESD for PT14. The predicted environmental concentrations in the food of the predators (PEC_{oral}) are equivalent to the expected concentrations of coumatetralyl in poisoned target rodents.

According to the ESD for PT14, these are estimated in a similar way to the non-target body concentrations for primary poisoning.

According to the ESD for PT14 as a realistic worst case, the concentration in the rodent after 5 days of successive feeding exclusively on rodenticide bait is assumed (immediately after the last meal on day 5). However, Racumin 3D contains cholecalciferol, which acts as a stop feeding agent (CAR for cholecalciferol, 2018). Therefore, it could be reasonable to assume that rodents stop eating before the ESD default value of 5 days. However, the calculations for secondary poisoning are still based on the ESD default (N = 5 days) following the decision made at WG I 2017.

Coumatetralyl:

As a realistic worst case, the concentration of coumatetralyl is estimated in rodents after 5 days of successive feeding exclusively on rodenticide bait (immediately after the last meal on day 5). However specific results based on residue data in rats are available for coumatetralyl. In that respect the Rapporteur Member State (DK) proposed to use these existing residue data instead of calculating EC_n values to address secondary poisoning for birds and mammals (Doc IIB, Appendix I – CAR, 2009).

Several studies investigated the levels of residue in rats which were fed three consecutive days with bait containing coumatetralyl at same dose level as Racumin 3D (0.0375 % (w/w) or 375 ppm). Berny *et al.* (1999) showed that the coumatetralyl residues detected in the rat carcasses ranged from 0.6 to 13.1 mg as/kg bw with an average value of 4.3 and 6.2 mg as/kg bw in males and females, respectively. More recently O'Connor *et al.* (2003) and Fisher *et al.* (2003) showed similar results with an average of coumatetralyl residues detected in the rat whole body of approximately 4 mg as/kg, respectively. Based on these experimental data, the Rapporteur Member State (DK) proposed to use as a realistic worst case the value of **13.1 mg a.s/kg bw** (highest residue level measured in rats in the study of Berny (1999) for

acute exposure and the value of **6.2 mg a.s/kg bw** (average residue level measured in the same study) for **chronic exposure**. Further details are given in the CAR for Coumatetralyl (Doc IIB, Appendix I – CAR, 2009).

A more recent study investigated potential secondary poisoning of ferrets with Racumin D3 (Blackie & Eason, 2013b). In this study rats were exposed to the bait over three nights, then killed and poisoned carcasses were fed to captive ferrets. Residue levels were measured in treated rats but the analysis was limited to the liver with no estimation of coumatetralyl residues in the rat whole body. Knowing that predatory mammals consumed the majority of the carcasses offered, the residue levels in the liver are not representative of the real exposure. Therefore the approach as proposed and used by the Rapporteur Member State (DK) was used for the evaluation of secondary poisoning to non- target animals (Section 2.10).

Interestingly this study also monitored the bait consumption of treated rats over 3 days. As expected, the presence of cholecalciferol as a co-formulant, induced a definite stop feeding-effect. The average bait consumption dramatically decreased from 26.5 and 23.3 g on the 1st two nights to 3.9 g on the 3rd night of the trial.

Cholecalciferol:

Worst case, intermediate case and normal case acute exposure and chronic exposure, rodents feeding for n days (EC_n rodent)

It should be highlighted that the assumptions in the ESD for PT14 to evaluate the risk for secondary poisoning are applicable for anticoagulants and in the absence of any further guidance this was also used for cholecalciferol.

The ESD for PT14 considers a tiered approach of the daily consumption of poisonous bait by the target rodent from 100% (realistic worst case, PD=1), to 50% (intermediate case, PD=0.5) to 20% (normal case, PD=0.2).

The realistic worst case - in order to elucidate a full-scale scenario, a situation with PD = 1 (i.e. 100% of food items are poisoned bait) has to be considered. In the intermediate and normal use it seems very unlikely that an animal should not take the normal available food within its range, as the occurrence of its preferred food has been one of the factors determining its presence. Therefore, PD values 0.2, 0.5 and 1 are included in the following calculations.

The resulting oral predicted environmental concentrations for exposure of predators were estimated as follows (ref. EUBEES spreadsheet[18]):

[18]Available via: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/ESD/TRAINING_COURSE/PT14_RODENTICIDES [10.12.2012]

Table 2.6.8-5: EUBEES spreadsheet for assessment of secondary poisoning - Cholecalciferol

Symbol		Variable/parameter	Unit	Type of data*	Realistic worst case	Inter-mediate	Normal case
INPUT	C	Concentration of active ingredient in fresh diet	mg/kg	D/S	100	100	100
	AV	Avoidance factor (1 = no avoid, 0 = complete avoid.)	[-]	D/S	1	1	1
	PT	Fraction of diet obtained in treated area	[-]	D/S	1	1	1
	PD	Fraction of food type (treated bait) in diet	[-]	D/S	1	0.5	0.2
	El	Fraction of daily uptake eliminated	(per day)	RD	0.3	0.3	0.3
	F_{rodent}	Fraction of poisoned rodents in predator's diet (acute = 1)	[-]	D	1	1	1
		Fraction of poisoned rodents in predator's diet (chronic = 0.5)	[-]	S	0.5	0.5	0.5
OUTPUT	EC_n	estimated C, rodent on day 5 before feeding	mg/kg a.s.	O	15	7.3	2.9
	PEC oral, predator	PEC in food of predator on day 5 after last meal ('acute')	mg/kg rodent	O	23	11	4.6
		PEC in food of predator on day 5 after last meal ('chronic')	mg/kg rodent	O	11	5.7	2.3

*D=Default, S=Set, O=Output, RD=refined Default

PEC_{oral} was further used for the evaluation of secondary poisoning to non- target animals (Section 2.10).

Ref-MS Information:	The applicant used an adjusted FIR/BW value of 0.082 in secondary poisoning calculations (default value is 0.1). Ref-MS accepts the adjusted value as it only results in marginally different values that does not impact the outcome of the risk assessment.

2.7 ENVIRONMENTAL EFFECTS ASSESSMENT

The representative product contains the active substance substances cholecalciferol at 0.01% (w/w) (100 ppm) and coumatetralyl at 0.0375% (w/w) (375 ppm) and non-toxic components, and it is designed to be used around buildings (indoor and outdoor) to control mice and rats. It is a ready to use, sachet bait that is placed in tamper-resistant bait stations. For trained professional use at covered and protected bait points can also be used, however only in such a way that they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. The bait components are not expected to affect the fate of the active substances in the environment or have an effect on its ecotoxicity profile.

No significant direct exposure of either the aquatic or terrestrial environment by the indoor use is anticipated. However since outdoor uses may also be made around buildings, toxicity to soil organisms and higher tier animals *via* direct and indirect consumption of contaminated earthworms and rodents may occur. The risk to aquatic organisms is considered to be negligible as indicated in the ESD PT14 (2003).

The data provided for cholecalciferol (in the Competent Authority Report: SE, 2018) and coumatetralyl (summarised in the Competent Authority Report: DK, 2009) are sufficient to assess the toxicity / classification of the product by extrapolation. No further consideration to the product is therefore required. No synergistic effects are expected between any of the components in the formulation since the mode of action between the two active substances is different; the increased resistance of target species to anticoagulants (coumatetralyl) is effectively overcome with the presence of cholecalciferol which causes hypercalcemia. For non-target species, such as birds, aquatic organisms (fish, invertebrates, algae), and earthworms, both active substances have shown to be of medium to low toxicity.

No further consideration to the product is therefore required.

2.8 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

The product Racumin 3D, is a highly viscous soft block cereal based bait. It is not flammable and does not possess explosive or oxidising properties. It is considered to be stable for up to three years when stored in the commercial container at ambient temperatures.

2.9 RISK CHARACTERISATION FOR HUMAN HEALTH

2.9.1 General aspects

Racumin 3D will be used for the control of mice and rats, in and around buildings. Baiting points are to be inspected at intervals appropriate to the severity of infestation and refilled according to consumption, at least once a week. When control is completed, all bait has to be collected and disposed of.

The product is not intended for use by non-professionals. Despite this it can not be excluded that the general public come in contact with the product. However, the predicted exposure of general public is limited to the scenario for accidental mouthing of bait by toddlers. Other exposure scenarios were considered negligible or not relevant.

2.9.2 Critical end points

2.9.2.1 AEL for Cholecalciferol

An AEL of 0.00083 mg/kg bw/day should be used for short-term, medium-term and long-term operator exposure, corrected for an oral absorption of 50%, (Assessment Report Cholecalciferol (PT 14), January 2018). An appropriate limit value for the risk assessment for toddlers is the Total Upper Intake Level (UI) for children 1-10 years, 50 µg/child/day, from EFSA Scientific Opinion (2012), which is referred to in the CAR for cholecalciferol. This value is appropriate since the model for hand to mouth exposure of toddlers includes oral exposure only.

2.9.2.2 Dermal absorption for Cholecalciferol

Dermal absorption of cholecalciferol from the product "Racumin 3D" has been determined using *in vitro* human epidermis. A value of 0.16% for dermal absorption has been used for the exposure assessment.

2.9.2.3 AEL for Coumatetralyl

The biocidal active substance coumatetralyl is listed on Annex I according to the directive 98/8 EC[19]. Adjusted for oral absorption of 75% a systemic $AEL_{subchronic}$ of 0.017 µg/kg bw/day has been established for coumatetralyl. The AEL_{acute} established for coumatetralyl amounts to 0.031 µg/kg bw/day.

2.9.2.4 Dermal absorption for Coumatetralyl

Dermal absorption of coumatetralyl formulated as Racumin Paste being the representative formulation submitted for EU review was tested under *in vivo* as well as under *in vitro* conditions. The studies were submitted in the context of Annex I listing of the active substance coumatetralyl. Based on the study results dermal absorption of coumatetralyl was set to 1.14%.

2.9.3 Professional use – Direct exposure

The dominant route of exposure for professional users making applications of Racumin 3D is dermal exposure. An exposure study commissioned by a consortium of rodenticide manufacturers under the auspices of CEFIC data (pilot study)[20] showed levels of inhalation exposure for pest control operators using wax block baits were negligible. The vapour pressures of coumatetralyl (1×10^{-5} at 20 °C) and cholecalciferol (6×10^{-5} at 25 °C) are also very low. Oral exposures are not likely for professional applicators because gloves are worn when using the product, as recommended on the product label. Thus contact with the face and mouth through hand-to-mouth contact will be avoided. It is also noted that the product, as supplied, is sealed in paper bags as ready to use bait sachets which will further reduce the risk for direct (hand) contact with the formulated paste bait product.

[19] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

[20] Snowden, P.J. Pilot study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide "baits". Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1301,27 November 2003, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

2.9.3.1 Risk characterisation Professional users – Tier 1 – HEEG approach

A quantitative risk assessment for the use of Racumin 3D is presented below, using agreed defaults from the various TMs for rodenticides[21] and the indicative CEFIC[22,23] exposure data for the use of rodenticide baits. It is considered that the indicative data associated with the use of 'wax block' bait products are the most representative available, based on the physical consistency of Racumin 3D. However, as Racumin 3D is supplied as a paste bait sealed in paper bags, the indicative values for wax block bait, derived from the CEFIC exposure study are expected to be precautionary and serve as an upper limit on the potential exposure associated with the use of Racumin 3D.

Table 2.9.3-1: Summary of direct exposure Professional use – Tier 1

Scenario		Exposure (µg/kg bw/day)	
		Coumatetralyl	**Cholecalciferol**
Inhalation exposure		Negligible	Negligible
Oral exposure		Negligible	Negligible
Dermal exposure			
DIRECT EXPOSURE – PROFESSIONAL USE			
Professional pest control operator – Rat control	no PPE	**0.481**	**0.018**
	PPE	**0.024**	**0.001**
Professional pest control operator – Mouse control	no PPE	**0.054**	**0.002**
	PPE	**0.003**	**0.0001**

[21] Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFFIC Rodenticides Working Group, report and addendum 2006.

