INFOTOX (Pty) Ltd

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Retrieval and scientific interpretation of ecotoxicological information

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Report Compiled for
2022 Environmental Science ZA (Pty) Ltd (Envu)

Derogation Risk Assessment Report for Solid Rodenticides Containing Coumatetralyl, a CMR Substance of Concern (Reproductive Toxicity Hazard)

Product trade names:

RACUMIN® Rat and Mouse Wax Blocks (L8465)

RACUMIN® 3D Paste (L10218)

RACUMIN® Paste (L6401)

RACUMIN® Tracking Powder (L2800)

INFOTOX Report No 002-2025 Rev 3.0

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19 March 2025

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Managing Director

19 March 2025

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Expertise and Declaration of Independence

This report was prepared by INFOTOX (Pty) Ltd ("INFOTOX"). Established in 1991, INFOTOX is a professional scientific company, highly focused in the discipline of ecotoxicological risk assessment. Both occupational and environmental human health risks, as well as risks to ecological receptors, are addressed.

Dr Willie van Niekerk, Managing Director of INFOTOX, has BSc, Hons BSc and MSc degrees from the University of Potchefstroom and a PhD from the University of South Africa. He is a Qualified Environmental Professional (QEP), certified by the Institute of Professional Environmental Practice (IPEP) in the USA (No 07960160), and a registered Professional Natural Scientist (Pr Sci Nat, Environmental Science, No 400284/04). Dr Van Niekerk has specialised in chemical toxicology and human health risk assessments, but he has experience in many other areas in the disciplines of analytical and environmental sciences.

Dr Marlene Fourie has BSc and Hons BSc degrees from the University of Stellenbosch and MSc and PhD degrees from the University of Pretoria. Her field of specialisation is reproductive biology/toxicology. Dr Fourie also has an MSc-degree in epidemiology from the University of Pretoria. Following positions as Medical Natural Scientist at the Andrology Unit, Department of Urology, University of Pretoria and the Pretoria Academic Hospital from 1987 to 2001, she joined INFOTOX as a Medical Biological Scientist. Dr Fourie has conducted many health risk assessments and projects relating to the health status of communities. She is a registered Professional Natural Scientist (Pr Sci Nat, Toxicological Science, No 400190/14). Dr Fourie has completed the Globally Harmonised System (GHS) course *Classifying and Labelling Chemicals According to the UN GHS*, presented by the United Nations Institute for Training and Research (UNITAR) in 2017, with previous experience in GHS classification since 2010.

This specialist report was compiled for 2022 Environmental Science ZA (Pty) Ltd (Envu). We do hereby declare that we are financially and otherwise independent of 2022 Environmental Science ZA (Pty) Ltd (Envu).

Signed on behalf of INFOTOX (Pty) Ltd, duly authorised in the capacity of Managing Director:

Willem Christiaan Abraham van Niekerk

19 March 2025

Executive Summary

This document is a risk assessment report supporting an application for derogation for the restricted use of certain registered solid rodenticide products, containing the active ingredient coumatetralyl. The paste and wax block formulations are supplied to professional pest control operators ("PCOs") and to the general public, but the tracking powder formulation is intended for use by PCOs only.

The solid products are identified as substances of concern due to classification as reproductive hazards category 1B according to the Globally Harmonized System of Classification and Labelling of Chemicals ("GHS"). The classification is due to the active ingredient coumatetralyl, which is classified in GHS reproductive toxicity category 1B (H360D), indicating a hazard to the development of the unborn child ("D").

Product names, registered suppliers and Act 36 of 1947 registration numbers:

Product	Act 36 of 1947 registration numbers	Registered manufacturer / supplier / distributer
RACUMIN® 3D Paste	L10218	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Paste	L6401	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Rat and Mouse Wax Blocks	L8465	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Tracking Powder	L2800	2022 Environmental Science ZA (Pty) Ltd.

Intended product use:
Solid anti-coagulant rodenticide products for use as follows:

Product	Use (according to label)
RACUMIN® 3D Paste	… for the control of rats and mice indoors and outdoors.
RACUMIN® Paste	A universal bait for rodent control in all areas, including dumps and animal stables.
RACUMIN® Rat and Mouse Wax Blocks	Weatherproof bait to control Norway rats, roof rats and house mouse in … garden, home and animal dwellings, factories, warehouses, storage premises, industrial areas, food establishments and newly established plantations. For the control of gerbils in public health environments and agricultural plantations.
RACUMIN® Tracking Powder	… for control of the Norway rat, roof rat and house mouse. For use in and around human and animal dwellings, factories, warehouses, other storage premises. For control of gerbils in agricultural situations.

The occupational human health risk assessments presented here are based on internationally-accepted human risk assessment principles and methods. The health and ecological risk assessment guidance of the following major international regulatory agencies is followed:

- The Danish CA Assessment Report on Coumatetralyl, Product-type PT 14 (Rodenticides) with the view of satisfying regulatory requirements for placing biocidal products on the market, submitted 20 February 2009.
- The German Competent Authorities ("CAs") functioning as the Evaluating Competent Authority of the European Community ("EC") to carry out the assessment report evaluating coumatetralyl as a biocidal product, Product type 14 (rodenticide) with the view of satisfying regulatory requirements for placing biocidal products on the market, submitted by the German CA on 13 February 2018.
- Coumatetralyl is currently not registered for use as a rodenticide in the US; therefore, documents potentially compiled by the US Environmental Protection Agency ("USEPA") are not available for review.

Human health risk assessment

The scope of the solid rodenticide human health risk assessment ("HHRA") is determined by the registered product use. The purpose is to evaluate the risks of reproductive/developmental toxicity effects in persons exposed to coumatetralyl in the identified products listed above. Since developmental effects are the only health endpoints (aside from mortality) for which dose-response values are available in toxicological studies, there is no other choice but to base acceptable exposure levels of males and children on this health endpoint as well. Therefore, the absence of a risk to health in general, and specifically the absence of a risk to the developing foetus, is implied by a finding of "acceptable exposures or risks".

The following human exposure scenarios were identified for assessment:

- Primary dermal exposure of non-professionals (domestic users) and professional PCOs handling, placing, refilling and disposing of unused paste and wax block baits.
- RACUMIN® tracking powder is intended and assessed for primary use by professional PCOs only. Exposure is by the inhalation and dermal routes.
- Secondary human exposures are assessed as:
    - Accidental dermal contact of adult non-professionals with the product in the use phase, or with product residues on dead or dying rodents.
    - Accidental exposure of infants/toddlers transiently mouthing or chewing on bait, or mouthing contaminated hands in the case of accidental contact with the tracking powder.

Adult coumatetralyl paste or wax block users, whether professional PCOs or non-professionals, wearing gloves, are not at risk of health effects, including effects on the development of the foetus in case of pregnant females. In some of these cases, acceptable risks are also demonstrated for adults not wearing gloves. However, this can never be used to negate the need for recommending the use of gloves on product labels. Recommending the use of gloves is a protective measure for all bait users, and also protects against diseases carried and spread by rodents.

Calculated inhalation risks of PCOs using RACUMIN® tracking powder are high if the recommended factor-20 respirators are not used, but are acceptable when respirators are used. The calculated exposure doses represent likely worst-case scenarios. PCO health risks associated with dermal exposure are acceptable when gloves are worn, as is recommended on the labels. Calculations of tracking powder dermal exposure when "wearing gloves" also assumes protection of the fore-arms and other exposed skin areas. Therefore, PCOs should wear gloves at all times while handling the product, while cleaning up residual product at the end of the campaign, and while handling dead rodents. Wearing of coveralls, to exclude dermal exposure as far as possible, should also be recommended.

The calculated tracking powder inhalation risks emphasise the necessity of avoiding dust generation during the application and clean-up phases, and of PCOs wearing the recommended respiratory protection. The product is, in any case, not intended for the domestic/amateur/non-professional market. In order to protect PCOs, wearing of factor-20 respirators, which is currently recommended only on the safety data sheet ("SDS"), should also be recommended on the label. Use of dust blowers to apply the tracking powder inside burrows must be prohibited. Warnings against the application of excessive amounts of the product should be provided, and indoor clean-up of residual powder by sweeping with a broom must be prohibited. An indoor clean-up method not generating dust should be recommended, e.g., clean-up with damp (not wet) disposable wipes, to be discarded with used gloves in sealed plastic bags at the end of clean-up.

Secondary exposure of infants/toddlers chewing on solid bait products are at risk of a health effect. Transient mouthing may also result in a risk to health. However, accidental exposure of bystanders, specifically children, can be limited by clear communication of the pesticide applicator (professional

or non-professional) to such bystanders, and by following label instructions to rather use tamper-proof bait boxes, and to keep the bait out of reach of children and uninformed persons.

Regardless of the precautionary measures followed, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception. All product labels must clearly display the contact details of a local/national poison centre.

Environmental (ecological) risk assessment

Secondary exposure in mammals and birds of prey describes the ingestion, by natural predators in the environment, of dead or dying target animals, that is, rats or mice in the case of coumatetralyl formulations. The general conclusions of international regulatory assessments based on available toxicity values in predatory birds and non-target predatory mammals is that secondary risks to mammalian and avian predators cannot be excluded. However, mitigation measures such as limiting access by non-target organisms and frequent inspections to search for and correctly dispose of rodent carcasses can limit the risk of secondary poisoning of non-target animals.

Responsible product application and care, with clear instructions on product labels and SDSs to prevent contamination of waterways, should limit aquatic contamination to negligible. Therefore, no risk assessment for secondary poisoning through the aquatic food chain is required, and also no risk assessment for non-mammalian or non-avian terrestrial organisms.

The environmental effects versus societal needs/benefits balance

There is no question that there is a legitimate societal need for cost-effective, relatively inexpensive rodenticides, considering the serious and potentially lethal human diseases, e.g., hantavirus, typhus and the bubonic plague, that are spread by mice and rats. Furthermore, rodent plagues imply a burden of economic costs of property, food and crop damage and spoilage.

Continued access to cost-effective rodenticides can be approached as an issue of environmental justice. The balance of societal need and benefits, versus the overt poisonous nature of the product, is always to be considered regarding any regulatory decisions to limit access to rodenticides. This is particularly important to socio-economically disadvantaged communities. Such communities bear a double burden of more frequent rodent infestations, with concomitant exposure to diseases spread by rodents, possible rat-bite injuries to infants, damage to property and food spoilage and contamination, and limited resources to use other, non-poisonous solutions.

Restricted use applied for

The restricted use applied for is according to the intended product use:

- An anti-coagulant poison for control of the Norway rat, roof rat and house mouse. For use in and around human and animal dwellings, factories, warehouses and other storage premises. For control of gerbils in agricultural situations.
- RACUMIN® tracking powder is for the use of professional PCOs only and should not be accessible for use or purchase by the general public, amateur or non-professional persons.
- The other RACUMIN® coumatetralyl solid rodenticides are for use by professionals and non-professionals.

Mitigation measures

Mitigation measures presented in Section 9 of this report should be implemented in full, with particular emphasis on the following:

- 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.
- Precautions, e.g., keeping the product away from children, pets and directions for use on the product label must be followed.

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Domestic users should be encouraged to use adequate tamper-resistant bait boxes, but it is not suggested that bait box use must be mandatory to the South African consumer, where a need for access to low-cost rodenticides is foreseen, specifically in low-income groups. Mandatory use of bait boxes implies an additional cost premium, which might cause rodenticide use to be unaffordable to those needing it most (see Section 9.2 for a complete discussion).
- Search for and remove dead rodents at frequent intervals during treatment.
- Remove the remaining product at the end of treatment period. Clear disposal instructions must be provided on the label. Broom sweeping of tracking powder residues is not allowed.
- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.
- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- The use of gloves is highly recommended when handling rodenticide products, particularly the tracking powder, and when handling dead rodents.
- PCOs applying or cleaning up tracking powders must wear respirators with a particle filter mask (protection factor 20) conforming to European Norm EN149FFP3 or EN140P3 or equivalent.

Support for the restricted use application

The balance of societal need and benefits, versus the overt toxic nature of the product, is always to be considered regarding any regulatory decisions to limit access to rodenticides. This is particularly important to socio-economically disadvantaged communities. Such communities bear a double burden of more frequent rodent infestations, with concomitant exposure to diseases spread by rodents, possible rat-bite injuries to infants, damage to property and food spoilage and contamination, and limited resources to use other, non-poisonous solutions.

When the above mitigatory measures are applied, accidental poisoning of bystanders, children, pets and non-target animals can be effectively limited. Therefore, the applications for derogation of the products assessed in this report are supported, provided that recommended mitigation measures are effectively implemented.

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List of Abbreviations

AAPCC	American Association of Poison Control Centers
AEL	Acceptable exposure level
AVK	Anti-vitamin K
BW	Body weight
CMR	Carcinogenicity, mutagenicity, and reproductive toxicity
EC	European Commission
EC50	The concentration of a compound resulting in a half-maximal response, e.g., immobilisation of invertebrates or inhibition of algal growth
ECB	European Chemicals Bureau
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemical's
ECHA	European Chemicals Agency
ErC50	The aqueous concentration of a test substance resulting in a 50% reduction in growth rate of aquatic organisms
EU	European Union
FGARS	First generation anticoagulant rodenticides
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEEG	Human Exposure Expert Group
HHRA	Human health risk assessment
IDS	USA Incident Data System
IPCS	International Programme on Chemical Safety
K_{oc}	Partition coefficient organic carbon-water
K_{ow}	Octanol-water partition coefficient
LD50	The dose (mg/kg body weight) of a chemical that is lethal to 50% of exposed experimental animals
LC50	Lethal concentration 50, the concentration required to kill half of a group of aquatic test animals
LOAELs	Lowest-observed-adverse-effect levels
LOC	Level of concern
NOAELs	No-observed-adverse-effect levels
NRC	US National Research Council
OECD	Organisation for Economic Co-operation and Development
PCOs	Pest control operators
PNECs	Predicted no-effect concentrations
POD	Point of departure
PPE	Personal protective equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDSs	Safety data sheets
STOT RE	Specific target organ toxicity (repeated exposure)
TNsG	Technical Notes for Guidance
TRA	Targeted Risk Assessment
UF	Uncertainty factors
UFA	Uncertainty in extrapolating animal data to humans
UFH	Variation in susceptibility among the members of the human population

UF_{Sev}	Additional factor for severity of effects.
USEPA	United States Environmental Protection Agency

List of Terms

Acute toxicity	Adverse effects following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.
Anticoagulants	Chemical substances that decrease the clotting of blood, which, at sufficient blood concentrations, can cause excessive bleeding.
Carcinogenicity	Substance that causes cancer.
Derogation	An exemption from or relaxation of the consideration of this product for removal from the market due to it being considered a CMR product of concern.
Developmental toxicity	Any developmental malformation of the foetus, caused by a toxic substance. that is caused by the toxicity of a chemical or pathogen.
Environmental Fate	Behaviour in or movement of a chemical substance after having been released to the environment. The behaviour in or movements through the environmental compartments of air, soil and water, and the preferred final destiny compartment(s) are described.
Epidemiology	Study of the determinants, occurrence, and distribution of health and disease in a defined population.
Exposure assessment	Identification of environmental pathways, potentially exposed groups, routes of direct and indirect exposure, and estimates of concentrations and duration of exposure.
Genotoxicity	Damage to the cell genes, which may result in mutations.
Mutagenicity	Property of chemical agents to induce genetic mutation.
Neurotoxicity	Ability of a chemical to cause damage or malfunction of the neurological system.
Receptors	People/organisms exposed to the substance of interest.
Registrar	Registrar of the fertilisers, farm feed, agricultural remedies and stock remedies Act, 1947 (Act 36 of 1947) in the Department of Agriculture, Land Reform and Rural Development.
Reproductive toxicity	A substance or agent that can cause adverse effects on the reproductive system, causing the inability to reproduce offspring.
Risk characterisation	Integration of the components described above. The risk characterisation will also provide a review of documented human exposure incidents
Routes of exposure	Inhalation, ingestion, and dermal contact
Surrogate	A chemical with properties, including potential toxicity, that are likely to be similar to another substance of interest for which little information about the properties and/or toxicity are known. “Transferring” the known properties of the surrogate to that of the uncharacterised substance is known as the “bridging principle”, or “read-across” for the purposes of hazard and risk assessment.
Target organ toxicity	The effects on the organ impacted by a hazardous substance
Teratogenic	Causing defects in a developing foetus
Uncertainty review	Identifies the nature and, when possible, the magnitude of the uncertainty and variability inherent in the characterisation of risks

1 Introduction

1.1 Products identification

This document is a risk assessment report supporting an application for derogation for the restricted use of the registered solid rodenticide products listed below.