[22] Snowden, P.J. Pilot study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide "baits". Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1301,27 November 2003, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

[23]Chambers, J.G and Snowden, P.J. Study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide "baits". Synergy laboratories Limited, Thaxted UK, laboratory report number SYN/1302, 8 March 2004, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished

The following table provide a comparison of the exposure estimates regarding the two exposure situations, i.e. subchronic exposure and acute exposure, with the proposed AEL (in terms of percentage of the AEL) for professional users.

Table 2.9.3-2: %$AEL_{chronic}$ and %AEL_{acute} for exposure Professional user – Tier 1

Scenario	Active substance	$AEL_{chronic}$ (µg/kg bw/day)	AEL_{acute} (µg/kg bw/day)	Exposure (µg/kg bw/day)	%$AEL_{chronic}$	%AEL_{acute}
Professional pest control operator – Rat control – no PPE	Coumatetralyl	0.017	0.031	0.481	2831	1553
	Cholecalciferol	0.83	0.83	0.018	3	3
Professional pest control operator – Rat control – PPE	Coumatetralyl	0.017	0.031	0.024	142	78
	Cholecalciferol	0.83	0.83	0.001	0.1	0.1
Professional pest control operator – Mouse control – no PPE	Coumatetralyl	0.017	0.031	0.054	315	173
	Cholecalciferol	0.83	0.83	0.002	0.4	0.4
Professional pest control operator – Mouse control – PPE	Coumatetralyl	0.017	0.031	0.003	16	9
	Cholecalciferol	0.83	0.83	0.0001	0.01	0.01

2.9.3.1.1 Overall assessment of the risk for Professional User – Tier 1

The results of the exposure estimates predicted using the HEEG approach show that regarding direct exposure the situation is favourable for cholecalciferol with the intended use of Racumin 3D for professional users. Predicted exposures for coumatetralyl are above the AEL for professional users. However, these predicted exposures for pest control operators are based on a generic exposure model which provides a first tier assessment.
A higher tier assessment for this product has also been made (see following section) based on exposure figures generated in a formulation specific exposure study: "Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin® Paste by Professionals and Amateurs (W. Maasfeld and G. Müller; MR-203/03, Jan. 16, 2004)". This exposure study, accepted by the RMS (Denmark) in the Annex I inclusion process of coumatetralyl (product-type PT14)[24] confirms actual levels of exposure to coumatetralyl and cholecalciferol are lower than those predicted using the HEEG approach and are within the respective AEL values for coumatetralyl and cholecalciferol.

[24] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

Coumatetralyl

With respect to professional users, considering the subchronic exposure conditions, the estimated systemic direct exposure accounts for 2831% of the $AEL_{subchronic}$ if no protective gloves are worn. Assuming protective gloves are worn the estimated systemic exposure accounts for 142% of the $AEL_{subchronic}$. With respect to acute exposure situations and no gloves are worn, the estimated systemic direct exposure accounts for 1553% of the AEL_{acute}. Where gloves are worn the direct systemic exposure is estimated to be 78% of the AEL_{acute}.

Cholecalciferol

With respect to professional users, the estimated systemic direct exposure accounts for 3% of the AEL (long term and acute). Accordingly with the intended use of Racumin 3D there is no unacceptable risk anticipated for the professional user even if no gloves are worn. However, according to good occupational practice it is recommended to wear gloves when handling the sachets.

In conclusion, according to the HEEG approach when using Racumin 3D the exposure to coumatetralyl is above the $AEL_{subchronic}$ and AEL_{acute}, for professional users, without the use of PPE. With the use of PPE (gloves) exposure to coumatetralyl is above the $AEL_{subchronic}$ but below the AEL_{acute} .

A higher tier assessment for Racumin 3D (see following section) based on a formulation specific exposure study confirms actual levels of exposure to coumatetralyl and cholecalciferol are within the respective AEL values for coumatetralyl and cholecalciferol.

2.9.3.2 Risk characterisation Professional users – Tier 2 – product specific study

An assessment of exposure by the dermal route has been undertaken using data generated in a formulation specific exposure study: *"Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin® Paste by Professionals and Amateurs (W. Maasfeld and G. Müller; MR-203/03, Jan. 16, 2004)"*. This exposure study has been accepted by the RMS (Denmark) in the Annex I inclusion process of coumatetralyl (product-type PT14)[25] for evaluating direct exposure to coumatetralyl formulated as Racumin® Paste. As both Racumin 3D and Racumin® Paste are the same formulation type, i.e. rodenticide paste based on vegetable oil, the results of this formulation specific study are an appropriate basis for estimating direct exposure of the professional user during the intended use of Racumin 3D.

The predicted exposures for professional users are summarised in Table 2.9.3-3 below:

[25] *Inclusion of active substances in Annex I or IA to Directive 98/8/EC*; Assessment Report for Coumatetralyl, Product-type PT14 (rodenticides); RMS – DK; 20 February 2009

Table 2.9.3-3: Summary of direct exposure Professional use – Tier 2

Scenario		Exposure (µg/kg bw/day)	
		Coumatetralyl	Cholecalciferol
Inhalation exposure		Negligible	Negligible
Oral exposure		Negligible	Negligible
Dermal exposure			
DIRECT EXPOSURE – PROFESSIONAL USE			
Subchronic exposure situation	no PPE	**0.111**	**0.00413**
	PPE	**0.00067**	**0.0000252**
Acute exposure situation	no PPE	**0.149**	**0.00558**
	PPE	**0.00443**	**0.000166**

Sub-chronic assessment is based on geometric mean indicative values. Acute exposure assessment is based on maximum indicative values

The following tables provide a comparison of the exposure estimates regarding the two exposure situations, i.e. subchronic exposure and acute exposure, with the proposed AEL (in terms of percentage of the AEL) for professional users.

Table 2.9.3-4: %AEL for exposure Professional user – Tier 2

Scenario	Active substance	AEL (µg/kg bw/day)	Exposure (µg/kg bw/day)	%AEL
Subchronic exposure - no PPE	Coumatetralyl	0.017	0.111	653
	Cholecalciferol	0.83	0.00413	<1
Subchronic exposure – PPE	Coumatetralyl	0.017	0.00067	4
	Cholecalciferol	0.83	0.0000252	<1
Acute exposure – no PPE	Coumatetralyl	0.031	0.149	481
	Cholecalciferol	0.83	0.00558	<1

Acute exposure – PPE	Coumatetralyl	0.031	0.00443	14
	Cholecalciferol	0.83	0.000166	<1

2.9.3.2.1 Overall assessment of the risk for Professional user – Tier 2

The results of the exposure estimates reveal that regarding direct exposure the situation is favourable with the intended professional use of Racumin 3D for professional users.

Cholecalciferol

With respect to professional users, the estimated subchronic systemic direct exposure accounts for less than 1% of the $AEL_{long\ term}$ for both the PPE and no PPE exposure scenarios. With regard to acute exposure conditions, the corresponding exposure estimates again account for less than 1% of the AEL_{acute}. Accordingly with the intended use of Racumin 3D there is no unacceptable risk anticipated for the professional user even if no gloves are worn. However, according to good occupational practice it is recommended to wear gloves when handling the sachets.

Coumatetralyl

With respect to professional users, considering the subchronic exposure conditions, the estimated systemic direct exposure accounts for about 650% of the $AEL_{subchronic}$ if no protective gloves are worn. Assuming protective gloves are worn the estimated systemic exposure accounts for less than 4% of the $AEL_{subchronic}$. With respect to acute exposure situations and no gloves are worn, the estimated systemic direct exposure accounts for about 480% of the AEL_{acute}. Where gloves are worn the direct systemic exposure is estimated to be about 14% of the AEL_{acute}.

In conclusion there is no unacceptable risk anticipated for the professional user with the intended use of Racumin 3D provided gloves are worn by professional pest control operators.

Ref-MS Information:	Ref-MS considers the formulation specific exposure study reliable and robust. The data used to assess Racumin 3D according to the HEEG approach refers to handling wax blocks. Although the handling and characteristics of Racumin 3D and a wax block are comparable, Ref-MS believes that the monitored data from the HEEG approach should be considered as worst case. Hence, data from the the formulation specific exposure study should be considered as a refinement. The scenario "professional pest control operator- rat control- PPE" shows, when assessed with data from the HEEG approach, that there is an unacceptable risk (142% $AEL_{chronic}$) for professionals using gloves when handling rat infestations. However, when the same scenario is assessed with data from the formulation specific study no unacceptable risk is found. Hence, Ref-MS considers this unacceptable risk for professionals calculated with the HEEG approach (based on handling wax blocks) to be unrealistic, when considering that Racumin 3D is formulated as a viscous paste sealed in paper bags as ready to use bait sachets.

2.9.4 General public – Indirect exposure

Indirect exposures as a result of using Racumin 3D are anticipated to be negligible, except for the scenario with toddlers mouthing (licking or ingesting) bait. This exposure scenario is therefore considered when assessing indirect exposure to Racumin 3D, even though the product contains Bitrex at 10 ppm for its bittering properties.

2.9.4.1 Risk characterisation General public – Toddlers mouthing bait

The exposure for a toddler mouthing poison bait is summarised in Table 2.9.4-1 below:

Table 2.9.4-1: Summary of indirect exposure to cholecalciferol associated with use of Racumin 3D

Scenario	Exposure (µg/kg bw/day)
	Toddler
Indirect Exposure	
Inhalation exposure:	NA
Dermal exposure:	NA
Accidental ingestion of bait by toddler – mouthing 10 mg of bait	0.1
Accidental ingestion of bait by toddler – mouthing 5 g of bait	50

NA- not applicable

Table 2.9.4-2: Summary of indirect exposure to coumatetralyl associated with use of Racumin 3D

Scenario	Exposure (µg/kg bw/day)
	Toddler
Indirect Exposure	
Inhalation exposure:	NA
Dermal exposure:	NA
Accidental ingestion of bait by toddler – mouthing 10 mg of bait	0.281
Accidental ingestion of bait by toddler – mouthing 5 g of bait	141

NA- not applicab

2.9.4.1.1 Risk characterisation for indirect exposures

The following tables provide a comparison of the exposure estimates regarding mouthing by toddlers, with the proposed AEL (in terms of percentage of the AEL).

Table 2.9.4-3: Comparison of estimated secondary systemic exposure to cholecalciferol [µg/kg bw/day] to the relevant acceptable exposure level

Scenario	Active substance	Exposure [µg/kg bw/day]	% of ADI
Mouthing of 10 mg bait	Cholecalciferol	0.1	**2**
Mouthing of 5 g bait	Cholecalciferol	50	**1000**

Cholecalciferol: ADI: 5.0 µg/kg/bw/day

Table 2.9.4-4: Comparison of estimated secondary systemic exposure to coumatetralyl [µg/kg bw/day] to the relevant acceptable exposure level

Scenario	Active substance	Exposure [µg/kg bw/day]	% of AEL[#]
Mouthing of 10 mg bait	Coumatetralyl	0.281	**906**
Mouthing of 5 g bait	Coumatetralyl	141	**454839**

Coumatetralyl: AEL_{acute}: 0.031 µg/kg bw/day

2.9.4.1.2 Overall assessment of the risk for the use of the active substance in biocidal products via indirect exposure

With regard to indirect exposure "Mouthing of poison bait by a toddler (10 kg)" was assessed, but refers to an exceptional exposure scenario.

Cholecalciferol

Considering mouthing of 10 mg Racumin 3D bait the corresponding exposure corresponds to 2% of the ADI. With mouthing of 5 g of bait the corresponding exposure amounts to 1000% of the ADI.

Coumatetralyl

Considering mouthing of 10 mg bait the exposure corresponds to 906% of the AEL_{acute} and mouthing of 5 g bait corresponds to 455000% of the AEL_{acute}.

For both the active substances the relevant AEL is exceeded. However, when assessing these results it has to be noted that the label clearly instructs the user to keep the product out of reach of children and uninvolved people. It furthermore has to be noted that in line with EU recommendations[26] the product contains further risk mitigation measures, i.e. the aversion agent Bitrex to avoid accidental ingestion and a blue dye making the product unattractive for non-target animals but is also seen to help identifying where accidental contact to the product occurs.