Report prepared for:		
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Contact details	Physical address	AMR Office Park 9 Concorde Road Bedfordview Johannesburg South Africa
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All products in Table 1.1.1 contain the rodenticide active substance coumatetralyl, which has been identified as a reproductive toxicity hazard.

Table 1.1.1: Assessed products.

Product	Act 36 of 1947 registration numbers	Registered manufacturer / supplier / distributer
RACUMIN® 3D Paste	L10218	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Paste	L6401	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Rat and Mouse Wax Blocks	L8465	2022 Environmental Science ZA (Pty) Ltd.
RACUMIN® Tracking Powder	L2800	2022 Environmental Science ZA (Pty) Ltd.

1.2 Regulatory context

In a document circulated to “All Regulatory Holders” on 14 April 2022, the Registrar: Act 36 Of 1947, of the Department of Agriculture, Land Reform and Rural Development (“Registrar” and “The Department”) refers to an assessment that was carried out at the international level to determine risks to human health due to exposure to active ingredients and their formulations that meet the criteria of carcinogenicity, mutagenicity, and reproductive toxicity (“CMR”) categories 1A or 1B according to the Globally Harmonized System of Classification and Labelling of Chemicals (“GHS”). The Department then stated that “*the assessment identified the need to reduce risks to human health associated with such products*”.

Category 1A covers substances that are known to be CMR, mainly according to human evidence. Category 1B covers substances presumed to be CMR based on data from animal studies.

The Registrar stated his intention to "*prohibit the use of ingredients and their formulations that meets* (sic) *the criteria of CMR categories 1A or 1B of the GHS as from 01 June 2024*".

However, in exceptional circumstances, the Registrar may grant registration of an implicated agricultural remedy when it can be demonstrated that:

"a) The risk to humans, animals or the environment from exposure to the active substance in an agricultural remedy, under realistic worst-case conditions of use, is negligible" (and other conditions not relevant to this INFOTOX report).

In February 2024, the Registrar issued a Guideline for the Application for a Derogation for an Agricultural Remedy Identified as a Substance of Concern.

This INFOTOX report deals with the assessment of risk to humans, animals and the environment, associated with the use of the rodenticide products indicated in Section 1. Specific attention is given to the risk of reproductive toxicity effects in occupational workers.

2 Background to human health risk assessment

2.1 The health risk assessment paradigm

A significant factor in the Organisation for Economic Co-operation and Development (OECD 2021) guidance document on key considerations for the identification and selection of safer chemical alternatives deals with the likelihood of exposure (human and ecological). OECD recommended that routes of exposure to a hazardous chemical that are unlikely, based on measured exposure data or physical-chemical properties of the substance of concern, should be excluded from the assessment. More correctly, the statement should refer to pathways of exposure (air, soil, water, and sediment), and routes of exposure (inhalation, ingestion, and dermal contact).

This recommendation of the OECD (2021) takes the assessment a step further from the hazard data of chemicals represented in the GHS, to the level where the potential for exposure of humans and ecological receptors is assessed, and through accounting for the toxicology of a substance or formulation, the level of risk is determined. This is aligned with the observations and recommendations of Karamertzanis et al. (2019).

Karamertzanis et al. (2019) evaluated the impact on classifications of carcinogenicity, mutagenicity, reproductive and specific target organ toxicity after repeated exposure in the first ten years of implementation of the REACH[1] regulation. The authors highlighted that classification for carcinogenicity, mutagenicity, reproductive toxicity, and specific target organ toxicity (repeated exposure) ("STOT RE") triggers several obligations for manufacturers, importers, and professional users.

Karamertzanis et al. (2019) then stated:
"*In addition to such consequences under other legislations* (sic)*, registrants are required to carry out exposure assessment and risk characterisation for substances that are classified and, hence, classification under REACH is a trigger for risk assessment for human health."*

[1] Registration, Evaluation, Authorisation and Restriction of Chemicals.

OECD (2021) referred to the European Centre for Ecotoxicology and Toxicology of Chemical's ("ECETOC")[2] Targeted Risk Assessment ("TRA") tool for calculating the risk of exposure from chemicals to workers, consumers, and the environment. This illustrates the logic of basing the final decision about the safety of a chemical or formulation on health risk assessment, rather than only on hazard identification, as represented in the GHS.

The original paradigm for regulatory human health risk assessment ("HHRA") in the USA was developed by the US National Research Council (NRC 1983). This model has been adopted and refined by the US Environmental Protection Agency ("USEPA") and other international agencies as published under the International Programme on Chemical Safety (IPCS 1999; IPCS 2010), and is widely used for quantitative human health risk assessments.

Figure 2.1.1 illustrates the health risk assessment paradigm in a simple diagram.

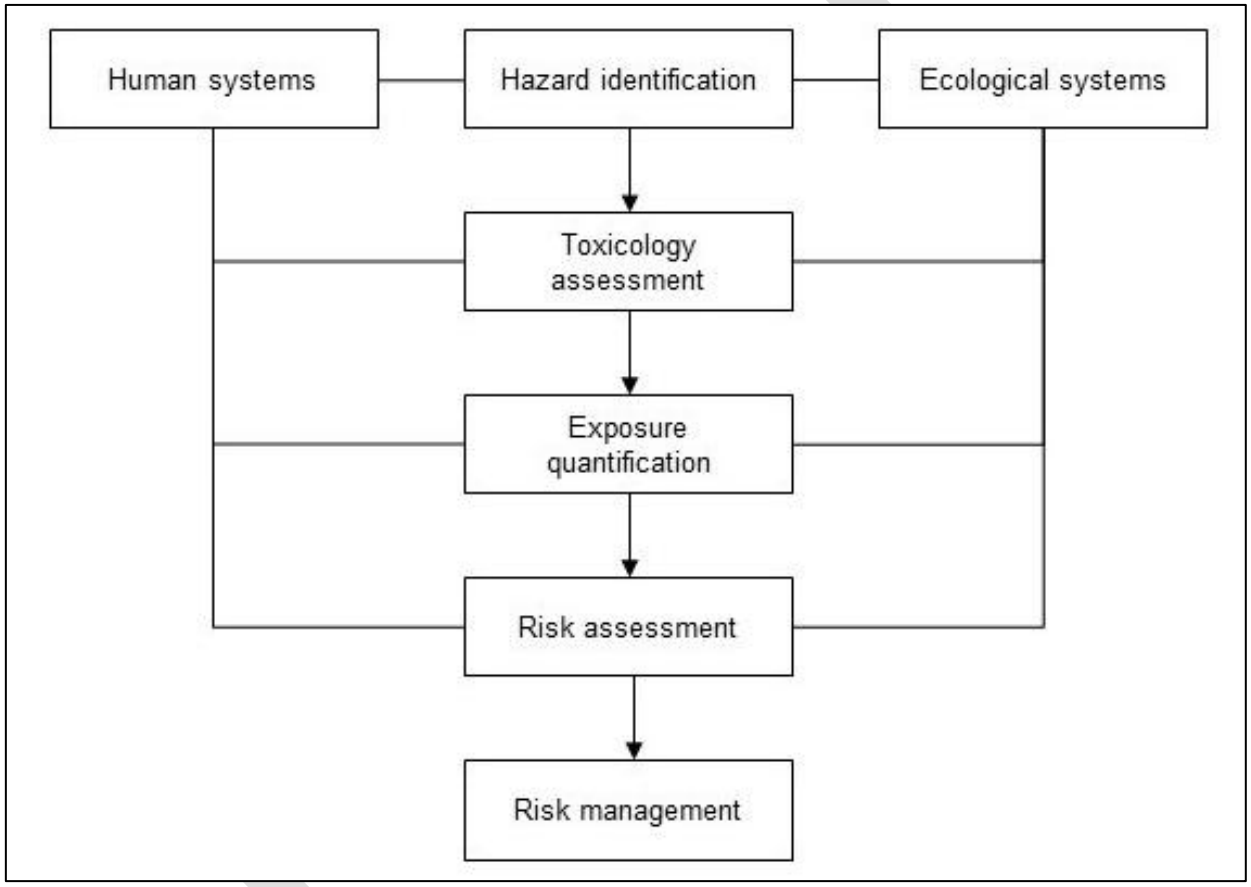

Figure 2.1.1: The holistic health risk assessment paradigm.

It is shown in this INFOTOX report that exposure assessment and health risk quantification are essential steps in managing health risks associated with hazardous chemicals.

2.2 Human health risk assessment methodology

The human health risk assessment ("HHRA") paradigm divides human health risk assessment into several logical steps, as illustrated in Figure 2.2.1. All of these are not fully applicable to the toxicological risk assessment for the purpose of derogation of rodenticides:

[2] http://www.ecetoc.org/tools/targeted-risk-assessment-tra/.

- **Hazard assessment** is the identification of the chemical constituent of concern and the hazard it poses, in this case reproductive/developmental toxicity hazards of coumatetralyl. This is discussed in Section 3.

- **Dose-response assessment** (toxicological assessment) addresses the relationship between levels of uptake and the manifestation of adverse effects (reproductive/developmental toxicity). Toxicological information from available reproductive/developmental studies and applied standard risk assessment methodologies are used to derive a point of departure ("POD") and acceptable exposure level ("AEL") or acceptable operator exposure level ("AOEL") for HHRA purposes, by applying appropriate uncertainty factors and safety factors for infants and children, referring to dose through the routes of exposure. The AEL is the exposure dose that is accepted as not associated with a risk to human health. The derived toxicological values will be protective specifically against potential reproductive/developmental effects of the product. This ensures compliance with the Guideline for the Application for a Derogation for an Agricultural Remedy Identified as a Substance of Concern, issued by the registrar: Act 36 of 1947, in February 2024.

- **Exposure assessment considers** the identification of environmental pathways, potentially exposed groups, routes of direct and indirect exposure, and estimates of concentrations and duration of exposure. A conceptual model of application practices and exposure pathways and routes applicable to the identified receptors was constructed to guide the exposure assessment for the health risk assessment.

  The HHRA considers the following potential <u>occupational exposure</u> scenarios:
  - The oral, dermal and inhalation routes of exposure of professional pest control rodenticide applicators.

  <u>Residential exposure</u> scenarios are assessed, because some of the rodenticides are for sale in retail outlets catering to the general public:
  - Assuming that non-professionals might not be diligent users of personal protective equipment ("PPE"), the exposure of domestic users (non-professionals) handling rodenticides without gloves, that is, dermal exposure, is assessed.
  - The normal procedure recommended on product labels is to place rodenticides for residential exposure out of reach of children, and away from food products or places where food may be stored or prepared. E.g., label instructions are: "*Set bait stations where these will be inaccessible to children and domestic animals*".
  - Nonetheless, accidental mouthing or ingestion of bait by infants/toddlers are assessed.

- **Risk characterisation** involves the integration of the components described above. The risk characterisation also provides a review of documented human exposure incidents, if available.

- **Uncertainty review** identifies the nature and, when possible, the magnitude of the uncertainty and variability inherent in the characterisation of risks.

3 Hazard identification

3.1 The need for GHS classification

Internationally, there is a demand for safer chemicals and technologies, and it is appropriate to utilise information in the GHS as a starting point. This INFOTOX report relates specifically to active

ingredients and their formulations that meet the criteria of CMR categories 1A or 1B in the GHS. Information in the GHS represents hazard data, not information on risk.

3.2 Coumatetralyl CMR hazard classification

The GHS hazard classification identifying the product as a CMR hazardous substance of concern, is: Reproductive toxicity category 1B (H360D); "D" indicating a hazard of developmental effects (effects on the growing foetus) (Table 3.2.1).

Active ingredient identification

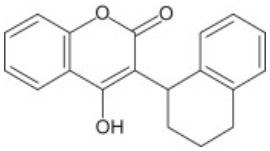 **Coumatetralyl**	**CAS #:** 5836-29-3 **Mol. formula:** $C_{19}H_{16}O_3$ **Molecular weight:** 292.3 g/mol **ISO common name:** 3-(alpha-tetralyl)-4-hydroxycoumarin

Table 3.2.1: CMR GHS classification of coumatetralyl.

Hazard class and category code	Hazard statement code	Hazard statement	Signal word	Pictogram
Carcinogenic	Not classified	Not applicable	Not applicable	Not applicable
Mutagenic	Not classified	Not applicable	Not applicable	Not applicable
Reproductive Toxicity Cat. 1B	H360D	May damage the unborn child	Danger	
Classification according to the European Chemicals Agency ("ECHA" online); harmonised EU classification.				

GHS Category 1B criteria for substance classification:

- **Presumed human reproductive toxicant - largely based on evidence from experimental animals**
- Animal studies provide clear evidence of an adverse effect on fertility or on foetal development in the absence of other toxic effects. If other toxic effects were present, the adverse effects on reproduction must have been regarded as not secondary to the toxic effects.

Table 3.2.2: Concentrations of coumatetralyl in the rodenticide products.

Formulation components	Active ingredient content	
	g/kg	% w/w
Paste bait		
RACUMIN® Paste	0.375	0.0375
RACUMIN® 3D Paste	0.375	0.0375
Wedge/block form		
RACUMIN® Rat and Mouse Wax Blocks	0.375	0.0375
Tracking powder		
RACUMIN® tracking powder	7.5	0.75

Hazard classification identifying products as CMR substances of concern:
Coumatetralyl is assigned the H-code H360D; "D" indicating developmental effects (effects on the growing foetus). The hazard classifications of RACUMIN® rodenticide products have been dealt with in the existing product registrations.

The coumatetralyl classification presented in Table 3.2.1 is according to the Summary of Classification and Labelling presented by the European Chemical Agency ("ECHA") (ECHA online). The *Reproductive toxicity hazard, category 1B (H360D)* is associated with a "*Specific Concentration limit*" of *Repr. 1B; H360D: C ≥ 0.003 %* according to the harmonised GHS classification relevant to Annex VI of European Community Regulation (EC) No 1272/2008 (CLP Regulation). The implication of the "*specific concentration limit"* is that the RACUMIN® rodenticide products, assessed in this report, should be classified as a GHS Category 1B Reproductive toxicity hazard, based on the relevant concentrations of coumatetralyl in the products (Table 3.2.2). The listed products are assigned the H-code H360D because the concentrations of coumatetralyl are sufficient to justify the reproductive toxicity classification (≥ 0.003 % mass) according to the ECHA classification limit for chemical mixtures containing coumatetralyl.

It is understood that the South African classification regulations actually refer to the GHS as presented in the latest revised edition of the UN "Purple Book". It is further understood that the Purple Book refers only to the concentration limit of 0.1%. Technically, with the exception of the tracking powder, the concentrations of coumatetralyl in the RACUMIN® product do not meet the criteria for classification of the rodenticide products according to the Purple Book. However, the decision to apply for derogation is motivated by the strict classification according the ECHA specific concentration limit.

4 Environmental fate and behaviour

4.1 Coumatetralyl in air

Coumatetralyl in solution is not considered volatile and is not expected to partition into the atmosphere to a significant extent (Danish CA 2009 and German CA 2018), due to:

- Low vapour pressure less than 1×10^{-3} Pa (20°C).
- Henry's law constant less than 6.64×10^{-2} $Pa.m^3.mol^{-1}$

Coumatetralyl is expected to rapidly photolyse and photodegrade, with a DT_{50} of approximately 2 to 7 hours, depending on the estimation method (Danish Ca 2009 and German CA 2018).

4.2 Coumatetralyl in water

Coumatetralyl is moderately soluble in water, depending on the pH (Danish CA 2009 and Lewis et al. 2016). Values at 20°C increase with increasing pH:

- At pH 5: 4.78×10^{-3} g/l.
- At pH 7: 4.60×10^{-1} g/l.
- At pH 9: 4.65 g/l.