In conclusion, the unacceptable risks that were identified for toddlers mouthing of bait highlight the need for extensive risk mitigation measures restricting the conditions for use of the product in such a manner that no uninvolved people can get access to the bait.

[26] European Commission; Risk mitigation measures for anti-coagulants used as rodenticides; Version dated 28/02/2007; ENV B.3/PC D (2007)

2.9.5 Combined exposure

Combined exposure to cholecalciferol associated with Racumin 3D is not anticipated to occur. Occupational exposures will occur via the dermal route, and such exposures are below the AEL for professional users. Inadvertent exposures to cholecalciferol are anticipated to be negligible, and so do not factor into a combined exposure analysis. Finally, potential acute exposures from ingestion of the product by an toddler are also very unlikely because the bait is placed in stations that are located in inaccessible places and the human taste deterrent included in the product will ensure that the toddler will expel the product from the oral cavity rather than swallow and ingest it.

In terms of the contribution of Racumin 3D to other body intakes of cholecalciferol, the risk assessment shows that for pest control operators, where repeat exposure might occur, the predicted exposures are very low (<1%) when compared to the agreed TUIL (Tolerable Upper Intake Level). Whilst it is possible that exposure to sunshine could take exposure to 10,000 IU, such levels would only be achieved through full-body exposure, i.e. sunbathing with minimal clothing. As persons using Racumin 3D would not be expected to be doing so in minimal clothing biocide exposure will not be additive to sunshine.

2.10 RISK CHARACTERISATION FOR THE ENVIRONMENT

In accordance with ESD for PT14 (2003) and TGD for Risk Assessment (2003) a quantitative approach is used in the risk assessment for coumatetralyl and cholecalciferol. However, it should be highlighted that for the risk assessment of primary and secondary poisoning a qualitative risk assessment for the acute situation is advised according to the agreed document "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006). The quantitative PEC/PNEC estimations are performed for the relevant environmental compartments, comparing compartmental concentrations (predicted environmental concentration = PEC) with the concentration below which unacceptable effects on organisms will most likely not occur (predicted no effect concentration = PNEC).

2.10.1 Aquatic compartment (incl. sediment)

The product is intended to be used within in tamper-resistant bait stations or covered and protected bait points in and around buildings, only. According to the ESD for PT14 for this exposure scenario the main exposure of the environment is expected to be soil, and other environmental compartments, such as the aquatic compartment, are considered not to be relevant. The use pattern precludes contamination of aquatic ecosystems, both freshwater and marine, and therefore $PNEC_{aquatic}$, $PNEC_{sed}$, and $PNEC_{STP}$ have not been calculated.

2.10.1.1 Aquatic risk assessment

No direct emissions to surface water (freshwater, marine and STP (sewage treatment plants)) should occur from the use of Racumin 3D in and around buildings. Therefore, aquatic PEC/PNEC ratios for the proposed use of coumatetralyl and cholecalciferol have not been determined.

2.10.1.2 Marine exposure

Refer to Section 2.10.1 above.

2.10.2 Terrestrial compartment

According to the use pattern of Racumin 3D the ESD for PT14 requires that exposure to the soil compartment should be considered for the application "in and around buildings". However, such exposure will be highly localised to the areas around the individual bait points. The basic assumptions and calculation procedures of the following PEC values are described in Section 2.5. The $PNEC_{soil}$ value is derived in accordance with TGD for Risk Assessment (2003, p. 118).

According to the ESD for PT14 exposure to the terrestrial environment is *via* direct release during application and indirect release *via* ingestion of bait and return to the soil as urine and faeces. The area affected by indirect release during application is assumed to be 55m long by 10m wide (ESD PT14, 2003). For rats, it is intended that up to 200g paste are used per bait point 3-10m apart in heavy infestations and 100g paste per bait 5-20m apart in light infestations. For mice, it is intended that up to 20g paste are used per bait point 2-10m apart in heavy infestations and 10g 5-20m apart in light infestations.

Coumatetralyl

Since the data set for coumatetralyl includes only one study with soil organisms (acute earthworm toxicity by van Erp, 2001; summarised in the CAR for Coumatetralyl, 2009[27]) an assessment factor of 1000 is applied to the LC_{50} value of this test:

$PNEC_{soil}$ = 225 mg a.s./kg soil / 1000 = 0.225 mg a.s./kg dwt soil*
This is converted to 0.199 mg/kg wwt, based on a conversion factor of 1.13 (EUSES 2.1.2 default).

Table 2.10.2-1: Calculated PNEC for coumatetralyl in the terrestrial compartment

Parameters	Concentration	Reference
$PNEC_{soil}$	0.199 mg/kg wwt	CAR for Coumatetralyl, 2009

Metabolites found in rat metabolism are hydroxy and dihydroxy coumatetralyl which are assumed to have a lower ecotoxicity towards soil organisms. As no data are available for the PNEC calculation for the metabolite, the results from studies performed with coumatetralyl will be used for calculation as a conservative worst case assumption (see also CAR, 2009).

Ref-MS Information:	*Since only one study for soil living organisms is available an assessment using the equilibrium partitioning method (EPM) should be performed. Below is a justification from the CAR for Coumatetralyl for not using EPM derived PNEC in the risk characterisation for Racumin 3D. *"The PNEC via EPM is much lower than the one derived from the earthworm test. According to the TGD the EPM may not be suitable for lipophilic compounds or substances with a specific mode of action nor for species that are exposed primary through food. Furthermore, this approach does not consider the effects on soil organisms of chemicals that are adsorbed to soil particles and taken up by ingestion. For coumatetralyl,*

[27] Assessment Report for Coumatetralyl PT14, Feb. 2009.

	which has a specific mode of action and where the species are primarily exposed through food, the EPM seems not to be a suitable method and the terrestrial risk assessment will be based on the PNECsoil of 0.225 mg/kg dry weight soil derived from the earthworm test. Furthermore, the applicant will not be asked to submit a soil micro-organisms or a plant test because the RMS do not think that such tests will change the decision of the effect assessment for the terrestrial compartment do the specific action of the antianticouagulants." (CAR Coumatetralyl, 2009, p. 17).

The calculated PEC/PNEC ratio for the terrestrial compartment is presented in the table below.

Table 2.10.2-2: PEC/PNEC ratios for exposure of soil to coumatetralyl in & around buildings

Exposure scenario: high infestation	$PEC_{local,soil}$ [mg/kg wwt]	$PNEC_{soil}$ [mg/kg wwt]	PEC/PNEC
Realistic Worst Case			
Parent:		0.199	
Realistic Worst Case for rats	0.0293		0.147
Realistic Worst Case for mice	0.0032		0.016
Metabolite			
Realistic Worst Case for rats	0.0497		0.250
Realistic Worst Case for mice	0.0073		0.037
Normal Case			
Parent:		0.199	
Normal Case for rats	0.0088		0.044
Normal Case for mice	0.0009		0.005
Metabolite			
Normal Case for rats	0.0149		0.075
Normal Case for mice	0.0022		0.011

Based on realistic worst case assumptions for control of rats and mice, maximum PEC/PNEC ratios of 0.147 (parent) and 0.250 (metabolite) and for the normal case of 0.044 (parent) and 0.075 (metabolite) were determined. The ratios are below the trigger value of 1. Under normal uses, the ratio is considerably lower. Therefore, the risk for the soil compartment due to the use of coumatetralyl as a rodenticide "in and around buildings" can be considered as low.

Cholecalciferol

Reliable data on the toxicity of cholecalciferol to primary producers (plants), consumers (earthworms) and decomposers (micro-organisms) of the terrestrial compartment are available. The NOEC value of 41 mg/kg dry weight soil based on 21-day biomass from the seedling emergence study with *Solanum lycopersicum* (tomato) was the lowest endpoint from long-term studies of three trophic levels. In section 4.2.3 of CAR Doc IIA for cholecalciferol it was concluded that if, acutely, plants are the most sensitive species and the plant EC50 is significantly lower than the NOECs/EC10 from the microorganisms and the long-term earthworm study, an AF of 100 should be applied to the lowest L(E)C50. Therefore, the endpoint recommended to use for the derivation of a PNECsoil was the lowest EC50 from the study on terrestrial plants, i.e. 192 mg/kg soil dw. Correcting for soil organic matter this is equivalent to 652.8 mg/kg soil dw.

$PNEC_{soil}$ = 652.8 mg/kg dw soil / 100 = 6.53 mg a.s./kg dwt soil
This is converted to 5.78 mg/kg wet weight soil, based on a conversion factor of 1.13 (EUSES 2.1.2 default).

Table 2.10.2-3: Calculated PNEC for cholecalciferol in the terrestrial compartment

Parameters	Concentration	Reference
$PNEC_{soil}$	5.78 mg/kg wwt	CAR for Cholecalciferol, 2018 Doc IIA, Section 4.2.3.2

The calculated PEC/PNEC ratio for the terrestrial compartment is presented in the table below.

Table 2.10.2-4: PEC/PNEC ratios for exposure of soil to cholecalciferol in & around buildings

Exposure scenario: high infestation	$PEClocal_{soil}$ [mg/kg wwt]	$PNEC_{soil}$ [mg/kg wwt]	PEC/PNEC
Realistic Worst Case			
Realistic Worst Case for rats	0.082	5.78	0.014
Realistic Worst Case for mice	0.009		0.002
Normal Case			
Normal Case for rats	0.025	5.78	0.004
Normal Case for mice	0.003		0.001

Based on realistic worst case assumptions for control of rats and mice, PEC/PNEC ratios of 0.014 and 0.002, respectively, were determined. The ratios are below the trigger value of 1. Under normal uses, the ratio is considerably lower. Therefore, the risk for the soil compartment due to the use of cholecalciferol as a rodenticide "in and around buildings" can be considered as low.

2.10.3 Groundwater contamination

Exposure to groundwater *via* soil contamination is considered to be negligible as it can be considered as a localised spot contamination immediately around the bait stations or bait points. The ESD for PT14 states that a detailed groundwater scenario is not considered necessary due to the limited quantities of active substance, the limited frequency of use and the limited treated area. Therefore groundwater contamination is highly unlikely.

However according to the decision made at WG Nov 2016, which was that a quantitative assessment should be made in all cases, even for 'localised' exposures, a quantitative assessment was carried out according to section 2.3.8.6 of the ECHA BPR Guidance, Volume IV Environment - Part B Risk Assessment..

Predicted concentrations in porewater (surrogate for groundwater) were as follows:

PECs for coumatetralyl range between 2.57E-04 – 5.38E-03 mg/L (realistic worst case) and 7,35E-05 - 1,62E-03 mg/L (normal case).

PECs for coumatetralyl metabolite range between 2,76E-04 - 9,13E-03 mg/L (realistic worst case) and 7.35E-05 – 2.74E-03 mg/L (normal case).

PECs for cholecalciferol range between 5.31E-07- 1.09E-05 mg/L (realistic worst case) and 1.33E-07 – 3.32E-06 mg/L (normal case).

According to the proposed normal use of Racumin 3D, estimated levels of the active substance and metabolite compounds in groundwater do not give rise to concern.

2.10.4 Atmosphere

The exposure of air is considered negligible in the scenario 'in and around buildings' according to the ESD for PT14 and in addition cholecalciferol and coumatetralyl have low vapour pressures

(cholecalciferol: 6.0 x 10^{-5} Pa at 25°C; coumatetralyl: <1.0 x 10^{-3} Pa at 20°C). Consequently, exposure of air will be negligible.

2.10.5 Non compartment specific effects relevant to the food chain (Primary and secondary poisoning)

Racumin 3D is a ready to use bait which is placed in tamper-resistant bait stations. For trained professional use covered and protected bait points can also be used, however only in such a way that they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. The combined factors of bait delivery methods and product make-up reduces the risk of primary and secondary poisoning exposure to non-target animals.

Coumatetralyl and other first-generation anticoagulants are not normally sufficiently toxic to rodents and non-target animals to cause death after a single moderate exposure. The toxicity of cholecalciferol is lower than that of coumatetralyl. Therefore the intake of a lethal dose due to occasional ingestion of small loose bait particles seems highly unlikely. Primary and secondary poisoning assessment to evaluate the potential toxicity to non-target animals have been conducted and are presented in the sections below. The basic assumptions and calculation procedures for determining the PEC and PNEC values used in the risk assessment are described in Section 2.5.

2.10.5.1 Primary Poisoning- Coumatetralyl

Currently it is suggested in the "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006) not to conduct a quantitative risk assessment for the acute primary poisoning. Instead a qualitative description of the toxicity of the substance compared to the possible single uptake has been given according to this addendum.

If the product is used according to the product label, primary exposure of non-target mammals and birds is highly unlikely. According to the product label directions Racumin 3D baits are placed in tamper-resistant bait stations. For trained professional use covered and protected bait points can also be used, however only in such a way that they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Racumin 3D does not consist of discrete particles (such as grains or small pellets) which could be readily carried away by rats / mice, instead pieces of the paste would have to be torn from the product. Since the active substance is not normally sufficiently toxic to rodents and non-target animals to cause death after a single moderate exposure, the intake of a lethal dose due to occasional ingestion of small loose bait particles seems highly unlikely. A first tier assessment assumes the animal in question consumes nothing but rodenticide in one daily meal.

Coumatetralyl have already been reviewed for Annex I inclusion according to Directive 98/8/EC. A primary and secondary poisoning assessment was performed for a paste with 0.0375% (w/w) coumatetralyl for use in and around buildings and the conclusions for Annex I inclusion can be found in the CAR dated Feb. 2009[28].* In the following the primary poisoning risk assessment is presented in accordance with the CAR for coumatetralyl and in line with the assumptions for cholecalciferol.

Ref-MS Information:	*Although there are some minor differences in the product compositions, Ref-MS accepts the read across between Racumin 3D and Racumin Paste, the representative product in the CAR of coumatetralyl.

[28] Assessment Report for Coumatetralyl PT14, Feb. 2009.

2.10.5.1.1 Birds (acute primary poisoning)

The expected content of the active substance in the sparrow after a single uptake incident if the sparrow consumes 100% of its daily food uptake as rodenticide at a single sitting is 129.5 mg/kg bw (see table below).

Table 2.10.5-1: Coumatetralyl estimated daily uptake of a.s. in indicator species – tree sparrow

Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
			mg/kg BW	mg/kg BW
ETE tree sparrow	estimated daily uptake of a compound	≅ 0	129.5	51.8
EC	estimated conc. of a.s. in indicator species	≅ 0	116.6	36.3
*If label directions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. **The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.5 for birds (instead of 1[29]), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).				

The LD_{50} of the active substance for birds is > 2000 mg/kg bw ([redacted], 1992a). Therefore, from this calculation the sparrow is unlikely to die if consuming 100% of its daily food uptake as rodenticide formulation. Note that this comparison only gives a first indication of the acute toxicity of the substance.

2.10.5.1.2 Mammals (acute primary poisoning)

The dog is considered as an example of a larger mammal which is potentially at risk from direct consumption of baits placed in and around a house.

In an acute oral toxicity study with dogs [redacted], 1960) a single dose LD_{50} value of 35 mg a.s/kg bw was reported for coumatetralyl. For the Tier 2 calculations it is assumed as a worst case that a dog eats 600 g bait.

Table 2.10.5-2: Coumatetralyl estimated daily uptake of a.s. in indicator species - dog

Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
			mg/kg BW	mg/kg BW
ETE dog	estimated daily uptake of a compound	≅ 0	22.5	16.2
EC	estimated conc. of a.s. in indicator species	≅ 0	20.3	11.3
*If label directions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.9 for mammals (instead of 1), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).				

A portion of 600 g coumatetralyl bait (0.0375 % a.s.) contains 225 mg coumatetralyl. Based on these assumptions, a 10 kg dog will ingest a dose of 22.5 mg/kg bw and thus might die after direct consumption of 600 g bait.

[29] AV can be set to 0.5 for birds product is a paste (agreed at Ca-Nov 2006, Doc. 4.3).

2.10.5.1.3 Bird (Long-term primary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values are presented in Table 2.10.5.1.3-1.

Calculation of the $PNEC_{oral}$ value for primary poisoning of birds is proposed, using the NOEC from the avian reproduction study:

Chronic toxicity NOEC (6 weeks) = 20 mg a.s./kg food (Barfknecht, 2004); corresponding to 2 mg a.s./kg bw.

Related to food (kg) of tree sparrow:
$PNEC_{oral}$ = NOEC (6 weeks) / AF
= 20 mg a.s./kg food / 30 = 0.667 mg a.s./kg food,
Related to dose [mg/kg body weight]
$PNEC_{oral}$ = 2 mg a.s./kg bw / 30 = 0.0667 mg a.s./kg bw.

Assessment Factors (AF) of 30 (for chronic toxicity endpoints) are proposed in the TGD for Risk Assessment (2003, Chapter 3, p. 130) for risk assessments secondary poisoning (related to predators). According to the instructions given in the addendum to Biocides to the TGD. CA-Nov 06 – Doc 4.3., no other AF is suggested for primary poisoning. These AF are therefore also used for the primary poisoning situation and most likely overestimate the risk.

Table 2.10.5-3: Coumatetralyl: PECoral / PNECoral ratios for tree sparrow using the different PNEC values and PEC values - chronic

Toxicity data	$PNEC_{oral,bird}$	$PEC_{oral,bird}$	PEC/PNEC ratio	Trigger limit
Based on food intake				
Chronic $NOEC_{food}$	0.667 mg a.s./kg food	375 mg /kg food	562	1
Based on bw				
Chronic $NOEC_{bw}$	0.0667 mg a.s./kg bw	36.3 mg /kg bw	544	1

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, a long-term primary poisoning risk for birds cannot be excluded if one assumes that they would feed largely on rodenticide bait.

2.10.5.1.4 Mammals (Long-term primary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values are presented in Table 2.10.5.1.4-1.

Calculation of the $PNEC_{oral}$ value for primary poisoning of mammals is proposed, using the NOEC from the subchronic oral toxicity test in rats (feeding study for 16 weeks, see CAR, Coumateralyl 2009, Doc IIA):

NOEC (90 days) = 0.0975 mg a.s./kg food and a **NOAEL** of 0.0068 mg a.s./ kg bw/day.

Related to food (kg) of dog:
$PNEC_{oral}$ = NOEC (90 days) / AF
= 0.0975 mg a.s./kg food / 90 = 0.00108 mg a.s./kg food*,
Related to dose [mg/kg body weight]

$PNEC_{oral}$ = 0.0068 mg a.s./kg bw / 90 = 0.0001 mg a.s./kg bw.

Assessment Factors (AF) of 90 (for 90 days test) are proposed in the TGD for Risk Assessment (2003, Chapter 3, p. 130) for risk assessments of secondary poisoning (related to predators). According to the instructions given in the addendum to Biocides to the TGD. CA-Nov 06 – Doc 4.3., no other AF is suggested for the primary poisoning situation and these AF are therefore also used for the primary poisoning situation even this might overestimate the risk.

Table 2.10.5-4: Coumatetralyl: PEC_{oral} / $PNEC_{oral}$ ratios for dog using the different PNEC values and PEC values - chronic

Toxicity data	$PNEC_{oral,mammal}$	$PEC_{oral,mammal}$	PEC/PNEC ratio	Trigger limit
Based on food intake				
Chronic $NOEC_{food}$	0.00108 mg a.s./kg food	375 mg /kg food	347,222	1
Based on bw				
Chronic $NOEC_{bw}$	0.0001 mg a.s./kg bw	11.3 mg /kg bw	113,000	1

Ref-MS Information:	* The chronic PNECoral,mammal used in these calculations is incoherent with the values reported in the CAR. The applicant argues that there is an error in the CAR where the NOEC is actually expressed as product used in the study (containing 0.75% coumatetralyl). The applicant has therefore amended the NOEC to 0.0975 mg a.s./kg is derived from the reported NOEC of 13mg product/kg from the 90d rat study: i.e. 13 x 0.75% = 0.0975 mg a.s./kg food. If using the NOEC reported in the CAR from the subchronic oral toxicity test (13 mg a.i. /kg food), the corresponding $PNEC_{oral}$ would be 13/90=0.14 mg a.i. /kg food, and PEC/PNEC=2679.

As indicated by a PEC/PNEC ratio far greater than the trigger limit of 1, there is a long-term primary poisoning risk for non-target mammals if assuming that their diet consists largely of poisoned rodents.

2.10.5.2 Primary Poisoning- Cholecalciferol

2.10.5.2.1 Birds (acute primary poisoning)

It is highly unlikely a small granivorous bird will enter a bait station and take a full daily meal of product, as Cholecalciferol + Coumatetralyl RB 0.0475 (0.1+0.375 g/kg) is a paste and the bird must repeatedly peck at it to break off bite sized pieces. Larger birds that cannot obtain access to the discretely placed bait will not ever encounter a full block. Therefore, for such birds it seems impractical to do a calculation based upon the assumption a bird eats its full daily ration from a paste bait. In the Addendum relevant to Biocides to the TGD (2006) it is suggested that the AV can be set to 0.5 for birds if the product is a paste.

Therefore the expected content of the active substance in the sparrow after a single uptake incident if the sparrow consumes 100% of its daily food uptake as rodenticide at a single sitting is 34.5 mg/kg bw (see table below) has been calculated. From this calculation the sparrow is unlikely to die if consuming 100% of its daily food uptake as rodenticide formulation. The LD_{50} of the active substance for birds is > 2000 mg/kg bw. Note that this comparison only gives a first indication of the acute toxicity of the substance.

Table 2.10.5-5: Cholecalciferol estimated daily uptake of the a.s. in indicator species – tree sparrow

Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
			mg/kg BW	mg/kg BW
ETE tree sparrow	estimated daily uptake of a compound	≅ 0	34.5	13.8
EC	estimated conc. of a.s. in indicator species	≅ 0	31.1	9.7
*If label directions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. ** The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.9 for mammals and AV=0.5 for birds (instead of 1[30]), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).				

2.10.5.2.2 Mammals (acute primary poisoning)

The dog is considered as an example of a larger mammal which is potentially at risk from direct consumption of baits placed in and around a house. In an acute oral toxicity study with dogs [redacted] 1999) a single dose LD_{50} value of 80 mg a.s./kg bw was reported for cholecalciferol. For the Tier 2 calculations it is assumed as a worst case that a dog eats 600 g bait.

A portion of 600 g cholecalciferol bait (0.010 % a.s.) contains 60 mg cholecalciferol. Based on these assumptions, a 10 kg dog would ingest a dose of 6 mg/kg bw from a single bait and would probably survive.

The "worst-case" reported LD_{50} of the active substance for dog is 80 mg/kg bw. From this calculation the dog does not die under these situations.

Table 2.10.5-6: Cholecalciferol estimated daily uptake of the a.s. in indicator species - dog

Symbol	Variable/parameter	Normal Use*	Realistic worst case Tier 1**	Realistic worst case Tier 2 **
			mg/kg BW	mg/kg BW
ETE dog	estimated daily uptake of a compound	≅ 0	6.0	4.3
EC	estimated conc. of a.s. in indicator species	≅ 0	5.4	3.0
*If label directions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. ** The Tier 2 realistic-worst-case exposure estimates are based on default values of AV=0.9 for mammals and AV=0.5 for birds (instead of 1[30]), PT=0.8 (instead of 1) and EL= 0.3 (instead of 0.1).				

When the toxicity of cholecalciferol is compared to the possible single event which would occur should a predator consume its entire daily food intake as cholecalciferol bait, there is no indication that significant lethal doses would be obtained for birds, but for dogs risk for death exists (since exposure is in the region of LD50).

[30] AV can be set to 0.5 for birds product is a paste (agreed at Ca-Nov 2006, Doc. 4.3).

2.10.5.2.3 Bird (Long-term primary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values from tier 1 and tier 2 are presented in the following table.

Table 2.10.5-7: Cholecalciferol: PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values from tier 1 and tier 2 assessments (tree sparrow) - chronic

Toxicity data	$PNEC_{oral,bird}$	$PEC_{oral,bird}$	PEC/PNEC ratio	Trigger limit
Tier 1				
Chronic $NOEC_{food}$	0.2 mg a.s./kg food	100 mg /kg food	500	1
Tier 2				
Chronic $NOEC_{bw}$	0.025 mg a.s./kg bw	9.7 mg /kg bw	388	1

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, a long-term primary poisoning risk for birds cannot be excluded if one assumes that they would feed largely on rodenticide bait.