Coumatetralyl is hydrolytically stable at pH 4 to 9, but is rapidly photodegradable, with a half-life (DT_{50}) of 8.6 hours to 3.6 days, depending on the available light intensity, e.g., summer versus winter (German CA 2018). It is not readily biodegradable in water (Danish CA 2009).

The log of the octanol/water partition coefficient (log K_{ow}) at 20°C is listed as:

- 1.5 “under neutral conditions”, but ranges from -0.1 at pH 9 to 3.4 at pH 5 (German CA 2018).
- 3.46 at pH 7 (Lewis et al. 2016).

According to the German CA (2018) the log K_{ow} is below the bioaccumulative screening criterion of log K_{ow} 4.5. Fish bioconcentration factors for edible parts, viscera and whole fish are listed as 3.32, 20.8 and 11.4 respectively, reflecting a relatively low potential to bioconcentrate.

4.3 Coumatetralyl in soil

The organic carbon partition coefficient ("K_{oc}") in soil indicates the mobility of a chemical in soil, that is, the propensity of a chemical substance to bind to the organic matter present in soil. A high Koc value is associated with a strong bond to the soil particles, and thus less mobility (less likely to move, or leach, through soil). A lower Koc value indicates chemical mobility, and faster leaching rates through soil. A higher Koc can thus also indicate potential accumulation of a chemical in soil over time, under conditions of continuous addition to soil.

The K_{oc} of coumatetralyl is 301.8 litre/kg, the average value from a range of 71 to 735, obtained from screening tests with 5 soil types (Danish CA 2009, cited by the German CA 2018). The Danish CA (2009) concluded that coumatetralyl is moderately leachable in sandy soil, but that no leaching was observed in loamy sand and sandy loam. Lewis et al. (2016) considered coumatetralyl moderately mobile, based on a cited K_{oc} of 453, close to the average value reported by the German CA (2018). The potential for groundwater contamination should thus be moderate to low and the German CA (2018) calculated a soil / water partitioning coefficient, $K_{soil\text{-}water}$, of 9.054 m^3/m^3 from a mean Koc value of 295.99 litre/kg, based on a pool of values reported for different soil types.

Although not readily biodegradable, coumatetralyl is rapidly degraded in soil, with calculated DT_{50} values of 5.9 to 8.7 days at 22°C, corresponding to 13.1 to 19.4 days at 12°C (German CA 2018).

4.4 Summary

The environmental fate concerns regarding coumatetralyl are summarised in Table 4.4.1.

Table 4.4.1: Summary of environmental fate concerns for coumatetralyl.

Concern	Notes	Reference
Volatilisation	Not volatile	Danish CA (2009) and German CA (2018)
Aquatic bioconcentration/ bioaccumulation	Not considered persistent in the aquatic environment. Although stable to hydrolysis, coumatetralyl is highly susceptible to photolysis.	German CA (2018)
Groundwater contamination	Moderate to low potential	German CA (2018)
Sediment contamination	Insufficient information	Danish CA (2009) and German CA (2018)
Persistence in soil	Not persistent, is rapidly degraded in soil.	German CA (2018)
Residues of concern	Major soil metabolite is 13-hydroxycoumatetraly, no specific toxicity data provided.	German CA (2018)

5 Environmental assessment

5.1 Primary vs secondary environmental exposure

Primary exposure of non-target species, that is, direct contact with and ingestion of the rodenticide, is not expected, since the usual rodenticide label instructions are to place the bait out of reach of animals. However, the use of bait boxes is not mandatory, although regularly recommended on labels; therefore, attention is given to primary exposure and risk assessments conducted by the reviewed regulatory authorities (e.g., the Danish and German CAs, referred to below).

Secondary exposure in mammals and birds of prey describes the ingestion, by natural predators in the environment, of dead or dying target animals, that is, rats or mice in the case of solid coumatetralyl formulations.

The assessment of secondary exposure where predators have access to dead or dying rodents is not trivial. One approach to the study of secondary exposures of predators requires field studies conducting detail experimental examinations, e.g., of the stomach content of predators. The experimental data are then incorporated into complex probabilistic risk assessments. However, these complex assessments do not guarantee sufficient evidence to support definitive conclusions, since important uncertainties and data gaps tend to remain.

Coumatetralyl is a first-generation anticoagulant rodenticide ("FGAR"). FGARs are referred to as 'multi-dose anticoagulants', meaning that rodents must consume several consecutive feedings of bait before a lethal dose is accumulated. Once ingested, FGARs also break down quicker than second-generation anticoagulant rodenticides. Therefore, the risk of secondary poisoning is less if rodents poisoned with an FGAR is ingested by predatory non-target animals (APVMA 2023).

5.2 Toxicity to non-target species

Coumatetralyl toxicity to non-target species

As can be expected of a rodenticide ingredient, coumatetralyl is very toxic to mammals; more toxic than to birds. (German CA 2018).

An LD50 value of 35 mg/kg bw is reported by the German CA (2018) for the assessment of acute primary exposure (ingestion of the bait) by mammals.

The predicted no-effect concentrations ("PNECs") used in the assessment of primary and secondary poisoning are:

- $PNEC_{oral\text{-}mammals}$ = 1.0 x 10^{-4} mg/kg bw.
- $PNEC_{oral\text{-}mammals}$ = 0.14 mg/kg food (secondary poisoning).

The avian acute toxicity LD50 of coumatetralyl is 2 000 mg/kg bw, interpreted as showing "*only a low acute avian toxicity"*, supported by the fact that mortalities were not observed in the treated groups (Danish CA 2009). The LD50 is used for the assessment of primary acute ingestion in birds (German CA 2018).

The proposed PNECs for the assessment of primary and secondary ingestion are:

- $PNEC_{oral\text{-}birds}$ = 0.0667 mg/kg bw.
- $PNEC_{oral\text{-}birds}$ = 0.667 mg/kg food (secondary poisoning).

Coumatetralyl is toxic to organisms in the aquatic compartment, as demonstrated by acute toxicity study results in fish (LC50 = 53 mg/litre), invertebrates (EC50 > 14 mg/litre) and algae (72h ErC50 > 18 mg/litre) (Danish CA 2009).

Secondary poisoning through the aquatic food chain is not assessed, because responsible product application and care, with clear product label and safety data sheet ("SDS") instructions to prevent contamination of waterways, should limit aquatic contamination to negligible.

The acute toxicity of coumatetralyl to earthworms is considered as low. The coumatetralyl LC50 calculated for exposure of the test species (*Eisenia fetida*) for up to 14 days is 225 mg/kg dw soil (Danish CA 2009), from which a $PNEC_{soil}$ of 0.2 mg/kg soil wet weight was derived (German CA 2018).

5.3 Environmental assessments by international regulatory authorities

Potential aquatic toxicity was not assessed by the German CA (2018), since direct emissions to surface water were assumed negligible, because of the recommended application in bait boxes or directly deep into rat holes in and around buildings. This is also applicable to the use of the products registered in South Africa, since bait box use is recommended on all labels of products assessed in this report. In the case of, e.g., the wax block applications in new plantations of young saplings, it is recommended that blocks are placed in open-ended bait stations (e.g. bamboo pipes) in rodent runways. Although not completely excluding rainwater run-off of bait residues, this recommendation does limit the risk of aquatic contamination with coumatetralyl.

The German CA (2018) conducted an assessment of the risks of groundwater contamination and did not indicate a risk for a wax block product used in and around buildings.

In the terrestrial compartment, particularly with regard to non-target animals, the Danish CA (2009) have assessed a coumatetralyl paste bait formulation and concluded that a potential risk of primary poisoning to non-target species cannot be excluded, even though the physical nature of the paste bait should cause at least birds, and possibly also some other mammals to avoid the bait. Because of the lower toxicity to birds, pointed out in Section 5.2, a lower risk to birds is expected.

The German CA (2018) concluded that non-target mammals and birds are at risk of primary poisoning if they get access to a wax block coumatetralyl formulation. If the rodenticide wax block baits are applied in bait boxes, the risk for primary poisoning can be mitigated significantly, but it may not be possible to exclude exposure of all non-target animals.

Avian and mammalian predators feeding on contaminated soil organisms such as earthworms were found not to be at risk of secondary poisoning if the assessed wax block baits are deployed. Risks of secondary poisoning via the aquatic food chain was not assessed, because aquatic food chain contamination was likely to be insignificant (German CA 2018).

Regarding secondary exposure of mammals, the German CA (2018) concluded that the death of mammals and birds which had consumed poisoned rodents cannot be excluded. The risk in mammals is higher than in birds.

6 Human health and toxicological review

6.1 Pertinent human health effects

Coumatetralyl is an FGAR, as explained previously, a first-generation repeated-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms by inhibiting vitamin K. The result of biochemical interference is an increased bleeding tendency and, eventually, haemorrhage and death. The chemical "backbone" involved in the toxic effect is 4-hydroxycoumarin, which is common to some of the most common rodenticides, such as brodifacoum, bromadiolone, coumatetralyl, coumafuryl, and difenacoum (Murphy and Lugo 2015).

According to the 2022 Annual Report of the American Association of Poison Control Centers ("AAPCC"), more than 3 000 anticoagulant rodenticide ingestion incidents were reported in the

United States; approximately half of these in children younger than 6 (cited by Isackson and Irizarry 2024). Similar data are not available for South Africa, but the US data show that incident numbers can be significant.

Detailed recent data are not easily accessible, but the Office of Chemical Safety and Pollution Prevention of the USEPA (2022a) has performed an updated analysis of exposure incidents reported to both the USA Incident Data System ("IDS") and the AAPCC. Reviewing AAPCC data, a 46% decline in child rodenticide exposures was found from 2011 to 2017. In the IDS, FGAR incidents had increased by 81% from 2009 to 2018, but in the AAPCC, FGAR incidents had decreased over time from 337 incidents in 2004 to 187 incidents in 2017 (55% decrease). The increase in FGAR incidents was noted only in the IDS, and incident counts were low, namely 52 in the IDS in 2018.

Considering occupational exposure incidents, 21 were reported to the NIOSH SENSOR-Pesticides database from 2011 to 2015, 9 to the Californian database from 2012 to 2016, and 2 in the IDS (2015 to 2019). Overall, the USEPA (2022a) found a low frequency of 21 occupational incidents from 2011 to 2015, for all types of anticoagulant rodenticides, of which 15 cases involved zinc phosphide. Of the 21 occupational cases, 1 case was high in severity, 5 cases were moderate in severity, and 15 cases were low in severity. Ten cases sought care in an ER or hospital; and 11 cases contacted poison control for treatment and guidance (all 11 cases that contacted poison control were low in severity).

The health effect most frequently reported by the occupational cases was nausea, followed by altered taste (metallic or chemical taste), vomiting, upper respiratory pain/irritation, and shortness of breath. These symptoms are relevant to acute (single) exposure incidents. The severity statistics and the nature of the observed health effects demonstrate that proper training of pesticide applicators and the use of personal protective equipment are effective management tools limiting occupational exposure risks.

Similarly updated European incident data were not provided by the German CA (2018), but the Danish CA (2009) reported the following medical data derived from accidents with rodenticides registered in the "Medical Department" (no further identification provided) for a production period of more than 20 years up to the year 2002. Germany was the source of 35 complaints/adverse incidents with products containing coumatetralyl, of which 17 were requests for information: 7 attempted suicides, and 2 alleged wilful poisoning attempts.

Accidental ingestion of a maximum of 40 g of product was reported in 8 cases, without any symptoms. Two further symptomatic accidental cases were reported: oral absorption of two teaspoons of "Racumin Plus" by an adult showed a slight coagulation inhibition and a child having ingested an unknown amount required vitamin K1 therapy. No sequelae were observed in these cases. Unfortunately, the coumatetralyl content of the product was not specified.

Contact with eyes or skin had occurred in another 7 cases, either by accident or by lack of personal protective equipment (e.g., distributing a coumatetralyl powder formulation with bare hands). Symptoms were reported in 5 cases: 3 of short-term nausea, 1 of swelling and itching of the hands after washing, and 1 case of eye irritation. The irritation effect was regarded as definitely due to the product, the skin reaction as possibly caused by coumatetralyl powder contact, and the nausea as most probably a secondary reaction to the fear of being poisoned (Danish CA 2009).

According to current knowledge, coumatetralyl has no endocrine disrupting properties (Danish CA 2009 and German CA 2018).

6.2 Routes of absorption

Oral absorption

The Danish CA (2009) and the German CA (2018) adopted a coumatetralyl oral absorption factor of 75% for the risk assessment of a paste bait, and this is applied to other solid bait formulations as well.

Dermal absorption

The German CA (2018) reported the following values:

- 100% as a default value.
- 1.14% determined from in vivo and in vitro studies on a 0.375 mg coumatetralyl / g paste (0.038%) formulation. The value is also used for absorption from the RACUMIN ® wax blocks and tracking powder assessed in this report.

Inhalation

Coumatetralyl in solid preparations has a very low volatilisation potential. Due to its physico-chemical properties (low vapour pressure of less than 0.001 Pa at 20°C and low Henry's law constant of less than 0.0664 $Pa.m^3.mol^{-1}$) (Section 4.1), coumatetralyl is not expected to be present in the atmosphere in significant quantities when applied in solid form. The potential for inhalation exposure is thus low, but if inhalation exposure should take place, e.g., to dusts, a default absorption value of 100% is assumed (German CA 2018).

6.3 Toxicological studies

Metabolism (in mammals) is rapid and the main metabolite of coumatetralyl is 13-hydroxy-coumatetralyl, accounting for up to 27% of the applied dose. There is no evidence indicating that the metabolite is more toxic than the parent compound (Danish CA 2009).

The German CA (2013) reported the following acute oral toxicity information from a rat study in which the test formulation was a 0.0375 % coumatetralyl paste bait. The coumatetralyl content is equal to the registered South African paste baits assessed in this report.

- No mortality, no clinical signs of toxicity at 300 mg/kg bw of the test formulation.
- Mortality in 2/3 animals at 2 000 mg/kg bw of the test fomulation, within 24 hours of treatment.
- The "*oral LD50 of the test formulation was about 1 000 mg/kg bw"* (German CA 2018).

The Danish CA (2009) had calculated and reported the following LD50 values for coumatetralyl:

- Rat LD50 oral, in fasted animals:
  - Male rats: 30 mg/kg bw
  - Female rats: 15 mg/kg bw
- Rat LD50 dermal:
  - Male rats: 100 < LD50< 500 mg/kg bw
  - Female rats: 258 mg/kg bw
- Rat LC50 inhalation:
  - Male rats: approximately 0.063 mg.litre^{-1}(4 hours)$^{-1}$
  - Female rats: approximately 0.039 mg.litre^{-1}(4 hours)$^{-1}$

Short-term (28-days) teratogenicity was studied with rats and rabbits. The NOAELs from these studies are:

- Rat NOAELs:
  - 0.14 mg/kg-day for embryo- and/or fetotoxicity.
  - 0.035 mg/kg-day for maternal toxicity (LOAEL = 0.070 mg/kg-day).
- Rabbit NOAELs:
  - 0.025 mg/kg-day for embryo- and/or fetotoxicity (LOAEL = 0.05 mg/kg-day).
  - 0.0125 mg/kg-day for maternal toxicity (LOAEL = 0.025 mg/kg-day).

The Danish CA (2009) cited an unpublished repeated dose (subchronic 16-week feeding) study in the rat. The critical effect of coumatetralyl, as observed in other toxicological studies, is on blood coagulation. Reported observations are haemorrhage and prolonged blood clotting time. The oral NOAELs are:

- 0.0068 mg/kg-day (females).
- 0.0083 mg/kg-day (males).

Reproductive and developmental toxicity

The decision by the European authorities to classify coumatetralyl as a developmental hazard (H360D) needs some background discussion. The following information from unpublished studies are obtained from the Danish CA (2009).

A multigeneration study was not required, based on the high risk of death by haemorrhage from the natural events of reproduction and parturition, nullifying the study objective in any case, and based on the absence of potential long-term exposure of the public population. Teratogenicity studies were conducted in the rat and rabbit, and no effects on the developing foetus were seen in either species.