2.10.5.2.4 Mammals (Long-term primary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values from tier 1 and tier 2 are presented in the following table.

Table 2.10.5-8: Cholecalciferol: PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values from tier 1 and tier 2 assessments (dog) - chronic

Toxicity data	$PNEC_{oral,mammal}$	$PEC_{oral,mammal}$	PEC/PNEC ratio	Trigger limit
Tier 1				
Chronic $NOEC_{food}$	0.003 mg a.s./kg food	100 mg /kg food	33,333	1
Tier 2				
Chronic $NOEC_{bw}$	0.0001 mg a.s./kg bw	3.0 mg /kg bw	30,000	1

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, a long-term primary poisoning risk for non-target mammals cannot be excluded if one assumes that they would feed largely on rodenticide bait.

2.10.5.3 Conclusion - primary poisoning

As indicated by the PEC/PNEC ratios a long-term primary poisoning risk for non-target animals cannot be excluded if the assumption is made that their diet exclusively or largely consists of rodenticide bait. However, if repeated exposure were to occur, both birds and mammals were shown to tolerate exaggerated contaminated-feeding conditions in several reported secondary poisoning studies (please refer to CARs for coumatetralyl and cholecalciferol for details). Also, the bait is placed in discrete locations restricted to within the infested area and is protected to help prevent access by non-target animals. It is not dispersed or broadcast within the environment and in the rare instances where "accidental" exposure should occur; it is highly unrealistic this would be a repeated occurrence. There are a number of risk mitigation measures that are included on rodenticide labels that significantly control the potential exposure to non-target animals; hence reducing the risk of acute or repeated primary poisoning.

2.10.5.4 Secondary poisoning

Certain non-target animals are potentially at risk from rodenticides by eating rodents or other organisms which have taken up / accumulated the active substance.

2.10.5.4.1 Secondary poisoning *via* the aquatic food chain

As exposure to the aquatic environment is concluded to be negligible (supported under ESD for PT14), the risk from secondary poisoning *via* the aquatic food chain is considered to be irrelevant and an assessment has not been conducted.

2.10.5.4.2 Assessment of secondary poisoning *via* the terrestrial food chain - Risk to earthworm-eating mammals and birds

Biomagnification may occur *via* the terrestrial food chain. The food-chain:

soil → earthworm → worm-eating birds or mammals.

Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in this soil. Coumatetralyl has a very low log Kow of <1.5 and therefore its bioaccumulation potential is considered to be low. Although the log Kow of >5.0 of cholecalciferol would indicate some bioaccumulation potential the results of a BCF study demonstrates a low level of accumulation with a $BCF_{earthworm}$ of 0.15 (CAR for cholecalciferol, 2018). This lack of demonstrated bioaccumulation potential and the fact that exposure will be *via* discrete protected bait points and thus is very low, will mean that the risk of secondary poisoning due to the consumption of earthworms is negligible*.

Ref-MS Information:	* In the CAR for cholecalciferol (2018) an assessment was made indicating unacceptable risk (risk ration = 28.5) for wormeating mammals (but not for birds). Considering that the referensproduct contained 7.5 times more concentration of cholecalciferol, an unacceptable risk would apply also for Racumin 3D (risk ratio= 28.5/7.5= 3.8). As concluded below, the use of the Racumin 3D is expected to cause negative effects on the environment and due to the identified risk of primary and secondary poisoning of non-target organisms, therefore the product can only be authorised with very strict risk mitigation measures (i.e. the EU-harmonise use instructions and risk mitigation measures, CA-Nov16-Doc.4.1.b – Final).

2.10.5.4.3 Assessment of secondary poisoning - Risk to rodent-eating mammals and birds

Biomagnification may also occur *via* the food chain from consumption of contaminated rodents (typically only those consuming entire carcasses of poisoned animals).

bait → rodent → rodent-eating birds or mammals.

Ref-MS Information:	The applicant used an adjusted FIR/BW value of 0.082 in secondary poisoning calculations (default value is 0.1). Ref-MS accept the adjusted value as it only results in marginally different values that does not impact the outcome of the risk assessment.

2.10.5.4.4 Bird and Mammals (acute secondary poisoning) – Coumatetralyl

Application of coumatetralyl baits over a time period of several days does not result in an accumulation of coumatetralyl in the animals (body burden) but in an accumulation of toxic effects. The log Kow value of coumatetralyl is pH dependent, being greater than 3.0 at pH 5 but only 1.5 at pH 7 which may indicate a potential for accumulation, but the BCF value of 11.4 (whole fish) derived from the fish bioaccumulation study ([redacted], 1992b) and the depuration half life value of 14 hours from the same study do not suggest a bioaccumulation or bioconcentration concern. The depuration value in fish is fairly consistent with the observed plasma terminal elimination phase half life value of 36 hours in the rat following multiple doses ([redacted], 1999). [redacted] (2003) found no bioaccumulation of coumatetralyl in rat liver after 3 repeat doses at 12 week intervals.

Owing to their nature and use patterns, the only relevant pathway by which rodenticides may enter the food chain is via poisoned rodents (target or non-target) captured by predatory birds and mammals. Accordingly, secondary poisoning hazards are assessed following the scenarios set out in the ESD for PT14. The predicted environmental concentrations in the food of the predators (PEC_{oral}) are equivalent to the expected concentrations of coumatetralyl in poisoned target rodents.

For coumatetralyl, substance specific results based on residue data in rats are available in the CAR and were used instead of calculated EC_n values. For the acute exposure situation the highest measured value of 13.1 mg a.s/kg bw (rat) and for chronic exposure a measured value of 6.2 mg a.s/kg bw (rat) were used, please see section 2.5.4.2 for more details.

Birds (acute secondary poisoning)

The barn owl is under general concern to be endangered by secondary poisoning with anticoagulant rodenticides, particularly with compounds of the second generation ([redacted], 2001; [redacted] 1999).

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-9: Coumatetralyl: Acute secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (Barn owl) - acute

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Barn owl		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral, acute}$		mg/kg rodent	13.1	6.55	2.62
FIR	Food intake rate	g fw/day	72.9	72.9	72.9
BW	Body weight	g	294	294	294
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.25	0.25	0.25
$C_{internal, pred.}$	concentration in non-target animal	mg/kg BW predator	3.25	1.62	0.65
PEC/$PNEC_{bird}$ (0.0667 mg/kg bw)=			**49**	**24**	**10**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the acute secondary poisoning risk for birds cannot be excluded if it is assumed that their diet largely consists of poisoned rodents. Note that in the "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA

meeting Nov. 2006) it was agreed that this comparison is not intended to be used for risk characterisation or for a comparative assessment. Also a qualitative assessment should be performed.

One of the major miss-matches in the PEC/PNEC calculation above is that although acute secondary poisoning is assessed, the PNEC value is derived from a study in which birds were fed Coumatetralyl for a period of 6 weeks. When considering the acute dosage required to cause an adverse effect, even if birds were to consume 100% contaminated diet, the maximum exposure would result in consumption of only 1.55 mg/kg bw. The LD50 for birds is > 2000 mg/kg bw, therefore no adverse effects from acute secondary poisoning to birds is expected.

Mammal (acute secondary poisoning)

The weasel is considered as the representative species in assessing the risk from secondary poisoning.

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-10: Coumatetralyl: Acute secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (weasel) - acute

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Weasel		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral, acute}$		mg/kg rodent	13.1	6.55	2.62
FIR	Food intake rate	g fw/day	24.7	24.7	24.7
BW	Body weight	g	63	63	63
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.39	0.39	0.39
$C_{internal, pred.}$	concentration in non-target animal	mg/kg BW predator	5.14	2.57	1.03
PEC/$PNEC_{mammal}$ (0.0001 mg/kg bw) =			**51 400**	**25 700**	**10 300**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the acute secondary poisoning risk for non-target mammals cannot be excluded if it is assumed that their diet largely consists of poisoned rodents. Note that in the "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006) it was agreed that this comparison is not intended to be used for risk characterisation or for a comparative assessment. Also a qualitative assessment should be performed.

One of the major miss-matches in the PEC/PNEC calculation above is that although acute secondary poisoning is assessed, the PNEC value is derived from a study in which mammals were fed Coumatetralyl for a period of 90 days. When considering the acute dosage required to cause an adverse effect, even if non-target mammals were to consume 100% contaminated diet, maximum exposure would result in consumption of only 2.45 mg/kg bw. The LD_{50} of rat is between 15 mg/kg bw (female, fasted) and 30 mg/kg bw (male fasted). Therefore the weasel would not be expected to die if consuming 100% of its daily food uptake as rats exposed to rodenticide.

2.10.5.4.5 Birds and Mammals (Long-term secondary poisoning) – Coumatetralyl

For long term exposure, the ESD for PT14 assumes a worst-case scenario in which non-target animals consume 50% of their daily intake as poisoned rodents.

Birds (Long-term secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-11: Coumatetralyl: Long term secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PNEC values and PEC values (Barn Owl)

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Barn owl		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral\ chronic}$ (F_{rodent}=0.5)		mg/kg rodent	3.10	1.55	0.62
FIR	Food intake rate of rodent	g fw/day	72.9	72.9	72.9
BW	Body weight	g	294	294	294
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.25	0.25	0.25
$C_{internal,\ pred.}$	concentration in non-target animal	mg/kg BW predator	0.77	0.38	0.15
PEC/$PNEC_{bird}$ (0.0667mg/kg bw)=			**11.5**	**5.8**	**2.3**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the long-term secondary poisoning risk for birds cannot be excluded if assuming that their diet largely consists of poisoned rodents.

Mammals (Long-term secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-12: Coumatetralyl: Long term secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (weasel)

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Weasel		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral\ chronic}$ (F_{rodent}=0.5)		mg/kg BW predator	3.10	1.55	0.62
FIR	Food intake rate of rodent	g fw/day	24.7	24.7	24.7
BW	Body weight	g	63	63	63
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.39	0.39	0.39
$C_{internal,\ pred.}$	concentration in non-target animal	mg/kg BW predator	1.22	0.61	0.24
$PEC/PNEC_{mammal}$ (0.0001 mg/kg bw) =			**12 200**	**6 100**	**2 400**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the long-term secondary poisoning risk for non-target mammals cannot be excluded if assuming that their diet largely consists of poisoned rodents.

2.10.5.4.6 Bird and Mammals (acute secondary poisoning) - Cholecalciferol

The ESD for PT14 considers a tiered approach of the daily consumption of bait by the target rodent from 100% (realistic worst case, PD=1), to 50% (intermediate case, PD=0.5) to 20% (normal case, PD=0.2) for calculating acute secondary poisoning. The realistic worst case situation that has to be considered according to the ESD for PT14, in order to elucidate a full-scale scenario, is with PD = 1 (i.e. 100% of food items are poisoned bait). However, it is highly unlikely that this would be the situation as the chances of the average domestic pet, livestock or wild animal encountering and entirely consuming enough poisoned rodents at a single feeding to reach toxic levels to cause acute secondary poisoning is low. Therefore, reduced PD values of 0.2 and 0.5 are included in the following calculations.

The Barn owl and weasel were chosen as representative non-target animals in the following risk assessment for secondary poisoning; since these predatory animals are considered to be sensitive to rodenticides.

Birds (acute secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-13: Cholecalciferol: Acute secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (Barn owl) - acute

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):	Barn owl

Symbol	Variable/parameter	unit			
			PD=1	**PD=0.5**	**PD=0.2**
$PEC_{oral, acute}$		mg/kg BW predator	23	11	4.6
FIR	Food intake rate	g fw/day	72.9	72.9	72.9
BW	Body weight	g	294	294	294
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.25	0.25	0.25
$C_{internal, pred.}$	concentration in non-target animal	mg/kg BW predator	5.6	2.8	1.1
$PEC/PNEC_{bird}$ (0.025 mg/kg bw)=			**226**	**113**	**49**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, there is an acute secondary poisoning risk for birds cannot be excluded if it is assumed that their diet largely consists of poisoned rodents.

In addition it was agreed in document "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006) that this comparison is not intended to be used for risk characterisation or for a comparative assessment.

When considering the acute dosage required to cause an adverse effect, even if birds were to consume 100% contaminated diet, the maximum exposure would result in consumption of only 1.93 mg/kg bw. The LD_{50} for birds is > 2000 mg/kg bw/day, therefore no adverse effects from acute secondary poisoning to birds is expected. In the 8-day dietary GLP bird studies ([redacted] 1982 b and c) no effects on ducks and quails were observed at concentration up to 312 ppm (93.6 ppm a.s.) in their diet. Table 2.4.2.3.1-1 shows that Barn owls could be exposed to concentration of cholecalciferol in rat/mouse of 0.39 to 1.93. These concentrations are a factor of 48 to 240 x lower than the NOEC observed in the studies above. Hence any effect of an accidental ingestion of cholecalciferol by a Barn owl is highly unlikely to occur. The PNEC as derived is not relevant for the risk assessment as it assess a non-realistic acute scenario.

Mammal (acute secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-14: Cholecalciferol: Acute secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (weasel) - acute

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Weasel		
Symbol	**Variable/parameter**	**unit**			
			PD=1	**PD=0.5**	**PD=0.2**
$PEC_{oral, acute}$		mg/kg BW predator	23	11	4.6
FIR	Food intake rate	g fw/day	24.7	24.7	24.7
BW	Body weight	g	63	63	63
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.39	0.39	0.39
$C_{internal, pred.}$	concentration in non-target animal	mg/kg BW predator	8.9	4.5	1.8
$PEC/PNEC_{mammal}$ (0.0001 mg/kg bw) =			**89 200**	**44 600**	**17 800**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, an acute secondary poisoning risk for mammals cannot be excluded if it is assumed that their diet largely consists of poisoned rodents. In the "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006) that this comparison is not intended to be used for risk characterisation or for a comparative assessment.

When considering the acute dosage required causing an adverse effect, even if non-target mammals were to consume 100% contaminated diet, the maximum exposure would result in consumption of only 3.06 mg/kg bw/day.

In the acute oral study showing the lowest LD_{50} value in rats (worst-case for wild animals) no mortality was observed in either sex at 12.5 mg/kg bw ([redacted], 1983 scored as reliability 2). Table 2.4.2.3.1-2 shows that weasel could be exposed to internal concentration of cholecalciferol ranging from 0.61 to 3.06 mg/kg bw. These concentrations are a factor of 4 to 20 x lower than the No Lethal Dose observed in the study above. Hence any lethal effect of an accidental ingestion of cholecalciferol by weasel seems highly unlikely to occur. The PNEC as derived is not relevant for the risk assessment as it assess a non-realistic acute scenario.

2.10.5.4.7 Birds and Mammals (Long-term secondary poisoning) – Cholecalciferol

For long term exposure, the ESD for PT14 assumes a worst-case scenario in which non-target animals consume 50% of their daily intake as poisoned rodents. Once again, the chances of the average domestic pet, livestock or wild animal encountering and entirely consuming enough poisoned rodents (dying above ground in areas accessible to a foraging non-target animal) on a periodic basis to accumulate enough cholecalciferol to cause secondary poisoning is low. The most likely scenario which may lead to secondary poisoning would be in those cases of severe or chronic rodent infestations where many rodents (particularly rats since they consume more rodenticide) would be poisoned over the course of days or weeks. This would need to be coupled with hungry pets / livestock, or some other free-ranging animal exhibiting a daily opportunistic foraging strategy, while not shying away from domestic areas. However, such scenarios would be under professional care and routinely monitored, further minimising the long-term availability of rodent carcasses.

Birds (Long-term secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-15: Cholecalciferol: Long term secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (Barn Owl)

NON -TARGET ANIMALS (PREDATORS/CARNIVORES):			Barn owl		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral\ chronic}$ (F_{rodent}=0.5)		mg/kg BW predator	11	5.7	2.3
FIR	Food intake rate of rodent	g fw/day	72.9	72.9	72.9
BW	Body weight	g	294	294	294
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.25	0.25	0.25
$C_{internal,\ pred.}$	concentration in non-target animal	mg/kg BW predator	2.8	1.4	0.56
$PEC/PNEC_{bird}$ (0.025 mg/kg bw) =			**113**	**56**	**23**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the long-term secondary poisoning risk for birds cannot be excluded if it is assumed that their diet largely consists of poisoned rodents.

Mammals (Long-term secondary poisoning)

PEC_{oral} / $PNEC_{oral}$ ratios using the different PEC values are presented in the following table.

Table 2.10.5-16: Cholecalciferol: Long term secondary poisoning PEC_{oral} /$PNEC_{oral}$ ratios using the different PEC values (weasel)

NON -TARGERT ANIMALS (PREDATORS/CARNIVORES):			Weasel		
Symbol	Variable/parameter	unit	PD=1	PD=0.5	PD=0.2
$PEC_{oral\ chronic}$ (F_{rodent}=0.5)		mg/kg BW predator	11	5.7	2.3
FIR	Food intake rate of rodent	g fw/day	24.7	24.7	24.7
BW	Body weight	g	63	63	63
FIR/BW	FIR/BW ratio; feeding rate	[-]	0.39	0.39	0.39
$C_{internal,\ pred.}$	concentration in non-target animal	mg/kg BW predator	4.46	2.23	0.89
PEC/$PNEC_{mammal}$ (0.0001 mg/kg bw) =			**44 600**	**22 300**	**8 900**

As indicated by a PEC/PNEC ratio greater than the trigger limit of 1, the long-term secondary poisoning risk for non-target mammals cannot be excluded if assuming that their diet largely consists of poisoned rodents.

2.4.2.3.3 Conclusion on secondary poisoning

a) Information provided based on standard PEC/PNEC approaches

As indicated by the PEC/PNEC ratios calculated above a secondary poisoning risk for non-target animals cannot be excluded if the theoretical assumption is made that their diet largely consists of contaminated rodents and these worst case intakes are compared with PNECs derived according to the guidance. The PEC/PNEC ratios for mammals are significantly higher than those for birds.

b) Further risk mitigating factors

Besides the label instructions on placement of baits, and the need to collect poisoned rats, the Racumin 3D product was specifically designed to address the issue demonstrated by the above risk assessment. Racumin 3D contains a bittering agent at 10 ppm, which is the optimal level between conserving the efficacy of the product (avoid bait palatability issues with target organisms) and achieving a deterring factor to continued feeding in case of incidental ingestion by pets. The anti-feeding action of the cholecalciferol on the target organisms, further reduces the residues likely to be accumulated in poisoned rats/mice (avoid 'super-charging' beyond lethal levels), by which the exposure of non-target mammals will be reduced compared to rodenticide baits without cholecalciferol. Racumin 3D is applied as a bait and is placed in discrete locations restricted to within the infested area and baits are protected to help prevent access by non-target animals. It is not dispersed or broadcast within the environment. There are a number of risk mitigation measures that are included on rodenticide labels that significantly control the potential exposure to non-target animals; by the virtue of which any exposure is infrequent and incidental. Moreover, the presence of a bittering agent and cholecalciferol in the formulation further reduces the risk of secondary poisoning even in the case of incidental exposure.

2.11 RISK CHARACTERISATION FOR THE PHYSICO-CHEMICAL PROPERTIES

The product Racumin 3D is a highly viscous soft block cereal based bait. It is not flammable and does not possess explosive or oxidising properties. It is considered to be stable for up to three years when stored in the commercial container at ambient temperatures.

2.12 MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extend. As an outcome of these discussions a set of three standard SPCs (Summary of product characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final). The terms and conditions of use for Racumin 3D are therefore in agreement with the harmonised and relevant sentences, see below *Summary of Product Characteristics (SPC)*.

2.13 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

2.13.1 Administrative information

2.13.1.1 Trade name(s) of the product

Trade name(s)	- Racumin 3D - Racumin DUO - Racumin PLUS - Racumin PRO - Racumin NEO - Racumin Jump - Racumin Boost

2.13.1.2 Manufacturer(s) of the product

Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair CS90106, 69266 Lyon Cedex 09 France
Location of manufacturing sites	INDUSTRIALCHIMICA Srl, Via Sorgaglia 40, 35020 Arre (PD) Italy Kollant S.r.l., via C. Colombo 7/7 A, I-30030 Vigonovo (VE) Italy

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

Active substance	Coumatetralyl
Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair CS90106, 69266 Lyon Cedex 09 France
Location of manufacturing sites	AlzChem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr. Albert Frank Str. 32, 83308 Trostberg Germany

Active substance	Cholecalciferol
Name of manufacturer	Fermenta Biotech Limited
Address of manufacturer	DIL Complex, Ghodbunder Road, Majiwada 400 610, Maharashtra Thane India

Location of manufacturing sites	Fermenta Biotech Limited, P.O. Nagwain, Himachal Pradesh District Mandi - 175 121Takoli, India Fermenta Biotech Limited, Z-109 B & C, SEZ II, Taluka - Vagara, Gujarat District Bharuch – 392130 Dahej, India

2.13.2 Product composition and formulation

2.13.2.1 Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Coumatetralyl	Coumatetralyl	Active Substance	5836-29-3	227-424-0	0.038
Cholecalciferol		Active Substance	67-97-0	200-673-2	0.01

Information on the full composition is provided in the Confidential Annex to this PAR.

2.13.2.2 Information on the substance(s) of concern

No substance of concern was identified upon the assessment.

2.13.2.3 Candidate(s) for substitution

As a consequence of the harmonised classification, the active substance coumatetralyl meets the criteria for exclusion according to Article 5(1) BPR because the following exclusion criteria (c) is met: toxic for reproduction category 1B.
The active substance cholecalciferol meets the criteria for exclusion according to Article 5(1) BPR because the following exclusion criteria (d) is met: endocrine disrupting properties.
Therefore, both active substances meets the conditions laid down in Article 10 of Regulation (EU) 528/2012, and are consequently candidates for substitution.

2.13.2.4 Type of formulation

RB - Bait (ready for use)

2.13.2.5 Classification and Labelling according to the Regulation (EC) No 1272/2008

Classification	Repr. 1B; H360D Aquatic Chronic 3; H412

GHS Pictograms	
Signal Word	Danger
Hazard Statement (H-Phrase)	H360D May damage the unborn child. H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements (P-phrase)	P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P501 Dispose of contents/container in accordance with local regulation

2.13.3 Authorised use(s)

2.13.3.1 Use description

Table 1. Use # 1 – House mice and/or rats – trained professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus domesticus* House mouse Juveniles and adults *Rattus norvegicus* Brown rat Adults and juveniles
Field(s) of use	Indoor -
Application method(s)	Bait application Bait formulations: - Ready-to-use bait to be used: • Tamper-resistant bait stations • Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.

Application rate(s) and frequency	Mice: 20 g/bait point, Rats: 100-200 g /bait point Mice 20 g of bait per bait point. Rat 100-200 g of bait per bait point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper , 20g Type of packaging: Bucket Material of the packaging: Inner LDPE plastic bag(s) in a plastic PP Bucket Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (1 up to 3kg) Type of packaging: Box Material of the packaging: Inner PE/PET plastic bag(s) in a cardboard box Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Bag Material of the packaging: PET/PA/PE plastic bag, with handle and reclosable zip. Size/volume of the packaging: up to maximum 10 kg.

Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- Do not use the product in pulsed baiting treatments.

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

- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.