Although the developmental studies with coumatetralyl in rat and rabbit failed to indicate developmental toxicity, the compound is structurally and mechanistically analogue to the human developmental toxicant warfarin, which is also an anticoagulant anti-vitamin K ("AVK") substance. EU experts unanimously agreed that AVK rodenticides should collectively be regarded as teratogens (Danish CA 2009) and this stance had not changed at the time of the German CA (2018) assessment.

Neurotoxicity, genotoxicity and carcinogenicity

Neurotoxic effects were not observed in any of the unpublished acute or subchronic laboratory animal tests (Danish CA 2009) and were not reported in the German CA (2018).

In vitro genotoxicity tests were negative, and thus coumatetralyl is unlikely to be genotoxic (Danish CA 2009). It was considered unlikely that coumatetralyl is carcinogenic, based on the lack of

mutagenic/genotoxic effects and the absence of any other effects that may lead to non-genotoxic carcinogenesis. Furthermore, carcinogenic effects have not been reported in humans on long-term warfarin administration of (a coumarin compound as is coumatetralyl). Lastly, according to current epidemiological models, the manifestation of carcinogenic effects is dependent on repeated long-term exposure, which is not relevant to rodenticide use patterns.

7 Approaches to rodenticide health risk management

7.1 USEPA human health risk management strategy

Coumatetralyl is not a registered rodenticide in the USA, but the USEPA overall risk management strategy is to limit potential non-target exposures. This strategy is followed because the available hazard and toxicity profile for the rodenticides informed the pivotal conclusion that *any* potential exposure may result in adverse effects and potential risks of concern; therefore, quantitative risk assessments are not required or conducted. Rather, the USEPA determined that labelled uses of these products should be modified, as needed, to assure that occupational and non-occupational dermal and inhalation exposures are limited as far as possible. The occupational mitigation measures most recommended are the use of suitable PPE.

7.2 The European Union approach to human health risk management

7.2.1 Rodenticide users and use phases

The Danish CA (2009) and the German CA (2018) based the human health risk assessments on the 2007 version of the EU Technical Notes for Guidance ("TNsG"), originally described in ECB (2004). The German CA (2018) based the primary exposure scenarios on an exposure study already submitted for coumatetralyl, but re-evaluated taking into consideration the Biocides Human Health Exposure Methodology (ECHA 2015) and the 2007 version of the TNsG on Human Exposure (ECB 2007). The TNsG provides indicative exposure values for a range of generic exposure scenarios discussed in the TNsG, amongst these for European Union ("EU") Product Type 14: Rodenticides.

The TNsG assumes a general rule that rodenticides are formulated, sold (packaged) and applied (placed) in such a way that humans and non-target animals should not be exposed. Bait stations where the rodenticide is to be placed should protect people and non-target animals from exposure and the use of bait boxes is usually recommend. In case bait boxes are not practical, the bait station must be covered in order to prevent access by non-target animals and unaware bystanders.

Rodenticide users

The TNsG (ECB 2007) distinguishes two main types of users, namely:

- Users in contact with the biocidal product as a consequence of their professional life. In this assessment of products registered in South Africa, "professional" users are viewed as occupationally exposed PCOs:
    - Industrial users: involved in manufacturing, handling and/or packaging of actives or products in industry. These are not applicable to the health risk assessments presented in this report.

- Professional users: those using end-products outside industry. In South Africa, the term PCO is applicable and PCOs are required to be registered in South Africa. PCOs are relevant to the health risk assessments presented in this report.
- Professional users are sometimes assessed according to sub-categories of "trained" and "untrained" professionals. An example of an "untrained" professional would be a person managing orchards or plantations where rodenticides are used to protect young saplings from rodents stripping the bark. In the case of untrained professional users, at least a basic knowledge of the associated hazards, PPE use and the interpretation and implementation of safety instructions on product labels and SDSs is assumed.

- Non-professional users (consumers): "*member of the general public who may primarily be exposed to biocides by using a consumer product"* (ECB 2007). In the case of the rodenticides assessed in this report, the "*consumer product*" referred to is a rodenticide product accessible to lay persons, sold in shops where the product is accessible to the general public.
  - According to the TnsG the consumer is "*unlikely to take informed measures to control exposure and to follow exactly the instructions for using the biocidal product*".
  - The non-professional use pattern is expected to involve a lower frequency and/or duration of use.

Rodenticide use phases

The TNsG (ECB 2007) distinguishes the following phases, based on handler use patterns:

- Application,
- Use, and
- Disposal phases.

The TNsG (ECB 2007) phase descriptions are:

Application phase:

- Transfer of bait from the product packaging to the bait station. The place where the bait is dispensed ("placed") is referred to as the bait station.
- Several bait station constructs are possible, such as merely hiding the rodenticide under a cover, to prevent or at least diminish contact after placing, or placing the rodenticide in a pipe, long enough to prevent bait contact by scavenger or predatory non-target animals, or application of the solid bait in a secure, tamper-proof bait box. More elaborate enclosed bait boxes, which have holes for the rodents to enter, are available.
- Bait boxes/stations should be placed in such a way that bystanders, such as children, and non-target animals, cannot reach the bait. However, contamination of the surroundings with rodenticide from spillage caused by the rodents, or due to the rodents' contaminated urine, faeces and carcasses, is possible.
- The most prominent handler exposure scenarios, based on formulation use patterns, are:
  - Placing of bait boxes.
  - Loading of bait boxes or bait stations with grain bait, bait pellets or wax blocks/rounds/wedges from larger containers.
  - Securing large paraffin blocks at bait stations in sewers.
  - Applying bait by hand.

Use phase (after application):

- This is the baiting period, when the biocidal product is available for consumption by the target organism.

- Rodenticides are usually confined to areas with a minimum of human access. The TNsG assumes that bait-boxes in private and industrial areas are “locked off” to prevent contact, but this assumption is not applied in the risk assessment of products registered in South Africa, and is not applicable to the application of powder formulations.
- The largest number of bystanders are exposed in this phase, e.g., unaware workers, adults and children in the vicinity, usually accidentally or by curiosity. Bystander exposure includes possible contact of the general public, or unaware workers, with dead rodents or spilled bait, assessed mainly as part of the disposal (clean-up) phase.
- Human exposure could be by accidental touching (dermal contact) and, in the case of children, by transient mouthing or chewing of bait.

Disposal (clean-up) phase:
- Final inspection of rat holes, bait points, drain and sewerage, as professionals decide when to stop the local campaign, and are assumed to remove/clean the bait stations, which may result in exposure.
- Normally, the same person applies the rodenticide, disposes of empty packaging, collects residues and dead rodents, and empties containers for disposal.

7.2.2 Solid rodenticide application practices and exposure variables

Exposure terminology

Primary and secondary exposure scenarios are distinguished in the TNsG (ECB 2007):
- Primary exposure “*occurs to the individual who actively uses the biocidal products, i.e. the user*”. The user may be a professional at work or a non-professional, that is, a consumer (see previous definitions of professionals and non-professionals).
- Secondary exposure “*may occur after the actual use or application of the biocidal product”*. The TNsG further differentiates between professional user secondary exposure as:
    - *Intentional secondary* exposure, that is, any secondary exposure incurred during a worker’s regular employment duties, e.g., a carpenter exposed to wood dust impregnated with a biocide.
    - *Incidental secondary* exposure scenarios not necessarily incurred during employment but resulting from the professional use of a biocide, e.g., home laundering of contaminated work clothes.
    - The ECB (2007) concluded that, in most instances, secondary exposure scenarios are best assessed using the methodology for non-professional users (consumers).

Intentional secondary exposure, as defined above, is not applicable to rodenticides, because the rodenticides are not applied to consumer products, or to surfaces to which persons (occupational or the general public) might subsequently be exposed.

While reviewing the human health risk assessments of EU competent authorities, it was apparent that the term “secondary exposure” was generally applied to bystanders in accidental contact with rodenticides, principally during the use- and disposal phases (see definitions below). Such accidental contact should, in any case, also account for the incidental secondary dermal exposure to contaminated clothing being laundered, because of the conservative (high-end) accidental exposure values that are used (see the exposure values descriptions provided below). The term “secondary exposure” is applied accordingly in this solid rodenticide human health risk assessment report, meaning accidental contact of adult or child bystanders with the product.

Secondary exposure also includes inappropriate contact with dead rodents or left-over bait, e.g., a bystander cleaning up dead rodents or left-over or spilled bait, dragged away from the bait station by rodents. Secondary exposure of bystanders is assessed and the risks are reported numerically, or relative to the primary exposures and risks of PCOs.

Application practices

The TNsG (ECB 2007) assumes a general rule that rodenticides are formulated, sold (packaged) and applied (placed) in such a way that humans and non-target animals should not be exposed. Bait stations where the rodenticides are to be placed should protect people and non-target animals from exposure. Nevertheless, the TNsG considers primary exposure to the rodenticide applicator. This is relevant to the solid formulations assessed in this report.

The TNsG (ECB 2007) describes the use of bait stations, including bait boxes (box-like bait stations) for solid rodenticide products as follows:

- These boxes/stations, especially when tamper-proof, are used to prevent human contact with the rodenticide.
- Several application methods are available, such as merely hiding the rodenticide under a cover, to prevent or at least diminish contact after placing, or placing the rodenticide in a pipe, long enough to prevent contact with the bait. More elaborate enclosed bait boxes, which have holes for the rodents to enter, are available.
- Boxes/stations should be placed in such a way that bystanders, such as children, and non-target animals, cannot reach the bait. However, contamination of the bait boxes' surroundings with rodenticide from spillage caused by the rodents, or due to the rodents' contaminated urine, faeces and carcasses, is possible.

Paste baits are not specifically described, but application practices are assumed similar to that for wax blocks and treated products, with some variations described in more detail in Section 8.1.1.

Wax bait wedges, rounds or blocks

- Wax bait wedges, rounds or blocks are usually placed in bait boxes.

Contact powders

- Contact powders (tracking powders) may be used indoors and outdoors.
- Rodents pick up the powder on their feet; the powder is subsequently consumed during grooming.
- The concentration of rodenticide in contact powders is usually much larger than in other edible solid baits.
- The treated areas should be covered, to prevent bystander and non-target animal exposure.

Exposure variables

In the case of solid rodenticides, the product "as supplied" is applied during the application and use phase. The use exposure variables are thus similar. A smaller mass of rodenticide might be applied during the use phase, but, for ease of presentation in this report, exposure and risks during the application and use phases are assumed similar. Risks indicated for the "application phase" are thus also valid for the "use phase", although it might, in an unknown proportion of cases, slightly overestimate exposure during the "use phase". This is of little practical importance, because the rodenticide label instructions do not prescribe the application of different masses during the use phase.

Some disposal phase activities, such as cleaning up and disposing of spilled bait and dead rodents, might also be applicable during the use phase, but are not considered separately in the "use" phase. The conservative disposal phase exposure variables are viewed as sufficiently representative of exposure during clean-up and disposal activities in the use phase.

The TNsG summarises exposure data gathered largely in the Nordic countries. The amounts and frequencies of exposure provided in the tables are according to the formulated products for which data were collected in the Nordic countries and might not be directly applicable to the South African products. Substantiated product- and scenario-specific data are preferred, e.g., from South African suppliers, but the TNsG exposure data may be used when actual measured data are not available.

TNsG application phase, "use" phase and disposal (clean-up) phase exposure variables are presented in this section. The TNsG primary exposure data compiled for the application phase are summarised in Table 7.2.2.1, and that for the useApplication phase exposure variables are summarised in Table 7.2.2.1, as presented in the TNsG (ESB 2007).
phase (after the initial application, while in use) in Table 7.2.2.2. Secondary exposure assumptions for accidental contact by adults and children are presented as applicable to specific product formulations, in the relevant exposure and/or risk assessment described in Section 8.

Application phase exposure variables:
Application phase exposure variables are summarised in Table 7.2.2.1, as presented in the TNsG (ESB 2007).

Table 7.2.2.1: TNsG-based exposure variables for solid rodenticide application.

Formulation	Amount per application	Handling duration	Event frequency (per day)		Days per year	
			Normal	Worst case	Normal	Worst case
Professional applicator						
Wax blocks	250 g	5 min	4	8	55	220
Powder	250 g	10 min	2	4	55	110
Bait station placing*	40 g	As above	2 x bait stations, 4 times per year			
Non-professional applicator						
Wax blocks	20 to 40 g	<5 min	1	1	1	20
Bait station placing*	40 g	As above	2 x bait stations, 4 times per year			
*Likely of bait stations supplied with loaded bait, which is not the norm in South Africa.						

Post-application use phase exposure variables:
The duration and frequency variables (ECB 2007) are based on professionals and non-professionals, the latter assumed similar to the general public user, attending the feeding stations and replacing/adding new baits.

Table 7.2.2.2: TNsG-based exposure variables during the post-application use phase.

Formulation	Amount per application	Handling duration	Event frequency (per day)		Days per year	
			Normal	Worst case	Normal	Worst case
Professional						
Wax blocks	250 g	<5 min	$^1/_7$	1	110	220
Powder	250 g	<5 min	1	1	24	110

Formulation	Amount per application	Handling duration	Event frequency (per day)		Days per year	
			Normal	Worst case	Normal	Worst case
Non-professional						
Wax blocks	20 to 40 g	<5 min	1	1	1	20
Powder	250 g	<5 min	1	1	1	20

Disposal phase exposure variables:

- Bystander exposure includes possible contact of the general public, or unaware workers, with dead rodents or spilled bait.
- PCOs and non-professionals (general public users) are assumed to remove/clean the bait box, which may result in handling of surplus formulated product. Default exposure variables are presented for each assessed formulation in Scenario 8.
- Disposal activities include cleaning up and disposal of rodenticide dragged away from the bait station by rodents. Disposal should include handling of carcasses, which may have residues of the active substances on the skin or having bled on the floor. However, it appears that dead rats and mice often are swept up with a broom, together with other refuse (ECB 2007), implying that dermal contact might not be extensive.
- Brooming may give rise to dust containing the active substance, which may give rise to exposure by the inhalation route.

7.2.3 Toxicity values and human health risk calculations

Regulatory authorities derive limit values protecting the health of humans; that is, exposure levels or dose values that are not expected to result in adverse effects on health of the general population, including sensitive individuals and children.

Since developmental effects are the only health endpoints (aside from mortality) for which dose-response values are available in toxicological studies, there is no other choice but to base acceptable exposure levels of males and children on this health endpoint as well. Therefore, the absence of a risk to health in general, and specifically the absence of a risk to the developing foetus, is implied by a finding of “acceptable exposures or risks”.

The German CA (2018) conducted human health risk calculations using the systemic Acceptable Exposure Levels (“AELs”) for coumatetralyl set in the Assessment Report by the Danish CA (2009) (Table 7.2.3.1). The AEL is the exposure dose that is accepted as not associated with a risk to human health. Since coumatetralyl is not volatile, significant levels in air are unlikely. It follows that the most relevant modes of exposure for operators and consumers are by dermal contact or oral absorption (German CA 2018).

The subchronic exposure AEL presented in Table 7.2.3.1 is provided for the sake of completeness, but the subchronic exposure scenario is not assessed by the Danish CA (2009) or the German Ca (2018), since it is not considered applicable to the rodenticide use scenarios.

Table 7.2.3.1: Summary of coumatetralyl AELs.

*Point of departure (POD)	Uncertainty Factors	AEL	**Study and toxicological effects
Acute exposure			
NOAEL administered = 0.0125 mg/kg-day	UF_A= 10 UF_H= 10 UF_{Sev} = 3 Total UF= 300	3.1 x 10^{-5} mg/kg-day	A correction factor for limited oral absorption of 0.75 was applied to the administered NOAEL. See section 6.3 for the rabbit teratogenicity study information.
Subchronic exposure (medium term)			
NOAEL administered = 0.0083 mg/kg-day	UF_A= 10 UF_H= 10 UF_{Sev} = 3 Total UF= 300	1.7 x 10^{-5} mg/kg-day	A correction factor for limited oral absorption of 0.75 was applied to the administered NOAEL. See section 6.3 for the rat repeated dose (subchronic) study information.
Chronic exposure			
Not assessed, because repeated long-term exposure of consumers is not foreseen (German CA 2018). The potential for accumulation in the body is not high, based on results from radioactivity studies in rats, summarised by the Danish CA (2009). The site of accumulation is the liver, but the rate of excretion from the liver is not known. Seven days after a single treatment, approximately 50% of the administered radioactivity remained in the body. After repeated dosing, the retained radioactivity decreased to 18%. Further detailed information from the unpublished study is not provided.			
** Source: Danish CA (2009). *Point of Departure (POD): Data point derived from dose-response data, used to extrapolate risks associated with lower environmentally relevant human exposures. NOAEL: no-observed-adverse-effect level. LOAEL: lowest-observed-adverse-effect level. UF: uncertainty factor. UFA: extrapolation from animal to human (interspecies). UFH: potential variation in sensitivity among members of the human population (intraspecies). UF_{Sev}: additional factor for severity of effects.			