2.13.3.2 Use description

Table 2. Use # 2 – Mice and/or rats – trained professionals – outdoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus domesticus* House mouse Juveniles and adults *Rattus norvegicus* Brown rat Adults and juveniles
Field(s) of use	Outdoor For use around buildings, at recycling sites (pickup stations), as well as for protection of infrastructure such as buildings and systems for energy supply and communication. The product may also be used against rats in urban parks and other similar public areas and at high-frequency pedestrian streets in the urban environment. Not for other uses in parks, open areas, outdoor waste dumps or landfills.
Application method(s)	Bait application Bait formulations: - Ready-to-use bait to be used in: • Tamper-resistant bait stations • Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.
Application rate(s) and frequency	Mice: 20 g/bait point, Rats: 100-200 g /bait point Mice 20 g of bait per bait point. Rat 100-200 g of bait per bait point.
Category(ies) of users	Trained professional

Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper , 20g Type of packaging: Bucket Material of the packaging: Inner LDPE plastic bag(s) in a plastic PP Bucket Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Box Material of the packaging: Inner PE/PET plastic bag(s) in a cardboard box Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Bag Material of the packaging: PET/PA/PE plastic bag, with handle and reclosable zip. Size/volume of the packaging: up to 10 kg

Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period**.**
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Follow any additional instructions provided by the relevant code of best practice.

Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.13.3.3 Use description

Table 3. Use # 3 –House mice – professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus domesticus* House mouse Juveniles and adults
Field(s) of use	Indoor -
Application method(s)	Bait application Ready-to-use bait for use in tamper resistant bait stations.
Application rate(s) and frequency	20 g/bait station 20 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be: 5-20 meters for low infestations 2-10 meters for high infestations
Category(ies) of users	Professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper , 20g Type of packaging: Bucket Material of the packaging: Inner LDPE plastic bag(s) in a plastic PP Bucket Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Box

	Material of the packaging: Inner PE/PET plastic bag(s) in a cardboard box Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Bag Material of the packaging: PET/PA/PE plastic bag, with handle and reclosable zip. Size/volume of the packaging: up to 10 kg

Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Follow any additional instructions provided by the relevant code of best practice.

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.13.3.4 Use description

Table 4. Use # 4 – (Not relevant in Sweden) – Rats – professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* Brown rat Adults and Juveniles
Field(s) of use	Indoor -
Application method(s)	Bait application Ready-to-use bait for use in tamper resistant bait stations.
Application rate(s) and frequency	100-200 g/bait station 100-200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be: 5-20 meters for low infestations

	3-10 meters for high infestations
Category(ies) of users	Professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper , 20g Type of packaging: Bucket Material of the packaging: Inner LDPE plastic bag(s) in a plastic PP Bucket Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (1 up to 3kg) Type of packaging: Box Material of the packaging: Inner PE/PET plastic bag(s) in a cardboard box Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Bag Material of the packaging: PET/PA/PE plastic bag, with handle and reclosable zip. Size/volume of the packaging: up to 10 kg

Use-specific instructions for use

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.13.3.5 Use description

Table 5. Use # 5 – – House mice and/or rats (rats not relevant in Sweden) – professionals – outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus domesticus* House mouse Juveniles and adults *Rattus norvegicus* (Not relevant in Sweden) Brown rat Adults and juveniles
Field(s) of use	Outdoor Outdoor around buildings For use around buildings as well as for protection of infrastructure such as transformer station or equivalent. Not for use in parks, open areas, waste dumps or landfills.
Application method(s)	Bait application Ready-to-use bait for use in tamper resistant bait stations.
Application rate(s) and frequency	Mice: 20 g/bait station, Rats: 100-200 g /bait station Mice 20 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be: 5-20 meters for low infestations 2-10 meters for high infestations Rat 100-200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be: 5-20 meters for low infestations 3-10 meters for high infestations
Category(ies) of users	Professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper , 20g Type of packaging: Bucket Material of the packaging: Inner LDPE plastic bag(s) in a plastic PP Bucket Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Box Material of the packaging: Inner PE/PET plastic bag(s) in a cardboard box

	Size/volume of the packaging: Number of packed plastic bag(s) per packaging: 1 (up to 10kg of bait per packed bag) or 2 (up to 7.5kg) or 3 (up to 5kg) or 4 (up to 3.5kg) or 5 (up to 3kg) Type of packaging: Bag Material of the packaging: PET/PA/PE plastic bag, with handle and reclosable zip. Size/volume of the packaging: up to 10 kg

Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

- Follow any additional instructions provided by the relevant code of best practice.

Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

- When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.13.3.6 General directions for use[31]

Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

[31] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.

- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not open the sachets containing the bait.

FOR PROFESSIONALS ONLY

- Remove the remaining bait or the bait stations at the end of the treatment period.

FOR TRAINED PROFESSIONAL ONLY
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [in accordance with the applicable code of good practice, if any]".

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.
- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

FOR PROFESSIONAL ONLY:

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- The product information (i.e. label and/or leaflet) shall clearly show that:
• the product shall not be supplied to the general public (e.g. "for professionals only").
• the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
• users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Do not wash the bait stations with water between applications.

FOR TRAINED PROFESSIONAL ONLY:

- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").

- Do not use in areas where resistance to this combination of active substances can be suspected.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
- Hazardous to wildlife.

Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.

Shelf life 2 years.

Other information

- Content of coumatetralyl: 0.0375 % w/w (pure), 0.038 % w/w (technical material).

- Content of cholecalciferol: 0.01 % w/w (pure), 0.01 % w/w (technical material).

- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.

- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

- This product contains a bittering agent and a dye.

3 SUMMARY

3.1 GROUNDS FOR DECISION

3.1.1 Function and efficacy

Racumin 3D is a rodenticide (product type 14) containing the active substances coumatetralyl and cholecalciferol. The concentration of coumatetralyl is the same as in the representative formulation of the active substance approval (0.038 % w/w (technical material)). The concentration of cholecalciferol is substantially lower, 0.010 % w/w., compared to the nominal concentration of cholecalciferol in the representative formulations for the active substance approval (0.075 % w/w). The main effect of cholecalciferol in Racumin 3D is as a stop-feeding agent, while the rodenticidal effect (mortality of target rodents) mainly results from coumatetralyl exposure.

The product is a ready-for-use bait block, which is intended for trained professional use and professional use for the control of brown rats (*Rattus norvegicus*) and mice (*Mus musculus domesticus*) in and around buildings. The product has been shown to be efficacious for the intended uses.

3.1.2 Exclusion criteria

Both active substances, coumatetralyl and cholecalciferol, in the biocidal product Racumin 3D, meet the criteria for exclusion under Article 5(1) of the EU Biocidal Products Regulation (528/2012).

Coumatetralyl is classified as toxic for reproduction category 1B. Coumatetralyl therefore meets the exclusion criterion set out in Article 5(1)(c) of Regulation (EU) No 528/2012.

Cholecalciferol is a pro-hormone and therefore meets the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 (4) to be considered as having endocrine-disrupting properties that may cause adverse effects in humans. Cholecalciferol therefore meets the exclusion criterion set in Article 5(1)(d) of Regulation (EU) No 528/2012.

3.1.3 Applicability of Article 5.2 in the Reference Member State Sweden

The use of a biocidal product with active substances meeting the exclusion criteria in Article 5(1) shall be restricted to Member States in which at least one of the conditions set out in Article 5(2) is met.

As stated in the Commission Implementing Regulation (EU) 2017/1378[32], renewing the approval of coumatetralyl as an active substance, as well as in the Commission Implementing Regulation (EU) 2019/637 [33], approving cholecalciferol as an active substance, rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. The Swedish Chemicals Agency finds that non-chemical controls or prevention methods for rodent control, such as mechanical or electrical traps, may not be sufficiently efficient.

The use of Racumin 3D would be to prevent or control a serious danger to human and animal health in which rodents are involved, for which alternative methods are insufficient. Therefore, the Swedish

[32] COMMISSION IMPLEMENTING REGULATION (EU) 2017/1378 of 25 July 2017 renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14

[33] COMMISSION IMPLEMENTING REGULATION (EU) 2019/637 of 23 April 2019 approving cholecalciferol as an active substance for use in biocidal products of product-type 14

Chemicals Agency finds that the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied for use in the Reference Member State Sweden.

Furthermore, as also described in the approval decisions for the active substances, insufficient rodent control may cause not only significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, entailing economic and social consequences.

The Swedish Chemicals Agency concludes that not approving the product would have a disproportionate negative impact on society when compared with the risk to animal health or the environment arising from the use of the product. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus satisfied for use in the Reference Member State Sweden.

The use of a biocidal product containing active substances approved in accordance with Article 5(2) of Regulation (EU) No 528/2012 shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised.

3.1.4 Candidates for substitution

The active substances shall be considered as candidates for substitution according to Article 10(1) a, since they meet at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2). In addition, the condition set out in Article 10(1) e, *i.e.* that there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, even with very restrictive risk management measures, is also considered to be met.

3.1.5 Comparative assessment

The active substances coumatetralyl and cholecalciferol meet the criteria for exclusion according to Article 5(1) c and d, respectively, as well as for substitution according to Article 10(1) a and e, of Regulation (EU) No 528/2012. Therefore, in line with Article 23 (1) of the same Regulation, a comparative assessment for the product Racumin 3D has been conducted.

Based on its content of coumatetralyl, which has an anti-vitamin K (AVK) mode of action, Racumin 3D is included in the group of anticoagulant rodenticides. When performing a comparative assessment of an anticoagulant rodenticide, the competent authorities of the Member States shall take into account the Annex of the Commission Implementing Decision (EU) 2017/1532. In the annex, questions concerning the comparative assessment submitted by the Member States to the Commission are addressed. A number of alternatives to the anticoagulants are listed, but it is noted that these alternatives do not meet the conditions of Article 23 (3) (a) or (b) of the EU Biocides Regulation. The Swedish Chemicals Agency does not find reasons to deviate from the conclusions set out in the Annex to the Commission Implementing Decision (EU) No 2017/1532 in the comparative assessment for Racumin 3D, and considers that the conditions set out in Article 23 (3) (a) and (b) of the EU Biocides Regulation are not met. The fact that Racumin 3D also contains cholecalciferol, which acts as a stop feeding agent, does not change the outcome of the comparative assessment. In accordance with Article 23 (6) of the EU Biocides Regulation the authorisation of the product Racumin 3D may be granted for a period not exceeding five years.

3.1.6 Summary of Risk Assessment for human health and environment:

The evaluation of the product Racumin 3D regarding the risks for human health shows that no unacceptable risks were identified for professional users when using gloves when handling the product.

In contrast, unacceptable risks were identified for children mouthing of bait. This highlights the need for extensive risk mitigation measures for the product.

Unacceptable risks were also identified in the environmental risk assessment. The identified high risk quotients for primary and secondary poisoning of non-target birds and mammals, signal that the use of this product poses a high potential risk to the environment. The conclusion that rodenticide bait products constitutes a risk for non-target animals is supported by numerous studies where coumatetralyl and other anticoagulant rodenticides have been detected in non-target animals. One recent example is a national environmental screening study, commissioned by the Swedish Environmental Protection Agency, where coumatetralyl was detected in all (n=10) of the red foxes analysed. Of the avian samples (nine different species) analysed in the study (n=43), 68% of the birds were exposed to at least one anticoagulant rodenticide, and 29% were exposed specifically to coumatetralyl[34].

3.1.7 Authorisation according to Article 19 (5)

Due to the identified unacceptable risks, the conditions for granting an authorisation according to Article 19 (1)(b)(iv) of Regulation (EU) No 528/2012 (BPR) are not fulfilled. In consequence, the product can only be authorised in accordance with Article 19 (5), as this article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society, when compared to the risks to human health arising from the use of the biocidal product. An authorisation can only be granted with the most extensive mitigation measures available in order to protect human health and the environment. The view on which measures that are appropriate in order to reduce the risks may differ between Member States where the conditions to grant an authorisation are considered to be met.

3.1.8 Risk Mitigation Measures considered appropriate in Ref-MS Sweden

In the Commission Implementing Regulations on the active substances approval, a number of risk mitigation measures that are required at product approval are specified. These include *e.g.* that products authorised for use by professionals shall only be authorised for use in tamper-resistant bait stations, whereas for trained professionals products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non- target species and humans as tamper-resistant bait stations. Products shall contain an aversive agent and a dye. All risk mitigation measures identified at the active substances approval apply for Racumin 3D.

In addition, factors such as category of users may be considered as risk mitigation measures (see 'Risk mitigation measures for anticoagulants used as rodenticides' (CA-March07-Doc.6.3)). According to the Swedish view on suitable measures to reduce the risks and avoid development of pest populations resistant towards the active biocide substances, extended knowledge and skills are needed to efficiently use rodenticides, thus all products **against rats** should be approved in user category class 1 only (trained professionals with a special permit) in Sweden. All professional users in this category need a special license that is given after proven operative skills in pest control activities and examination from a theoretical course given by the Public Health Agency of Sweden. The training comprises, among other things, how to choose the best suitable and efficient campaign methods and how to take care of dead animals and unused bait in order to minimize risks for health and environment. A trained user can therefore be expected to apply a stepwise integrated pest control strategy. Such a strategy comprises

[34] Rodenticide screening 2016–2018: Exposures in birds (raptors and gulls) and red foxes. Report No. C 440, October 2019. IVL Swedish Environmental Research Institute

extensive precautionary measures, for instance the use of mechanic alternatives, before, as a last resort, chemical pest control is applied. A trained user is also expected to use the products in a way that minimizes unintentional exposure. For example, the risk for children to accidentally consume rodenticides is believed to be higher when the product is used by the general public or a non-trained professional than when used by a trained professional. A trained user is also expected to, to a larger extent than a non-trained professional or amateur, remove dead animals correctly in order to minimize the risks for secondary poisoning.

Inappropriate handling of rodenticides may result in unacceptable environmental exposure and secondary poisoning of predatory and scavenger mammals and birds, without actually removing the pest problem (rodents). Furthermore, most householders in Sweden have a "householder's comprehensive insurance" covering pest control. To hire a trained professional user would therefore not necessarily increase costs for the general public in Sweden.

3.2 PROPOSAL FOR DECISION

The proposal for decision from the Swedish Chemicals Agency is to authorise the biocidal product Racumin 3D for use on the Swedish market. The terms and conditions of the authorisation must include all available and appropriate risk mitigation measures in order to reduce the identified risks for primary and secondary poisoning of non-target organisms to a minimum. The terms and conditions of the authorisation are presented in the Summary of Products Characteristics (SPC).

ANNEX 1. LIST OF STUDIES REVIEWED

A. List of new data submitted in support of the evaluation of the active substance

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIA 4.1/01	Krämer F. and Rüngeler W.	2012a	Determination of [redacted] Bayer CropScience AG, 40789 Monheim, Germany Study ID: AM019312MP1 GLP, unpublished	**Y**	**Y**	**Bayer AG**
IIIA 4.1/02	Krämer F. and Rüngeler W.	2012b	Validation of GLC-method AM019312MP1. Determination of [redacted] Bayer CropScience AG, 40789 Monheim, Germany Study ID: VB1-AM019312MP1 GLP, unpublished	**Y**	**Y**	**Bayer AG**

B. List of new data submitted in support of the evaluation of the <u>biocidal product</u>

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB 3.1.1 IIIB 3.1.2 IIIB 3.1.3 IIIB 3.5 IIIB 3.7.2 IIIB 3.7.4 IIIB 3.8.1 IIIB 3.8.2	Manka, S.	2013a	Determination of Physico-Chemical Properties and Storage Stability Test for Cholecalciferol + Coumatetralyl RB 0,010 + 0,0375 in Cardboard Boxes with PE Inliner– Interim Report 2 Weeks, Biogenius GmbH, 51429 Bergisch Gladbach, Germany, Report No. Mo4556	Y	Y	Bayer AG
IIIB 3.2	Krack, M.	2012a	Cholecalciferol + Coumatetralyl RB 0,010 + 0,0375 Batch No.: 2012-004743 Explosive Properties A14, Siemens AG, Frankfurt am Main, Germany, Report No. 20120343.01	Y	Y	Bayer AG
IIIB 3.3	Brux, A.	2012a	Oxidising Properties of Solids A17 of Cholecalciferol + Coumatetralyl RB 0,010 + 0,0375, Biogenius GmbH, 51429 Bergisch Gladbach, Germany, Report No. Mo4508	Y	Y	Bayer AG
IIIB 3.4.2	Krack, M.	2012b	Cholecalciferol + Coumatetralyl RB 0,010 + 0,0375 Batch No.: 2012-004743 Auto-flammability (Solids – Determination of Relative Self Ignition Temperature) A16, Siemens AG, Frankfurt am Main, Germany, Report No. 20120343.02	Y	Y	Bayer AG
IIIB 3.4.3	Brux, A.	2012b	Flammability of Solids A10 of Cholecalciferol + Coumatetralyl RB 0,010 + 0,0375, Biogenius GmbH, 51429 Bergisch Gladbach, Germany, Report No. Mo4507	Y	Y	Bayer AG
IIIB 3.6	Manka, S.	2013b	Determination of the Density of Cholecalciferol + Coumatetralyl RB 0,0375+0,01, Biogenius GmbH, 51429 Bergisch Gladbach, Germany, Report No. Mo4643	Y	Y	Bayer AG
IIIB 3.7.7	Boecker, T. & Lamshoeft, M.	2015	Storage stability of [benzopyranone-phenyl-ring-UL-14C] coumatetralyl in bait paste. Final Report. No.102000027163 Bayer CropScience AG, BCS-D-EnSa-Testing, Monheim, Germany. Bayer Reference M-9992318-1	Y	Y	Bayer AG

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB 3.7.8	Boecker, T.	2016	Long term stability test of the formulation Coumatetralyl + Cholecalciferol RB 0.0375% + 0.01% w/w in cardboard box with in-liner and buckets. Bayer CropScience AG, Monheim, Germany. Bayer reference M-586183-01-1	Y	Y	Bayer AG
IIIB 3.7.9	Frank, C.	2017a	Accelerated Storage Stability Test of the Formulation Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 2 Weeks at 54°C in Cardboard Box, Currenta GmbH & Co. OHG, Germany, Study No.: 2016/0093/02	Y	Y	Bayer AG
IIIB 3.7.10	Frank, C.	2017b	Accelerated Storage Stability Test of the Formulation Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 2 Weeks at 54°C in PP Pail, Currenta GmbH & Co. OHG, Germany, Study No.: 2016/0093/07	Y	Y	Bayer AG
IIIB 4.1	Frank, C.	2017c	Validation of an Analytical Method for the Determination of Cholecalciferol, Coumatetralyl and Denatonium Benzoate in the formulation Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01, Currenta GmbH, Germany, Study No.: 2016/0093/01	Y	Y	Bayer AG
IIIB5.10-01	[redacted]	2006	Field trial to determine the efficacy of bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling bromadiolone-resistant Norway rats (*Rattus norvegicus*) on a farm in Muensterland, [redacted] Study No.: KLN/BCS/2006-1	Y	Y	Bayer AG
IIIB5.10-03	[redacted]	2013a	Field Trial with Bait Containing Coumatetralyl (375 mg/kg) and Vitamin D_3 (100 mg/kg): Control of Norway Rats (*Rattus norvegicus*) in an Animal Home. [redacted] Study No.: 04892.	Y	Y	Bayer AG

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB5.10-04	[redacted]	2012	Field trial to determine the efficacy of paste bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling house mice (*Mus musculus domesticus*). [redacted] Study No.: KLN/BCS/2012-3.	Y	Y	Bayer AG
IIIB5.10-05	[redacted]	2013b	Feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) in anticoagulant-resistant Norway rats (*Rattus norvegicus*). [redacted] Study No.: BES-09-12	Y	Y	Bayer AG
IIIB5.10-06	[redacted]	2013	Field trial to determine the efficacy of a paste bait containing coumatetralyl (0.0375%) and cholecalciferol (0.01%) in controlling Norway rats (*Rattus norvegicus*). [redacted] Study No.: KLN/BCS/2012-06.	Y	Y	Bayer AG
IIIB5.10-07	[redacted]	2013c	Choice feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100 mg/kg) in Norway rats (*Rattus norvegicus*) of a wild strain. [redacted] Study No.: BES-13-002	Y	Y	Bayer AG
IIIB5.10-08	[redacted]	2013d	Feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100mg/kg) to prove the efficacy in the house mouse (*Mus musculus*) of a wild strain. [redacted] Study No.: FRM-13-003.	Y	Y	Bayer AG

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB5.10-09	[redacted]	2013e	Choice feeding trial with paste bait (coumatetralyl 375 mg/kg + cholecalciferol 100mg/kg) to prove the efficacy in the house mouse (*Mus musculus*) of a wild strain. [redacted] Study No.: FRM-13-004.	Y	Y	Bayer AG
IIIB5.10-13	[redacted]	2014a	Efficacy trial of Racumin Paste Bait (Coumatetralyl 0.0375% w/w) in Brown Rat (Rattus norvegicus). [redacted] Study No.: 14TOX006.	Y	Y	Bayer AG
IIIB5.10-14	[redacted]	2014b	Efficacy trial of a paste bait (0.0375% w/w Coumatetralyl + 0.010% w/w cholecalciferol) in Brown Rat (Rattus norvegicus). [redacted] Study No.: 14TOX007.	Y	Y	Bayer AG
IIIB5.10-15	[redacted]	2012	Expert Opinion: Stop-Feeding Effect and Conditioned Taste Aversion Induced by Vitamin D3 (Cholecalciferol) in the Norway Rat, [redacted] Doc ID: ES 05454.	Y	Y	Bayer AG
IIIB5.10-17	[redacted]	2015	Efficacy of a batch of paste bait containing coumatetralyl 375 mg/kg + vit. D3 100 mg/kg (batch ID 2012-004743), after 24 months storage. [redacted] Doc ID: Mo ES06197.	Y	Y	Bayer AG
IIIB5.10-18	[redacted]	2010	Field trial to determine the efficacy of a paste bait containing coumatetralyl (0.0375%) in controlling house mice *(Mus musculus domesticus).* [redacted] Doc ID: KLN/BCS/2010-4A	Y	Y	Bayer AG

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB5.10-20	[redacted]	2017	Field trial to determine the efficacy of a rodenticide paste formulation, containing 375ppm coumatetralyl and 100ppm cholecalciferol, in controlling an infestation with Norway rats (*Rattus norvegicus*) comprising anticoagulant-resistant animals on a farm in Muensterland. [redacted] Study No.: KLN/BCS/2016-5.	Y	Y	Bayer AG
IIIB6.1.1	[redacted]	2013a	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Acute Oral Toxicity Study in Rats "Acute Toxic Class Method". [redacted] study No. 39474 TAR.	Y	Y	Bayer AG
IIIB6.1.2	[redacted]	2013b	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Acute Dermal Toxicity Study in Rats. [redacted] study No. 39475 TAR.	Y	Y	Bayer AG
IIIB6.2e	[redacted]	2013c	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Acute Eye Irritation Study in Rabbits. [redacted] study No. 39477 TAL.	Y	Y	Bayer AG
IIIB6.2s	[redacted]	2013d	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Acute Dermal Irritation Study Toxicity Study in Rabbits. [redacted] study No. 39476 TAL.	Y	Y	Bayer AG
IIIB6.3	[redacted]	2013e	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Evaluation of Skin sensitisation Potential in Mice using the Local Lymph Node Assay (LLNA). [redacted] study No. 39478 TSS.	Y	Y	Bayer AG
IIIB6.4-02	[redacted]	2013	Cholecalciferol - *In Vitro* Absorption from a Ready Bait Formulation through Human Epidermis using [^{3}H]-Radiolabelled Cholecalciferol. [redacted] Report No. JV2207-REG.	Y	Y	Bayer AG

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No.	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIB7.8.1	[redacted]	2013a	Coumatetralyl + Cholecalciferol RB 0.0375 + 0.01 W; Acute Oral Toxicity Study in Rats "Acute Toxic Class Method". [redacted] study No. 39474 TAR.	Y	Y	Bayer AG
IIIB7.8.7.2	[redacted]	2013b	Evaluation of secondary poisoning risk for ferrets (*Mustela furo*) fed coumateralyl and cholecalciferol combination bait [redacted]	Y	Y	Bayer AG
IIIB8	Bayer AG	2018	Draft SDS: Racumin 3D Version 7 EU. 13.11.2017, printed 01.03.2018	N	N	Bayer AG
IIIB9-01	Bayer AG	2013	Label: Racumin 3D Professional	N	N	Bayer AG