Dose calculations are done as recommended by the TNsG (ECB 2004 and ECB 2007). For this purpose, dermal absorption was assumed as presented in Section 6.2 (1.14%) and a default body weight of 60 kg. The systemic dose is expressed as a percentage of the AEL, and the risk of a health effect is deemed unacceptable if the systemic dose is approximately 100 per cent, or more, of the AEL. Detailed calculations are presented for each coumatetralyl bait formulation assessed in Section 8.

In short, based on the TNsG (ECB 2004), the systemic dose is calculated with Equation 7.2.3.1.

Systemic dose (mg/kg-day) = Systemic exposure (mg/day) / body weight (kg) Equation 7.2.3.1

Systemic exposure is calculated with simplified Equation 7.2.3.2:

Systemic exposure = Exposure per event x events per day Equation 7.2.3.2

Where:

Systemic exposure	Systemic exposure per day (mg/day).
Exposure per event	Calculated as explained in Section 8 for the different product formulation types.
Events per day	Number of events per day; that is, estimated or default number of application- or clean-up events per day.

8 Human health risk assessment of solid rodenticides containing coumatetralyl

8.1 Paste baits

8.1.1 Exposure assessment

The assessed products and scenarios

Table 3.2.2 presents the percentage by mass of coumatetralyl in each solid formulation product, showing a concentration of 0.375 g/kg (0.0375 % w/w) in the RACUMIN® paste (pasta) bait products registered in South Africa and to be assessed in this report. The Danish CA (2009) and the German CA (2018) also assessed a "racumin" paste formulation containing the exact same concentration of coumatetralyl, which is thus directly applicable to the RACUMIN® paste formulation registered in South Africa.

The German CA described the paste bait as a ready-to-use bait supplied and used as a of 10 g sachet with a "highly viscous, dough-like log in a paper sachet", used in and around buildings. The registered South African product is also supplied in a ready-to-use sachet, with a pasta content and number of sachets to be deployed per bait station are summarised in Table 8.1.1.1. The German CA (2018) treated the pasta formulation supplied in a sachet as intended for use by non-professionals. Thus, exposure of professional pest controllers was considered not applicable and associated risks were not assessed. Use by professionals only is not specified on the product labels of paste baits registered in South Africa; therefore, application by non-professionals is assumed for the South African products.

The German CA (2018) summarised the potential for human exposure to pasta baits as presented in Table 8.1.1.2, grouped by routes of exposure. The summary list of scenarios assessed by the German CA, following from the identified relevant routes of exposure, is shown in Table 8.1.1.3. These will also be assessed for the registered South African products.

Table 8.1.1.1: RACUMIN® sachet paste content, numbers of sachets applied per bait point and label-recommended PPE use.

Product	Coumatetralyl % w/w (Table 3.2.2)	Sachet pasta content (g per bag)	*Recommended dosage rate (label)	*Number of bags presented per bait point	Gloves recommended on label
RACUMIN® Paste	0.0375	20	200 g	10 (Rats) 2 (Mice)	Yes
RACUMIN® 3D Paste	0.0375	10	200 g	20 (Rats) 2 (Mice)	Yes
*Highest recommended dosage rate and highest number of sachets recommended on label.					

Table 8.1.1.2: Main paths of human exposure.

Exposure path	Professional use	General public	Via food
Inhalation	Not applicable	Not relevant	Not applicable
Dermal	Not applicable	Not relevant	Not applicable
Oral	Not applicable	Not relevant	No

Table 8.1.1.3: List of scenarios assessed by the German CA for "racumin" paste rodenticide.

Scenario	Primary or secondary exposure and scenario description	Exposed group
Application and disposal – bait box	Primary exposure - biocidal product in sachets is placed in bait boxes by an adult; max. 20 sachets per bait point, 5 bait points	Non-professional
Application and disposal – skewered on a wire	Primary exposure - biocidal product in sachets is speared on a wire by an adult; max. 20 sachets per bait point, 5 bait points	Non-professional
Mouthing	Secondary exposure - swallowing/ingestion of baits by toddlers: a) Swallowing of one bite b) Transient mouthing of a bait (e.g. with repellent)	General public

Non-professional exposure

The German CA (2018) based the primary exposure scenarios on an exposure study already submitted for coumatetralyl, but re-evaluated taking into consideration the Biocides Human Health Exposure Methodology (ECHA 2015) and the 2007 version of the TNsG on Human Exposure (ECB 2007). See description of the TNsG in Section 7.2.1.

Application and disposal – bait boxes

The German CA (2018) described the scenario as follows:

- The biocidal product is directly applied by the non-professional user, who places the bait sachets at the baiting points.
- For disposal the non-professional user collects the sachets, which might be partly eaten and damaged.
- Product mass: 10 g paste/sachet.
- Indicative exposure value for the application of sachets: 0.4917 mg paste per placed sachet.
- Indicative exposure value for the disposal of sachets: 0.1138 mg paste per disposed sachet.
- Note: the indicative exposure is the 75th percentile of paste exposure to the skin of subjects handling sachets with 10g paste/sachet, determined in an experimental exposure study.
- The dermal absorption rate of coumatetralyl from a "viscous, dough-like" paste formulation is 1.14%, experimentally determined (Section 6.2).

The values applicable to the registered South African products are:

- The assumed adult body weight is 60 kg, as for the assessment of all other rodenticide products in this report.
- The coumatetralyl content of the registered paste bait products is as presented in Table 8.1.1.1.
- PPE use is not included in the calculations, because use by non-professionals is assessed, and it is assumed that that non-professionals might not be diligent users of PPE.
- The German CA (2018) assumed 10 sachets (instructions on registered products for rat infestation) placed at an assumed 10 baiting points, that is, a total number of 100 sachets placed.
- In the case of RACUMIN® 3D, assuming 10 bait points to be loaded, it is possible that a maximum of up to 200 sachets may be placed, considering a maximum possible number of 20 bags per bait point, to achieve the total of 200 g of bait per bait point for rats (Table 8.1.1.1).

In the first round of calculations, risks are calculated for the highest possible number of sachets, with the understanding that risks associated with application of RACUMIN® paste should be lower, since fewer bags need to be placed (10 per bait point, Table 8.1.1.1), although the indicative exposure values may be slightly higher, since the bag content is 20 g of paste, not 10 g.

Systemic exposure of a non-professional for the scenario of application in a bait box, with subsequent disposal of left-over of torn sachets, is calculated according to the German CA (2018):

- $Exposure_{dermal}$ = [(indicative $exposure_{application}$ + indicative $exposure_{disposal}$) x number of sachets x coumatetralyl content x dermal absorption factor] / body weight adult
- = [(0.4917 mg + 0.1138 mg) x 200 x 0.0375% x 1.14%] / 60 kg
- = 8.63×10^{-6} mg/kg-bw

Therefore, the maximum systemic exposures of a non-professional applying and cleaning up RACUMIN® paste formulations listed in Table 8.4.1.1, according to the assessed scenario, is:
- 8.63×10^{-6} mg/kg-bw

Application and disposal – sachets skewered on a wire

The German CA (2018) described the scenario as follows:
- This scenario represents a dermal contact worst case for all paste applications, where the biocidal product has to be fixed (e.g. to avoid that they are dragged away by rodents).
- The biocidal product is applied by the non-professional user, who secures the bait sachets after spearing them on a wire.
- For disposal the non-professional user retrieves the wire and collects the sachets, which might be partly eaten and damaged.
- Product mass: 10 g paste/sachet.
- Indicative exposure value for the application of sachets: 2.5233 mg paste per placed sachet.
- Indicative exposure value for the disposal of sachets: 1.2892 mg paste per disposed sachet.
- Number of sachets placed: 100.
- This is equivalent to 20 sachets (maximum number per baiting point, according to German applicant) placed at an assumed 5 baiting points.
- This is viewed as a likely maximum for registered South African paste bait rodenticides.

The other default values for the registered South African products are as for the bait point scenario, except for the coumatetralyl content, which is according to Table 8.4.1.1.

The German CA (2018) assumed 20 sachets (instructions on registered product) placed at an assumed 5 baiting points, that is, a total number of 100 sachets placed. In the case of RACUMIN® 3D, 20 sachets are also the maximum possible number per bait point, to achieve the total of 200 g per bait point for rats (Table 8.1.1.1). Assuming 5 bait points to be loaded, the maximum number of sachets is thus also 100.

Systemic exposure of a non-professional for the scenario of application of skewered bags, with subsequent disposal of left-over of torn sachets, is calculated according to the German CA (2018):

- $Exposure_{dermal}$ = [(indicative $exposure_{application}$ + indicative $exposure_{disposal}$) x number of sachets x coumatetralyl content x dermal absorption] / body weight adult
- = [(2.5233 mg + 1.2892 mg) x 100 x 0.0375% x 1.14%] / 60 kg
- = 2.72×10^{-5} mg/kg-bw

Therefore, the maximum systemic exposures of a non-professional applying and cleaning up registered South African paste formulations listed in Table 8.4.1.1, according to the assessed scenario, is:
- 2.72×10^{-5} mg/kg-bw

Secondary exposure: mouthing by infants/toddlers
- The German CA (2018) views the ingestion and mouthing of rodenticide bait by an infant/toddler as "*an exceptional scenario, which may occur accidentally*".

- Based on the TNsG (ECB 2007) consumption of up to 5 g is assumed if no bait boxes are used and no bittering agent is added.
- The risk of oral exposure is minimised by addition of a bittering agent (as for paste products registered in South African) and by an appropriate covering of baits (e.g. by use of a bait box), which is recommended for the registered South African products.
- The minimised accidentally ingested amount is expected to be 10 mg per mouthing event, since it is likely that that the bittered bait will be spit out and not swallowed.
- Inhalation exposure is considered not relevant due to the physical-chemical properties of coumatetralyl (see Section 6.2) and considering the specific use conditions (paste formulation to be placed out of reach of children and uniformed persons).
- The German CA (2018) accepts that the potential dermal exposure of toddlers/infants is covered by the oral exposure assessment.
- The default body weight of an infant/toddler is 10 kg.

The other default values for the registered South African products are:
- The adopted oral absorption rate of coumatetralyl is 75% (Section 6.2).
- The coumatetralyl content of the registered paste bait products is as presented in Table 3.2.2.
- A bittering agent is included in the products registered in South Africa; therefore, transient mouthing with ingestion of 10 mg per mouthing event is assumed.

Systemic exposure of an infant/toddler for the scenario of accidental ingestion by transient mouthing is calculated according to the German CA (2018) method:
- $Exposure_{oral}$ = Ingested amount x coumatetralyl content x oral absorption / body weight
- = (10 mg x 0.0375% x 75%] / 10 kg
- = 2.81×10^{-4} mg/kg-bw

Professional exposure

Based on informal queries to local rodenticide suppliers, it appears that pasta baits are not frequently used by professional pest control operators (“PCOs”). Therefore, it is assumed that the bait use of PCOs is similar to that of non-professionals (maximum of 200 sachets placed on one day) and that risks of professionals would be as for non-professionals.

8.1.2 Paste products risk assessment

The risk calculations are conducted by comparing the calculated coumatetralyl exposure doses (Section 8.1.1) to the acute AEL (Table 7.2.3.1) of 3.1×10^{-5} mg/kg-day. The calculation of risks is summarised in Table 8.1.2.1. Exposure doses less than 100 per cent of the AEL are considered acceptable.

Exposure and risk calculations are based on PPE use premises as indicated. It was considered that gloves may be mandated without inconvenience to non-professional users, and were included in the calculations. A dermal protection factor for gloves was not specifically provided by the Danish CA (2009) or the German CA (2018), but it appears to be more than the 95% protection often assumed for gloves. The RACUMIN® 3D calculations are done assuming 5% of the unprotected exposure if gloves are worn.

It is unlikely that exposure to RACUMIN® paste would exceed that of RACUMIN® 3D under the recommended application rates presented in Table 8.1.1.1; therefore, the risks shown for RACUMIN® 3D are also applied to RACUMIN® paste. Acceptable risks are calculated for non-professionals applying and disposing of sachets placed in a bait box, or skewered (“spiked”),

regardless of whether gloves are worn or not. As expected, risks are lower when gloves are used (Table 8.1.2.1).

The risk assessment for non-professionals demonstrates that the exposure of professional PCOs, expected to wear gloves, and applying the same amount of bait as assumed for non-professionals, would not experience unacceptable risks to health. Wearing gloves also protects against possible secondary exposure while handling dead rodents.

For secondary exposure, an unacceptable risk is identified for children accidentally mouthing baits with 0.0375% coumatetralyl. According to the German CA (2018) assessment, specific risk mitigation measures are required to prevent exposure to children. The mitigation measures for paste baits are not different from other bait forms and are discussed in the Discussion Section (Section 9). Any noted contact of a child with paste bait, or with any other type of rodenticide, should be brought to the immediate attention of a medical professional, without exception.

Table 8.1.2.1: Coumatetralyl paste bait health risks of non-professionals and infants/toddlers.

Route of exposure	Exposure dose (mg/kg-day)		Risk = (Dose/AEL) % AEL_{acute} (mg/kg-day) = 3.1×10^{-5}		
	Dermal (all adult)	Oral (infant/toddler)	Dermal	Oral	Acceptable Yes/No
Primary exposure, without PPE					
Application and disposal – bait box	8.63×10^{-6}	-	28%	-	Yes
Application and disposal – sachets skewered on a wire	2.72×10^{-5}	-	88%	-	Yes
Primary exposure, with gloves. Gloves are assumed to afford 95% dermal protection.					
Application and disposal – bait box	4.31×10^{-7}	-	1%	-	Yes
Application and disposal – sachets skewered on a wire	1.36×10^{-6}	-	4%	-	Yes
Secondary exposure					
Accidental mouthing by infants/toddlers	-	2.81×10^{-4}	-	907%	No

With regard to indirect (secondary exposure) to paste baits in use, a health risk related to adults in contact with dead rodents, due to paste residues on fur is considered of low relevance. Rather, gloves are recommended when handling dead rodents, in order to prevent contact with rodent-borne diseases; therefore, exposure to paste bait residues on rodent fur is considered negligible.

In conclusion, considering primary exposure during the application of RACUMIN® paste and RACUMIN® 3D paste, with or without gloves, are not associated with unacceptable health risks, whether used by professionals or non-professionals. This does not sanction product use or clean-up without gloves, and recommendations to wear gloves should remain on labels.

8.2 Wax blocks

8.2.1 Exposure assessment

Primary exposure of users occurs during the intended use of the wax blocks, described as follows: "*a highly active multi-feed, weatherproof bait to control Norway rats, roof rats and house mouse in normal in-premise locations, including garden, home and animal dwellings, factories, warehouses, storage premises, industrial areas, food establishments and newly established plantations. For the control of gerbils in public health environments and agricultural plantations*".

Table 3.2.2 presents the percentage by mass of coumatetralyl in each solid formulation product, showing the coumatetralyl content in the blocks/wax products is 0.375 g/kg (0.0375 % w/w).

The primary exposure calculations for professional users are presented in Table 8.2.1.1. The assessment parameters are as follows:

- Default exposure values were from the Technical Notes for Guidance (ECB 2007) on Human exposure to Biocidal Product Type 14: Rodenticides.
- Additionally, guidance from the Human Exposure Expert Group ("HEEG") of the EC Joint Research Centre Institute for Health and Consumer Protection was used (HEEG 2012). The HEEG provides guidelines towards a harmonised approach to biocide exposure assessment for industry and competent authorities including the number of manipulations in the assessment of anticoagulant rodenticides applicable to professional pesticide applicators.
- Calculations were adjusted to conservative assumptions of daily usage e.g. daily number of manipulations/handlings (including application and post application tasks) and product-specific information on amount of bait to be used per bait point.
- The HEEG (2012) professional applicators' daily bait handling frequency was used, numbering per operator per day:
    - 60 manipulations for application
    - 15 for handling baits during clean-up.
    - The primary exposure calculations for professional users are presented in Table 8.2.1.1. Are assumed not to use wax blocks on a daily basis.
    - The skin is the main exposure route and professional users are assumed to wear protective gloves.
- A default body weight of 60 kg for an adult, which is lower than the default of 70 kg often used (e.g., by the USEPA (2011)). The lower body weight results in a conservative (higher) dose estimate, and thus a higher risk estimate.
- Dermal absorption value of 1.14% (Section 6.2) is used.
- The skin is the main exposure route. Inhalation exposure is not expected (HEEG 2012). Primary oral exposure of pest control operatives is not expected, since good hygiene measures are routinely recommended on SDSs, e.g., washing before eating or smoking.

The primary exposure calculations for non-professional users are presented in Table 8.2.1.2. The assessment parameters are as follows:

- Default exposure values were from the Technical Notes for Guidance (ECB 2007) on Human exposure to Biocidal Product Type 14: Rodenticides, which provides values specific to non-professionals.
- Although the HEEG (2012) focused on professional use of rodenticides only, default exposure values that are equally applicable to non-professional users were occasionally used.

- Calculations were adjusted to conservative assumptions of daily usage e.g. daily number of manipulations/handlings (including application and post application tasks) and product-specific information on amount of bait to be used per bait point.
- Non-professionals:
  - Are assumed not to use wax blocks on a daily basis.
  - Numbers of wax blocks placed per baiting point (Table 8.2.1.2) are according to the product label, and the TNsG (ECB 2007) assumption of 2 bait points placed by a non-professional is used.
  - The skin is the main exposure route. Inhalation exposure is not expected (HEEG 2012). Primary oral exposure is not expected, since precautionary hygiene measures are presented on the label, e.g., "*wash with soap and water immediately after accidental skin contact*", etc.
  - Non-professional users are assumed not to diligently wear protective gloves. However, since label precautions include using gloves, this possibility is included in the calculations.
- A default body weight of 60 kg for an adult, which is lower than the default of 70 kg often used (e.g., by the USEPA (2011)). The lower body weight results in a conservative (higher) dose estimate, and thus a higher risk estimate.
- Dermal absorption value of 1.14% (Section 6.2) is used.
- The skin is the main exposure route.

Exposure and risk calculations are based on PPE use premises as indicated in the tables. A dermal protection factor for gloves was not specifically provided by the Danish CA (2009) or the German CA (2018), but the TNsG (ECB 2007) default penetration factor of 10% (90% protection) was used.

Secondary exposure of an adult occurs when adults accidentally touch wax blocks, or clean up wax block debris without knowing that it contains a hazardous rodenticide. It is assumed that dermal exposure will not be more than calculated for a non-professional intentionally applying or cleaning up the product. Thus, risks associated with non-professional use is an adequate estimate, and likely and overestimate, of accidental adult exposure. Calculations are not repeated.

Secondary accidental exposure of an infant is calculated, assuming that a bait box is not used and that there is a risk of the ingestion and mouthing of rodenticide bait by an infant/toddler as "*an exceptional scenario, which may occur accidentally*" (German CA 2018). The TNsG "eating child" scenario assumes one bite to be sufficient for the child or for parents to intervene and provides a "poison specialists" estimate that up to approximately 5 grams of rodenticide may be ingested in one bite (ECB 2007). As explained in the case of the paste products risk assessment (Section 8.1.2) the risk of oral exposure is minimised by addition of a bittering agent (as for the products registered in South Africa). Therefore, the German CA (2018) used the minimised accidentally ingested amount of 10 mg per mouthing event, since it is likely that that the bittered bait will be spit out and not swallowed. Calculations for the "minimised accidentally ingested" scenario according to the German CA (2018) method for paste baits are also applicable to the coumatetralyl wax blocks presented in Table 8.2.1.3. Since the German CA (2018) accepted that the potential dermal exposure of toddlers/infants is covered by the oral exposure assessment, a separate dermal assessment is not necessary.

Table 8.2.1.1: Coumatetralyl wax block professionals' exposure assessment.

Scenario and exposure variable description	Dermal exposure
Default values	**PCOs and forest keepers (plantations)**
Concentration of coumatetralyl in product	0.0375%
Body weight (kg)	60
Dermal absorption rate of coumatetralyl	1.14%
Wax block loading scenario (mixing phase not applicable to wax blocks)	
*Number of bait blocks / bait point	5 blocks, see table notes
Block mass of RACUMIN ®	8.5 g (supplier information)
Dermal product loading / bait point	11.81 mg product for 5 blocks, see table notes
Number of bait points loaded / day	60 (HEEG 2012)
Total product exposure (dermal) (PCOs and plantation keepers)	11.81 mg product x 60 = 708.7 mg
Cumatetralyl exposure/day (dermal)	0.266 mg/day
Coumatetralyl absorbed/day (dermal)	3.03×10^{-3} mg/day
Systemic dose (no gloves)	5.05×10^{-5} mg/kg-bw
Systemic dose (gloves, 10% penetration)	5.05×10^{-6} mg/kg-bw
Clean-up scenario	
Number of bait points cleaned up / day	15
Exposure to product / cleaning (default)	**5.7 mg/box cleaned (HEEG 2012)
Total product exposure (dermal)	85.5 mg/day
Coumatetralyl exposure/day (dermal)	0.032 mg/day
Coumatetralyl absorbed/day (dermal)	3.66×10^{-4} mg/day
Systemic dose (no gloves)	6.09×10^{-6} mg/kg-bw
Systemic dose (gloves, 10% penetration)	6.09×10^{-7} mg/kg-bw

*** Number of product contacts / bait point** (according to label, maximum per target pest):

- Rats: 5 blocks/bait station, 5 m apart; 5 is also the harmonised default number of blocks provided in HEEG (2012).
- House mice: 2 blocks/bait station; 5 metres apart.
- Rodents in new plantation: 1 block every second tree, every row (assumed 60 blocks placed at 60 trees on one day).
- Gerbils: 8 blocks per baiting point (secure bait station), space baiting points 10 to 15m apart, depending on severity of infestations.
- Number used for calculations: the likely maximum number of blocks is equated to that for rats (5 per station or bait box), which should be the more common application compared to gerbils.

Exposure to product / loading contact per bait point:
The HEEG (2012) default block mass is 20 g, and the empirically determined indicative dermal exposure is 27.79 mg product for 5 blocks with a total mass of 100 g.
The RACUMIN® block mass is 8.5 g. Thus, the total product mass per bait point is 8.5 g x 5 blocks = 42.5 g.
The extrapolated indicative dermal exposure from 5 RACUMIN® wax blocks is thus:
(42.5 g / 100 g) x 27.79 mg product = 11.81 mg product.

**** The number of disposed blocks per bait box** are not considered for the clean-up phase (HEEG 2012).

Calculations:
Product (wax block) exposure/day = mg product/bait point x bait point loadings/day.
Coumatetralyl exposure/day = 0.0375% (coumatetralyl w/w) x total product exposure/day.
Coumatetralyl absorbed/day = 1.14% (dermal absorption factor) x total coumatetralyl exposure/day.

Table 8.2.1.2: Coumatetralyl wax block non-professionals' exposure assessment.

Scenario and exposure variable description	Dermal exposure
Default values	**Non-professionals**
Concentration of coumatetralyl in product	0.0375%
Body weight (kg)	60
Dermal absorption rate of coumatetralyl	1.14%
Wax block loading scenario (mixing phase not applicable to wax blocks)	
*Number of bait blocks / bait point	5 blocks, see table notes
Block mass of RACUMIN ®	8.5 g (supplier information
Dermal product loading / bait point	11.81 mg product for 5 blocks, see table notes
Number of bait points loaded / day	2 (ECB 2007, non-professionals)
Total product exposure (dermal)	11.81 mg product x 2 = 23.62 mg
Cumatetralyl exposure/day (dermal)	0.009 mg/day
Coumatetralyl absorbed/day (dermal)	1.01×10^{-4} mg/day
Systemic dose (no gloves)	1.68×10^{-6} mg/kg-bw
Systemic dose (gloves, 10% penetration)	1.68×10^{-7} mg/kg-bw
Cleaning scenario	
Number of bait points cleaned up / day	2 (equal to loaded points)
Exposure to product / cleaning (default)	**5.7 mg/box cleaned (HEEG 2012; 5 blocks per box according to label, also for non-professionals)
Total product exposure (dermal)	11.4 mg/day
Coumatetralyl exposure/day (dermal)	0.004 mg/day
Coumatetralyl absorbed/day (dermal)	4.87×10^{-5} mg/day
Systemic dose (no gloves)	8.12×10^{-7} mg/kg-bw
Systemic dose (gloves, 10% penetration)	8.12×10^{-8} mg/kg-bw

* Number of product contacts / bait point (according to label, maximum per target pest):
- Rats: 5 blocks/bait station, 5 m apart, the harmonised default number provided in HEEG (2012) is also 5 blocks.
- House mice: 2 blocks/bait station; 5 metres apart.
- Rodents in new plantation: not applicable to non-professionals.
- Gerbils: 8 blocks per baiting point (secure bait station), space baiting points 10 to 15m apart, depending on severity of infestations.
- Number used for calculations: the likely maximum number of blocks is equated to that for rats (5/box or bait point), which should be the more common application compared to gerbils.

** The number of disposed blocks per bait box are not considered for this phase (HEEG 2012).

Product (wax block) exposure/day = mg product/contact x contacts x loadings/day.
Coumatetralyl exposure/day = 0.0375% (coumatetralyl w/w) x total product exposure/day.
Coumatetralyl absorbed/day = 1.14% (dermal absorption factor) x total coumatetralyl exposure/day.

Table 8.2.1.3: Coumatetralyl wax block infants secondary exposure assessment.

Scenario and exposure variable description	Oral exposure
Default values	**Infants/toddlers**
Concentration of coumatetralyl in product	0.0375%
Body weight (kg)	10 (German CA 2018)
Oral absorption rate of coumatetralyl	75% (Section 6.2)
Wax block minimised accidental ingestion	
$Exposure_{oral}$ = Ingested amount x coumatetralyl content x oral absorption / body weight = (10 mg x 0.0375% x 75%] / 10 kg = 2.81 x 10^{-4} mg/kg-bw	

8.2.2 Wax blocks risk assessment

The risk calculations are conducted by comparing the calculated coumatetralyl exposure doses (Section 8.2.1) to the acute AEL (Table 7.2.3.1) of 3.1 x 10^{-5} mg/kg-day. Exposure doses less than 100 per cent of the AEL are considered acceptable. The calculation of risks is summarised in Table 8.2.2.1.

The risk calculations for professionals demonstrates that dermal exposure of professionals not wearing gloves would not be acceptable, particularly while placing blocks. The risk of professionals wearing gloves is acceptable. Cleaning of bait boxes are not associated with a risk to health, whether gloves are worn or not. However, this finding does not mean that gloves need not be worn while cleaning up, since gloves also protect against possible secondary exposure while handling dead rodents and against diseases carried by rodents. As recommended on the label, professionals should wear gloves at all times while handling bait, while cleaning up and while handling dead rodents.

The risk assessment for non-professionals demonstrates that exposure while applying bait and cleaning up bait stations are not associated with a risk to health, whether gloves are worn or not. However, this finding does not negate the need for gloves, because gloves also protect against possible secondary exposure while handling dead rodents and against diseases carried by rodents. As recommended on the label, non-professionals should also wear gloves at all times while handling bait, cleaning up or removing dead rodents.

In the case of secondary exposure, an unacceptable risk is identified for children accidentally mouthing or chewing on wax blocks with 0.0375% coumatetralyl. According to the German CA (2018) assessment, specific risk mitigation measures are required to prevent exposure to children and are discussed Section 9. In any case, any noted contact of a child with rodenticide bait should be brought to the immediate attention of a medical professional, without exception.

Table 8.2.2.1: Coumatetralyl wax blocks health risks of primary and secondary exposure.

Route of exposure	Dermal exposure dose (mg/kg-day) (all adult)		Risk = (Dose/AEL) % AEL_{acute} (mg/kg-day) = 3.1 x 10^{-5}			
	Professionals	Non-professionals	Professionals	Acceptable Yes/No	Non-professionals	Acceptable Yes/No
Primary exposure: application						
Without gloves	5.05 x 10^{-5}	1.68 x 10^{-6}	163%	No	5.4%	Yes
With gloves	5.05 x 10^{-6}	1.68 x 10^{-7}	16%	Yes	0.5%	Yes
Primary exposure: clean-up						
Without gloves	6.09 x 10^{-6}	8.12 x 10^{-7}	20%	Yes	2.6%	Yes
With gloves	6.09 x 10^{-7}	8.12 x 10^{-8}	2.0%	Yes	0.3%	Yes
Secondary exposure: accidental mouthing by infants/toddlers		**Oral exposure dose (mg/kg-day)**		**Risk = (Dose/AEL) %**		**Acceptable Yes/No**
		2.81 x 10^{-4}		906%		No

In summary, it is reasonable to conclude that the coumatetralyl exposures of professional and non-professional users of the wax block/wedge product assessed in this report are acceptable and without a risk to health.

With regard to indirect (secondary exposure) to wax blocks in use, a risk to infants transiently mouthing or chewing on wax blocks would be associated with a risk to health, but is not likely to occur commonly, because the taste deterrent (bittering agent) included in the formulation will cause the child to spit out any chewings. Nonetheless, preventative measures recommended on the label, such as keeping the product out of reach of children, must be adhered to.

8.3 Tracking powder

8.3.1 Exposure assessment

The ECB (2007) describes the use of contact powders (tracking powders) indoors and outdoors as follows: "*rodents pick up the powder on their feet which is then consumed during grooming*". In the case of mixing with bait, as described in Table 8.3.1.1, ingestion by the target pest is more direct. The TNsG notes that the concentration of rodenticide in contact powders is much larger than in other solid bait types, because of the small amounts of tracking powder likely consumed during grooming. This can be seen in the comparison of coumatetralyl products concentrations (Table 3.2.2).

Primary exposure of users occurs during the intended use of the tracking powder, described as follows on the product label: "*An anti-coagulant poison for control of the Norway rat, roof rat and house mouse. For use in and around human and animal dwellings, factories, warehouses, other storage premises. For control of gerbils in agricultural situations*".

The tracking powder is for sale only to PCOs. It is not available to the general public, or at retail outlets such as supermarkets, hardware stores, etc. Therefore, the primary exposure risk assessment is concerned only with PCOs, not amateurs or domestic users. However, secondary exposure of adults and children in accidental contact with the product when used in and around "human dwellings" is assessed.

Directions for use, presented on the product label, are summarised in Table 8.3.1.1.

Table 8.3.1.1: RACUMIN® tracking powder directions for use.

Pest	Dosage	Remarks
Norway rat, roof rat	Undiluted.	Powder should be sprinkled, not too thinly, in rat holes, on rat runs and around hiding places. Leave … for at least 5 days and replenish as required.
Gerbils	1 teaspoon tracking powder per active burrow.	Deploy in active gerbil burrows as follows: • Day 1: close all visible burrows. • Day 2: apply 1 teaspoon of powder in each active burrow (re-opened overnight). • Replenish regularly until burrow activity ceases
Norway rat, roof rat, or house mice	One part + 15-20 parts bait material.	• Mix one part by mass of powder with 15-20 parts of bait material, e.g., 30 g in 450-600 g bait material. • Set out in places frequented by rats. • The bait must be laid out on at least 5 successive days or as long as consumed.
Gerbils	Regular baiting: 50 g bait mixture per baiting point. Heavy infestations: up to 100 g bait mixture per baiting point.	• Bait mixture: one part (by mass) powder in 20 parts bait material, e.g., 2.5 g in 50 g bait material to make up 50 g bait mixture. • Placement: 50 g bait mixture into secure bait stations within the colony area. • Monitor regularly at maximum intervals of 3 days; replenish bait as necessary. • In severe infestations, increase to 100 g per bait station.
Suggested bait mixture: Rats: 60% crushed maize, 35% rolled oats, 5% sugar. Traces of finely cut raw bacon. Gerbils: 95% of the grain type the gerbils have been feeding on + 5% sugar.		

Primary exposure of PCOs

Primary exposure of PCOs (professionals) is assessed during the application phase and the clean-up phase. Inhalation and dermal exposure are of main interest during the application phase. With outdoor use, exposure to the product is not applicable during the clean-up phase, because the powder is usually left in the rat burrows. With indoor use, removal by sweeping with a broom may disperse dust into air, resulting in inhalation and even dermal exposures.

The routes of exposure to be included in the risk assessment are approached as described below, based on TNsG data and product-specific use scenarios.

Inhalation of powder is assessed by the ECB (2007) for the application of contact powder with a dust blower, with an estimate of 5% inhalation exposure of the applied amount. This method is not an option on the RACUMIN® label. The method relevant to RACUMIN® is application directly into the rat/mouse hole or on their runs, indoors and outdoors, or while mixing a food-based bait, when dust may be generated. The product is available only to PCOs, who are expected to be trained and aware of the hazards of product use. Furthermore, clear label precautionary instructions are given not to inhale "dust" from the product.

The default values suggested by the TNsG allows for the use of up to 1 kg (250 g/event x 4 events; Table 7.2.2.1) as worst case per day, which is a significant amount of powder. It is doubtful that this is applicable to RACUMIN® powder, considering the relatively small amounts recommended (Table 8.3.1.1). Based on information provided by the registrant company, the average daily use is estimated at 75 g product per day. Allowing for variation in usage, and aiming for a conservative estimate, the amount of 75 g x 2 = 150 g per day will be used for RACUMIN® exposure and risks calculations.

For application inside a room, the ECB (2007) assumes "*immediate and homogenous"* distribution of the entire mass of particles in a default room size of 50 m^3, without ventilation. The air

concentration of the product is then simply calculated as the airborne mass per air volume (mg/m^3). The TNsG estimate of 5% inhalation exposure of the applied amount when using a dust blower is adjusted for the RACUMIN® risk assessment to an estimated 10% of the exposure assumed for dust blowing (10% of 5% of the applied amount = 0.5% of the applied amount). Other default values (ECB 2007) are the adult inhalation rate of 1.25 m^3/hour, that is, 0.021 m^3/min, and a default airborne product exposure period of 10 min/application event (Table 7.2.2.1), which, for the purposes of the RACUMIN® risk assessment, is assumed to be the exposure time per day, during which 150 g of powder is applied or mixed with food bait. Results are presented in Table 8.3.1.2.

Table 8.3.1.2: Indoor tracking powder air concentrations during the bait application phase.

Scenario and exposure variable description	Indoor
Applied powder mass/day (RACUMIN®-specific)	150 g
Dispersion in air: powder airborne/event	0.5% of 150 g = 0.75 g/event
Dispersion in a 50 m^3 room: powder air concentration	0.75 g / 50 m^3 = 0.015 g/m^3 (15 mg/m^3)
Event duration	10 minutes (TNsG default)
Inhalation rate (adult) (TNsG default)	1.25 m^3/hour = 0.0208 m^3/min
Volume air inhaled/event	10 min x 0.0208 m^3/min = 0.208 m^3
Amount of powder inhaled/event	15 mg/m^3 x 0.208 m^3 = 3.13 mg/event

Ingestion of tracking powder

Oral exposure is possible if hands and face are not washed/cleaned after the application, e.g., via contact to food items or by smoking (ECB 2007). Residues from clothes may also be transferred to objects that may get into contact with mouth. The product label clearly states "*Wash with soap and water immediately after accidental skin contact. Do not eat, drink or smoke whilst mixing and applying or before washing hands and face*." Furthermore, the powder is supplied only to PCOs, expected to be trained and aware of product hazards. Therefore, oral exposure of professionals is not considered an important route of primary exposure, and is not included in the assessment.

Dermal exposure to tracking powder

Dermal exposure is possible from direct contact without gloves or insufficient covering of the skin during application of the dusty formulation. An estimate of the dermal exposure is suggested at 1% of the applied amount (Table 8.3.1.1), without protection (ECB 2007).

The example calculations of the TNsG includes the following default values:

- The assumed density of the powder transferred to the skin is 0.38 g/cm^3.
- It is assumed that the powder will form a layer with thickness 0.01 cm on the skin.
- 150 g powder of RACUMIN® used per day.
- The assumed exposed skin is 2 000 cm^2, being the hands and forearms of an adult.

Using the default values, the TNsG equations (Equations 8.3.1.1, 8.3.1.2 and 8.3.1.3) can be used to calculate the amount of coumatetralyl on the skin:

$$A_{der} = C_{der} \, x \, V_{appl} \, x \, 1\%$$ Equation 8.3.1.1

Where:

A_{der} =	Amount of active substance on skin (mg).
C_{der} =	Average concentration of coumatetralyl in product on skin (mg/cm^3)
V_{appl} =	Volume of applied product in contact with skin (cm^3).

Where the terms can be substituted as follows:

$$C_{der} = \frac{Q_{prod} \times 1\% \times Fc_{prod}}{V_{prod} \times D}$$ Equation 8.3.1.2

Where:

C_{der} =	Average concentration of coumatetralyl in product on skin (mg/cm^3).
Q_{prod} =	Amount of undiluted product used (mg).
1% =	Percentage of product available for contact with skin (TNsG default = 1%)
FC_{prod} =	Weight fraction of coumatetralyl in the product [(% w/w)/100)].
V_{prod} =	Volume of undiluted product (cm^3). In the case of a powder rodenticide, the product volume is calculated with an assumed product density of 0.38 g/cm^3 on the skin (ECB 2007). Given that 150 g of product is applied per event, the volume applied product = (150 g / 0.38 g/cm^3) in cm^3.
D =	Dilution factor (1, unitless – not diluted).

and

$$V_{appl} = TH_{der} \, x \, AREA_{der}$$ Equation 8.3.1.3

Where:

V_{appl} =	Volume of product in contact with skin (cm^3).
A_{der} =	Thickness of layer of product on skin (default = 0.01 cm).
$AREA_{der}$ =	Surface area of exposed skin (cm^2).

Calculations of primary dermal exposure of PCOs during the application phase, using Equations 8.3.1.1 to 8.3.1.3, are presented in Table 8.3.1.3. The dermal absorption factor of 1.14% (Section 6.2) is used for the dermal calculations.

Primary inhalation exposure calculations with Equations 7.2.3.1 and 7.2.3.2, using the coumatetralyl content (0.75% w/w) and the inhalation absorption factor of 100% (Section 6.2) are presented in Table 8.3.1.4. Inhalation exposure is also calculated assuming that respiratory protection is used, as recommended on the RACUMIN® tracking powder SDS: "*Wear respirator with a particle filter mask (protection factor 20) conforming to European Norm EN149FFP3 or EN140P3 or equivalent*." A protection factor of 20 implies that the wearer's exposure to airborne hazards will be reduced by a factor of at least 20 when the respirator is used correctly.

Table 8.3.1.3: Dermal exposure with coumatetralyl during the powder application phase.

Exposure variable	Value
Powder application phase (deposit in holes/on runs/mixing of powder)	
C_{der} **(Equation 8.3.1.2) Average concentration of coumatetralyl in product on skin**	
Q_{prod}: Amount of undiluted product used (Table 7.2.2.1)	150 g x 1 000 mg/g = 150 000 mg
Fraction of product available for dermal contact	0.01 = 1% (TNsG default)
FC_{prod}: Weight fraction of coumatetralyl in product (Table 3.2.2)	(0.75% w/w)/100 =0.0075
Density of product particles on skin (default)	0.38 g/cm^3
V_{prod}: Volume of undiluted product (cm^3) applied	150 g / 0.38 g/cm^3
D: Dilution factor (1)	1 (not diluted)
C_{der} = Average concentration of coumatetralyl in product on skin (mg/cm^3)	(150 000 mg x 0.01 x 0.0075) (150 g / 0.38 g/cm^3)
V_{appl} **(Equation 8.3.1.3) Volume of product in contact with skin**	
TH_{der}: Thickness of layer of product in contact with skin (default = 0.01 cm)	0.01 cm
$AREA_{der}$: Surface area of exposed skin (cm^2)	Unprotected skin = 2 000 cm^2 (TNsG)
V_{appl} = Volume of powder in contact with skin (cm^3)	0.01 cm x 2 000 cm^2
$A_{der} = C_{der} \times V_{appl}$ **(Equation 8.3.1.1)**	
A_{der} = Amount of coumatetralyl on skin (mg)	(150 000 mg x 0.01 x 0.0075) x 0.01 cm x 2 000 cm^2 (150 g / 0.38 g/cm^3) = 0.57 mg

Table 8.3.1.4: PCOs application phase inhalation and combined dermal and inhalation exposure.

Scenario and exposure variable description	Dermal exposure	Inhalation exposure
Powder application phase (deposit in holes/on runs/mixing of powder)		
Applied powder mass/day (Table 7.2.2.1)	150 g	150 g
Concentration of coumatetralyl in product (Table 3.2.2)	0.75% w/w	0.75% w/w
Amount of powder inhaled/event (see Table 8.3.1.2 and explanatory text)	-	3.13 mg/event
Coumatetralyl exposure/event	0.57 mg/event (Table 8.3.1.3)	3.13 mg/event x 0.75% = 0.023 mg/event
Coumatetralyl absorption rate	1.14%	100%
Coumatetralyl absorbed per event	0.57 mg/event x 1.14% = 6.5 x 10^{-5} mg/event	0.023 mg/event x 100% = 0.023 mg/event
Body weight (kg)	60	60
Coumatetralyl systemic dose without PPE (mg/kg-bw)	1.08 x 10^{-4} (no gloves)	3.91 x 10^{-4} (no PPE)
Coumatetralyl systemic dose with PPE (mg/kg-bw)	1.08 x 10^{-5} (with gloves)	*Factor 20 respiratory protection: 3.91 x 10^{-4} x 1/20 = 1.95 x 10^{-5}
Total systemic dose: dermal + inhalation (mg/kg-bw)	4.99 x 10^{-4} (without PPE)	
	3.04 x 10^{-5} (with gloves and respiratory protection)	
*Factor 20 respiratory protection implies exposure reduction by a factor of at least 20, when used correctly.		

Primary dermal and inhalation exposure during clean-up is presented in Table 8.3.1.5. Inhalation and dermal exposure are estimated at 1% of the residual amount, assuming 50% residues still present. Duration of exposure may be taken as 5 to 30 minutes during a day (ECB 2007). A default value of 10 minutes is used for the RACUMIN® risk assessment calculations.

The calculated mass of product dispersed in air during clean-up is equal to the mass calculated for the application phase (0.75 g/event, compare Table 8.3.1.5 with Table 8.3.1.2). The assumed activity periods in both phases are 10 minutes, both taking place indoors, without respiratory protection; therefore, the mass of inhaled powder will be 3.13 mg/event in both phases. It follows that the risks associated with inhalation are also equal in the application and clean-up phases.

The dermal exposure calculations for the clean-up phase are based on the same fraction of product available for dermal contact as during the application phase, that is, 1% (ECB 2007). All other exposure values for the application phase are as for the clean-up phase, except the amount of powder residue, which is 50% of that applied in the application phase. Thus, it is reasonable to conclude that the dermal dose during the clean-up phase will be 50% of the dose during the application phase, as summarised in Table 8.3.1.5.

Table 8.3.1.5: PCOs clean-up phase dermal, inhalation and combined dermal and inhalation exposure.

Scenario and exposure variable description	Dermal exposure	Inhalation exposure
Clean-up phase (cleaning using a broom, and disposal)		
Concentration of coumatetralyl in product (Table 3.2.2)	0.75% w/w	0.75% w/w
Applied powder mass/day (Table 7.2.2.1)	150 g	150 g
Assumed residues still present at clean-up	75 g (50% of the applied mass)	75 g (50% of the applied mass)
Dispersion in air: amount airborne/event	-	1.0% of 75 g = 0.75 g/event (equal to the application phase) (Table 8.3.1.2)
Mass of powder inhaled in 10-min clean-up phase is equal to 10-min application phase (Table 8.3.1.2)	-	3.13 mg/event (equal to application phase, Table 8.3.1.2)
Coumatetralyl exposure/event	50% of application phase exposure = 0.285 mg	3.13 mg/event x 0.75% = 0.023 mg/event
Coumatetralyl absorption rate	1.14%	100%
Coumatetralyl absorbed per event	0.285 mg/event x 1.14% = 3.25×10^{-5} mg/event	0.023 mg/event x 100% = 0.023 mg/event
Body weight (kg)	60	60
Coumatetralyl systemic dose without PPE (mg/kg-bw)	5.42×10^{-5} (no gloves)	3.91×10^{-4} (no PPE)
Coumatetralyl systemic dose with PPE (mg/kg-bw)	5.42×10^{-6} (with gloves)	*Factor 20 respiratory protection: $3.91 \times 10^{-4} \times 1/20 = 1.95 \times 10^{-5}$
Total systemic dose: dermal + inhalation (mg/kg-bw)	4.45×10^{-4} (without gloves)	
	2.94×10^{-5} (with PPE)	

Secondary exposure

Indirect (secondary) exposure during the use phase is assessed according to the scenarios listed in the TNsG:

- Accidental contact by persons unaware of the nature of the dust, or curious children/infants.
- Exposure may resemble the scenario of dermal contact, calculated using the basic values applicable to PCOs. Inhalation exposure is thus considered negligible.
- The most likely resemblance is to the clean-up scenario, and accidental adult exposure is thus assumed equal to that phase.

Dermal exposure of children is assessed for infants/toddlers, since the rates of exposure relative to their body size are higher for younger children compared to older children and adults. Infants and toddlers are thus more vulnerable than older children and adults and thus the most sensitive indicators of likely risks of accidental exposure. Dermal doses of infants/children are calculated with a default body weight of 10 kg, and assuming that the total hand area is available for dermal exposure, equal to the USEPA (2011) default of 0.030 m^2 (300 cm^2) for a toddler aged 1 to 2 years.

According to the calculations presented in Table 8.3.1.5, the coumatetralyl absorption per dermal exposure event of an adult during the clean-up phase is 3.25 x 10^{-5} mg/event, assuming gloves are not worn, and that the skin area available for dermal exposure is 2 000 cm^2. Scaling this absorption to that of a child, with an available skin area of 300 cm^2, the dermal coumatetralyl absorption of a child would be:

- 3.25 x 10^{-5} mg/event x (300 cm^2 / 2 000 cm^2)
- = 4.87 x 10^{-4} mg/event

Ingestion by infants/toddlers is not included as a likely route by the ECB (2007), but accidental transient hand-to-mouth contact by an infant is assumed for the RACUMIN® assessment. The amount of accidentally ingested powder is assumed to be equal to that covering the area of hands in contact with the surface containing the biocide of interest, and in subsequent contact with the mouth, usually assumed to be an area of 20 cm^2 (USEPA 2005).

According to the calculations presented in Table 8.3.1.5, the mass of coumatetralyl available on 2 000 cm^2 of skin of an adult during the clean-up phase is 0.285 mg/event, assuming gloves are not worn. Scaling this availability to that of a child, with a hand area of 20 cm^2 in contact with firstly the powder and then the mouth, the mass of coumatetralyl available for ingestion by the child would be:

- 0.285 mg/event x (20 cm^2 / 2 000 cm^2)
- = 2.85 x 10^{-3} mg/event

Given an absorption rate of 75% by ingestion (Section 6.2), the amount of coumatetralyl absorbed by ingestion is:

- 2.85 x 10^{-3} mg/event x 75%
- = 2.14 x 10^{-3} mg/event

Finally, given a default infant body weight of 10 kg, the absorbed systemic doses are calculated:

- Dermal absorption dose: 4.87 x 10^{-4} mg/event / 10 kg = 4.87 x 10^{-5} mg/kg-day.
- Oral absorption dose: 2.14 x 10^{-3} mg/event / 10 kg = 2.14 x 10^{-4} mg/kg-day.

8.3.2 Tracking powders risk assessment

The risk calculations are conducted by comparing the calculated coumatetralyl exposure doses (Section 8.3.1) to the acute AEL (Table 7.2.3.1) of 3.1 x 10^{-5} mg/kg-day. Exposure doses less than 100 per cent of the AEL are considered acceptable. The calculation of risks is summarised in Table 8.3.2.1.

Table 8.3.2.1: Coumatetralyl tracking powder health risks of primary and secondary 6exposure.

Exposure scenario	Without PPE			With PPE		
	Dose (mg/kg-day)	Risk	Acceptable Yes/No	Dose (mg/kg-day)	Risk	Acceptable Yes/No
PCOs primary exposure: application phase						
Inhalation exposure	3.91×10^{-4}	1 260	No	1.95×10^{-5}	63	Yes
Dermal exposure	1.08×10^{-4}	349	No	1.08×10^{-5}	35	Yes
Sum of inhalation and dermal exposure	4.99×10^{-4}	1 609	No	4.35×10^{-5}	98	Yes
PCOs primary exposure: clean-up phase, indoors only						
Inhalation exposure	3.91×10^{-4}	2 100	No	3.26×10^{-5}	63	Yes
Dermal exposure	5.42×10^{-5}	175	No	5.42×10^{-6}	17	Yes
Sum of inhalation and dermal exposure	4.45×10^{-4}	1 435	No	3.80×10^{-5}	80	Yes
Secondary exposure						
Adult accidental dermal exposure	5.42×10^{-5}	175	No	Not applicable		
Infants/toddlers accidental dermal exposure	4.87×10^{-5}	157	No	Not applicable		
Infants/toddlers accidental oral exposure	2.14×10^{-4}	690	No	Not applicable		
Risk = (Dose/AEL) % AEL_{acute} (mg/kg-day) = 3.1×10^{-5} (Table 7.2.3.1)						

The risk calculations for PCOs demonstrates that dermal exposure of PCOs not wearing gloves would not be acceptable, during both the application and clean-up phases. The risks of PCOs wearing gloves (and a thick-weave overall covering the forearms) are acceptable. As recommended on the label, PCOs should wear gloves at all times while handling the product, while cleaning up residual product at the end of the campaign, and while handling dead rodents. Wearing of coveralls, to exclude dermal exposure as far as possible, should also be recommended.

The calculated inhalation exposure of PCOs, assuming handling of 150 g tracking powder during a work day, is unacceptable during the application and indoor clean-up phases when respiratory protection is not worn. The calculated inhalation risks are acceptable when the recommended factor 20 respirator is used (Table 8.3.2.1).

There is some uncertainty about the true air concentrations of coumatetralyl available for inhalation during indoor- and outdoor application events. The air concentrations were calculated based on the assumption that 0.5% of the applied powder is airborne. This is unlikely to be an underestimation, since it is half the assumed airborne percentage when sweeping residual powder with a broom during the clean-up phase. Brooming is known to generate significant amounts of airborne dusts; thus, assuming that half of the dust generation during brooming is applicable to the application phase results in a likely over-estimation.

Inhalation risks with the recommended factor-20 respiratory protection are acceptable; therefore, the numerical inhalation risk numbers should be interpreted as:

- Indicative of the significance of possible health risks should rodenticide application and clean-up be conducted without care to limit dust generation, and
- illustrating the necessity of strict, diligent and correct respirator use, even while taking precautions against dust generation.

The above interpretation is already mirrored in the spirit of the precautionary measures, particular with the aim of protecting against dermal and inhalation exposure, that are recommended on the tracking powder SDS.

However, these recommendations should also be emphasised on the product label, particularly with regard to:
- Emphasis on avoiding dust generation,
- wearing factor-20 respirators, which is currently not recommended on the label,
- clear residue clean-up instructions prohibiting sweeping with a broom, and
- clear instructions on indoor residues clean-up methods not generating dust, e.g., by clean-up with a damp disposable wipe, to be discarded appropriately.

In the case of secondary exposure, unacceptable risks are identified for children and adults in accidental dermal contact with the powder, and for infants/toddlers transferring powder from hands to mouth. According to the German CA (2018) assessment of paste baits, specific risk mitigation measures are required to prevent exposure to children and these are also applicable to the tracking powder. Recommendations are discussed in Section 9.3. In any case, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception.

9 Discussion

9.1 Summary of risks associated with solid rodenticide formulations

The HHRA results presented in this report, concerning the use of RACUMIN® solid rodenticide bait formulations registered in South Africa, and identified by name in Section 1.1, are summarised for professional PCOs, non-professional rodenticide users and non-professionals in contact with dead rodents, and infants/toddlers accidentally in contact with the rodenticides.

<u>Paste bait</u>
- Acceptable risks are shown for professional PCOs and for non-professionals applying and disposing of sachets placed in a bait box, or spiked (skewered onto a wire) in the case of both RACUMIN® paste bait products.
- Handling of paste baits with and without gloves are associated with acceptable coumatetralyl exposure and risks, but gloves should be worn in any case, to protect against diseases carried by rodents.
- An unacceptable risk is shown to the health of infants/toddlers transiently mouthing bait. It is not clear that a bittering agent is included; therefore, the use of tamper-proof bait boxes should be strongly recommended on the label. In any case, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception.

<u>Wax blocks/wedges</u>
- Exposures in the expected application handling scenarios of professional PCOs wearing gloves

are associated with an acceptable risk to health. Health risks are unacceptable if gloves are not worn. Health risks are acceptable during the clean-up phase, whether gloves are worn or not.
- Non-professionals applying bait and cleaning up bait stations are not at a risk to health due to coumatetralyl exposure, whether gloves are worn or not.
- The finding of acceptable health risks, even while not wearing gloves in some scenarios, does not mean that gloves need not be worn, since gloves also protect against possible secondary exposure while handling dead rodents and against diseases carried by rodents. As recommended on the label, gloves should be used at all times while handling bait, while cleaning up and while handling dead rodents.
- An unacceptable risk is shown for infants/toddlers accidentally mouthing or chewing wax blocks.

Tracking powder

- Tracking powder rodenticides are picked up on rodents' feet and is subsequently consumed during grooming. The concentration of coumatetralyl in tracking/contact powders is thus significantly more than in the other solid bait types, because of the small amounts likely consumed by rodents. A higher risk to health is thus expected for exposed humans, due to the higher coumatetralyl concentrations.
- The powdery nature of the product also increases the likely inhalation exposure dose, because fine powdery particles are probably easily suspended in air.
- Thus, it is not surprising that calculated inhalation risks, without respirator use, are high and unacceptable. When accounting for the recommended factor-20 respiratory protection, risks are acceptable. The calculated exposure doses are likely worst-case.
- The calculated inhalation risks emphasise the need for precautions avoiding dust generation, and of wearing the recommended respiratory protection, which is currently not recommended on the label. Use of dust blowers to apply the tracking powder inside burrows must be prohibited.
- Indoor application should consider avoiding unnecessary powder application, and indoor clean-up of residual powder by sweeping with a broom must be prohibited. An indoor clean-up method not generating dust should be recommended, e.g., clean-up with a damp disposable wipe, to be discarded with used gloves.
- Health risks associated with dermal exposure are acceptable when gloves are worn, as is recommended on the label. Calculations of dermal exposure when "wearing gloves" also assumes protection of the fore-arms and other exposed skin areas. Therefore, PCOs should wear gloves at all times while handling the product, while cleaning up residual product at the end of the campaign, and while handling dead rodents. Wearing of coveralls, to exclude dermal exposure as far as possible, should also be recommended.
- Unacceptable risks are identified for children and adults in accidental dermal contact with the powder, and for infants/toddlers transferring powder from hands to mouth. Specific risk mitigation measures are required to prevent exposure to children. Measures are recommended and discussed in Section 9.3. In any case, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception.

9.2 The risks versus societal needs/benefits balance

There is no question that there is a legitimate societal need for cost-effective, relatively inexpensive rodenticides, considering the serious and potentially lethal human diseases, e.g., hantavirus, typhus and bubonic plague, that are spread by mice and rats. Furthermore, rodent plagues imply a burden of economic costs of property, food and crop damage and spoilage.

The USEPA (2022b) approached this need is an issue of environmental justice*, "the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the*

development, implementation, and enforcement of environmental laws, regulations, and policies". In particular, care is taken with low-income populations who are particularly vulnerable to mouse and rat infestations that are most common in housing for lower socio-economic populations.

Other control measures, e.g., rodent exclusion, can be recommended as an alternative to the use of poisoned bait, but can be expensive and/or time-consuming, and thus not practical, for low-income households and in multi-family dwellings. Furthermore, the USEPA (2022b) points out that "*rodent prevention methods often rely on support from the entire community and may be more difficult in communities with a higher population density or with a lower quality of services (e.g., in areas with poor waste management services)*". In these instances, rodent control measures such as mechanical trapping and use of rodenticides may have a higher benefit to these populations relative to more affluent populations.

The poorest populations may thus experience a greater degree of rodent infestations and consequently may be disproportionately overburdened by exposure to the diseases transmitted by rodents. Clearly, the poor may be most affected by severe restrictions on the use of rodenticides, and particularly of second-generation anticoagulant rodenticides, which are cost-effective and currently fairly accessible in general hardware stores and in large supermarkets. Therefore, economically and socially disadvantaged populations may be disproportionately affected by availability or use restrictions of such rodenticides. Undesirable effects would include cost increases or reduction in rodent control, with subsequent detrimental health effects.

Considering the societal need and benefit of continued access to second-generation anticoagulant rodenticides, it is more advantageous to society to rather adopt these as important tools in an integrated pest management approach to the control of rodent infestations. Therefore, in balance, while identifying risks of concern to the environment, the USEPA (2022b) "*acknowledges that there are many benefits associated with these active ingredients and supports the continued registration of these active ingredients*".

Nonetheless, the USEPA and the EC strongly argues for mitigation measures provided as clear label instructions, to ensure that use in accordance with the label directions "*will not generally cause unreasonable adverse effects on the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide*". Mitigation measures proposed by international regulating entities are presented in Section 9.3.

9.3 Proposed mitigation measures

The following are application measures as proposed by the Danish CA (2009) and the German CA (2018) to protect man, animals and the environment, with some additions by the authors of this report:

- 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 (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Tracking powder labels and the SDS must indicate that the powder is intended for sale to and use by professional PCOs only, and not for sale to or use in the domestic/amateur/non-professional market.
- The tracking powder may be applied directly in the burrows, but the preferred and recommended application method, even for the tracking powder, is in bait boxes or other special containers.
- Tracking powder must not be applied with a blower.

- Bait must be unattainable to children, pets or other non-target animals in order to minimise the risk of poisoning.
- Nonetheless, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception.
- 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.
- To reduce the risk of secondary poisoning of non-target animals, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice (if such a code is applicable).
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the products in pulsed baiting treatments.
- Remove the remaining product at the end of treatment period. Brooming of tracking powder residues is to be prohibited and specific safe clean-up measures not generating dust must be recommended for the powder product.
- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.
- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- The product information (i.e., label and/or leaflet) shall clearly show that:
    - the product should be used in adequate tamper resistant bait stations (e.g. "*use in tamper resistant bait stations*").
    - Professional users shall properly label bait stations with the following information:
        - "*do not move or open*";
        - "*contains a rodenticide*";
        - product name or Act 36 of 1947 registration number;
        - active substance(s) and
        - "*in case of incident, call a poison centre (insert national phone number)*".
- Wearing gloves while handling rodenticides must be emphasised on all labels.
- While wearing gloves, collect and properly dispose of visible carcasses of target pests or non-target animals. Place carcasses in leakproof plastic bags or other suitable containers and dispose of in the trash or dispose of according to the label disposal instructions.
- Carcasses buried on site must be buried a minimum of 45 cm below the ground surface, preferably deeper.
- All carcasses must be disposed of in a way inaccessible to wildlife, to prevent secondary poisoning of predatory animals.

10 Conclusions

In support of the application for derogation regarding the restricted use of the registered solid rodenticide products, identified as substances of concern due to the reproductive toxicant properties of the rodenticide ingredient coumatetralyl, the human health risk assessment results lead to the following conclusions:

- Adult users of RACUMIN® paste baits and wax blocks, whether professional PCOs or non-professionals, wearing gloves, are not at risk of a health effect on the development of the foetus in case of pregnant females. Since developmental effects are the only health endpoints (aside

from mortality) for which dose-response values are available in toxicological studies, there is no other choice but to base acceptable exposure levels of males and children on this health endpoint as well. Therefore, the absence of a risk to health in general, and specifically the absence of a risk to the developing foetus, is implied by a finding of “acceptable exposures or risks”.

- For some of the solid bait products, in some cases, acceptable risks are also demonstrated for adults not wearing gloves. However, this can never be used to negate the need for recommending the use of gloves on product labels. Recommending the use of gloves is a protective measure for all bait users. Gloves also protect against diseases carried and spread by rodents.

- Calculated inhalation risks of PCOs using RACUMIN® tracking powder are high if the recommended factor-20 respirators are not used, but are acceptable when respirators are used.

- The calculated tracking powder inhalation risks emphasise the need to avoid dust generation during the application and clean-up phases, and of wearing the recommended respiratory protection. It should be kept in mind that the tracking powder is not intended for the domestic/amateur/non-professional market.

- In order to protect PCOs, wearing of factor-20 respirators, which is currently recommended only on the SDS, should also be recommended on the label. Use of dust blowers to apply the tracking powder inside burrows must be prohibited. Warnings against the application of excessive amounts of the product should be provided, and indoor clean-up of residual powder by sweeping with a broom must be prohibited. An indoor clean-up method not generating dust should be recommended, e.g., clean-up with damp (not wet) disposable wipes, to be discarded with used gloves in sealed plastic bags at the end of clean-up.

- Health risks associated with dermal exposure are acceptable when gloves are worn, as is recommended on the labels. Calculations of tracking powder dermal exposure when “wearing gloves” also assumes protection of the fore-arms and other exposed skin areas. Therefore, PCOs should wear gloves at all times while handling the product, while cleaning up residual product at the end of the campaign, and while handling dead rodents. Wearing of coveralls, to exclude dermal exposure as far as possible, should also be recommended.

- Infants/toddlers chewing on solid bait products are at risk of a health effect. Transient mouthing may also result in a risk to health. However, accidental exposure of bystanders, specifically children, can be limited by clear communication of the professional pesticide applicator to such bystanders, and by following label instructions to place the bait station out of reach of children and uninformed persons.

- Regardless of the precautionary measures followed, any noted contact of a child with a rodenticide should be brought to the immediate attention of a medical professional, without exception. All product labels must clearly exhibit the contact details of a local/national poison centre.

- A risk of detrimental environmental effects cannot be excluded in the case of primary bait exposure of non-target animals, or secondary exposure of non-target animals to contaminated dead or dying pray, because of the overt toxicity of the anti-coagulant active ingredient coumatetralyl. Therefore, it is of primary importance that all possible mitigation measures recommended in Section 9.3 should be followed to limit environmental effects.

- The restricted use applied for by the suppliers of rodenticides containing coumatetralyl is according to the intended product use:
  - An anti-coagulant poison for control of the Norway rat, roof rat and house mouse. For use in and around human and animal dwellings, factories, warehouses and other storage premises. For control of gerbils in agricultural situations.
  - RACUMIN® tracking powder is for the use of professional PCOs only and should not be accessible for use or purchase by the general public, amateur or non-professional persons.
  - The other RACUMIN® coumatetralyl solid rodenticides are for use by professionals and non-professionals.

- With application of the recommended mitigation measures, accidental exposure of bystanders, children, pets and non-target animals can be effectively limited.

- The balance of societal need and benefits, versus the overt toxic nature of the product, is always to be considered regarding any regulatory decisions to limit access to rodenticides. This is particularly important to socio-economically disadvantaged communities. Such communities bear a double burden of more frequent rodent infestations, with concomitant exposure to diseases spread by rodents, possible rat-bite injuries to infants, damage to property and food spoilage and contamination, and limited resources to use other, non-poisonous solutions.

- The application for derogation of the products assessed in this report is supported, provided that recommended mitigation measures are effectively implemented.

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