# 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 Maxforce® Ant and Cockroach Bait Granules (L5658)

# A Solid Insecticide Containing Hydramethylnon, a CMR Substance of Concern (Reproductive Toxicity Hazard)

## INFOTOX Report No 003-2025 Rev 2.0




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**Internal review by: WCA van Niekerk PhD ; Environmental Toxicologist QEP (USA); Pr Sci Nat (Environmental Science)**


**29 April 2025**

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WCA van Niekerk PhD QEP (USA) Pr Sci Nat (Environmental Science)
**Managing Director**

29 April 2025

## Internal review:

WCA van Niekerk PhD QEP (USA) Pr Sci Nat (Environmental Science)

# 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

29 April 2025

# Executive Summary

This document is a risk assessment report supporting an application for derogation for the restricted use of the registered product Maxforce® Ant and Cockroach Bait, containing the active ingredient hydramethylnon, supplied to the general public.

The product is identified as a substance of concern due to classification as a reproductive hazard category 1B according to the Globally Harmonized System of Classification and Labelling of Chemicals ("GHS"). The classification is due to the active ingredient hydramethylnon, which is classified in GHS reproductive toxicity category 1B (H360) with a hazard statement indicating that the active may damage fertility or the unborn child.

**Product name, registered supplier and Act 36 of 1947 registration number:**

| Product | Act 36 of 1947 registration number | Registered manufacturer / supplier / distributer |
|---|---|---|
| Maxforce® Ant and Cockroach Bait | L5658 | 2022 Environmental Science ZA (Pty) Ltd (Envu) |

**Intended product use**:
The granular ant and cockroach bait is supplied in a shaker can, from which it is directly applied to the intended target area, for the control of ants and cockroaches. Spray application is not relevant to this product. It is intended for the outdoors control of ants, in the residential setting on lawns and turf, including golf courses, and suitable for perimeter application around buildings. It is not a product of interest to the agricultural market, and thus not applied on agricultural crops, such as vegetables, etc. For indoor control of cockroaches, the product is sprinkled directly from the shaker can into cracks and crevices where cockroaches are active.

**Human health risk assessment**
The 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 Organisation for Economic Co-operation and Development ("OECD").
- The US National Research Council ("NRC").
- The US Environmental Protection Agency ("USEPA").
- The International Programme on Chemical Safety ("IPCS") which includes contributions by the World Health Organization ("WHO") and the International Labour Organization ("ILO").

The following international regulatory documents were consulted specifically for the hydramethylnon risk assessments:

- The US Environmental Protection Agency ("USEPA") Proposed Interim Registration Review Decision of Hydramethylnon (USEPA 2019).
- The USEPA Preliminary Environmental Fate and Ecological Risk Assessment in Support of the Registration Review for Hydramethylnon (USEPA 2018a).
- The USEPA document: Hydramethylnon. Draft Human Health Risk Assessment for Registration Review (USEPA 2018b).
- The USEPA document: Hydramethylnon Occupational and Residential Exposure Assessment for Registration Review (USEPA 2018c)

The scope of the 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 hydramethylnon in Maxforce® Ant and Cockroach Bait. Male fertility effects are the only health endpoints (aside from mortality) for which dose-response values are available in toxicological studies. Thus, there is no other choice but to base acceptable exposure levels of females on this

health endpoint as well. Therefore, the absence of a risk to health in general, and specifically the absence of a risk to male fertility, is implied by a finding of "acceptable exposures or risks".

The following human exposure scenarios were identified for assessment:

- Primary exposure of occupational and residential handlers applying the granular product directly from the shaker can in which it is provided.
- Post-application (re-entry) human exposures are assessed as:
    - Dermal exposure of adults and older children cleaning living spaces where the bait had been applied.
    - Younger children and toddlers in incidental dermal and oral contact with residues applied indoors.
    - Dermal exposure of adults (occupational and residential scenario) and children involved in physical activities on the turf/lawns where the product has been applied.
    - The most important occupational re-entry activity is maintenance of golf course tees, greens and freeways.
    - Residential post-application exposure includes adults and children playing/running/sitting on treated grass, and adults and older children mowing a treated lawn.
    - Incidental hand-to-mouth exposure of infants/toddlers in contact with the applied granular product is also assessed.
    - Recreational post-application exposure and risks are assessed for adult and children playing golf on treated golf courses.

Adult pesticide handlers, whether in the occupational or residential setting, are not at risk of a health effect when applying the product according to label instructions. This was found in scenarios where handlers are assumed not to wear gloves, although the use of gloves is required on the product label. Acceptable levels of exposure without wearing gloves cannot be used to negate the need for glove use recommendations on product labels. Recommending the use of gloves is a protective measure for all pesticide users and should remain on the Maxforce® Ant and Cockroach Bait label.

The occupational post-application re-entry activity presenting the greatest opportunity for potential exposure is golf course maintenance. Golf course maintenance exposure is expected to exceed exposures (and risks) associated with other occupational maintenance activities on lawns or sods. Associated exposure without using gloves did not result in unacceptable risks.

Residential post-application activities on treated lawns, such as physical activities on lawns, and mowing of grass were assessed, as well as indoor cleaning of treated living spaces. Such activities, even on the day of application, did not entail levels of exposure associated with unacceptable risks, for adults or for children. This conclusion is also applicable to toddlers assumed to inadvertently ingest hydramethylnon residues via incidental hand-to-mouth activity.

Recreational post-application activities were assessed for children and adults playing golf on treated greens, tees and fairways, assuming that the golf course was accessed even on the day of application. The calculated levels of exposure indicated acceptable risks to health of adults and children.

**Environmental (ecological) risk assessment**

Limited environmental risks are expected if Maxforce® Ant and Cockroach Bait is deployed as intended, and if excessive application is discouraged. It is important to note that environmental risks to birds, small mammals and terrestrial invertebrates are reduced due to the behaviour of the primary target (ants and cockroaches). Granular baits are designed to be highly attractive to the target insects and granules are expected to be rapidly and extensively removed from the application site to their nests, as indicated on the Maxforce® Ant and Cockroach Bait label. Once relocated to the

nests, the bait is not available for consumption by non-target organisms and the exposure potential and risk to non-target insects or other animals is reduced.

A risk of detrimental environmental effects is indicated for aquatic non-vascular plants (algae), and for scenarios of chronic exposure to fish, aquatic and sensitive sediment-dwelling invertebrates, but acute risks are not of concern in the aquatic environment. A risk is qualitatively assumed for sensitive non-target terrestrial invertebrates, but cannot be quantitatively confirmed or refuted, because methods to assess risk to terrestrial invertebrates other than honeybees are not currently available.

A risk of detrimental environmental effects cannot be excluded in the case of chronic consumption of the bait by birds or mammals. However, since Maxforce® Ant and Cockroach Bait is mainly intended for non-agricultural use, the opportunity for exposure of birds and mammals in the residential scenario should be limited. Thus, the environmental risk in the residential setting is expected to be low.

Dietary risks to honeybees are not likely for Maxforce® Ant and Cockroach Bait, since it is mainly intended for non-agricultural use. Nonetheless, a dietary risk to honeybees cannot be excluded, because pollen and nectar may receive hydramethylnon residues from any dust generated during broadcast applications of granules. Therefore, it is important to follow product application instructions on the label and to discourage excessive application of the product.

**Risk/benefit assessment**

Hydramethylnon has broad spectrum effects on a variety of insect pests, but it is particularly effective as a bait toxin against ants and cockroaches. It has a unique mode of action compared to other available alternative ant and cockroach control products, and thus occupies a particular niche in the market.

Although potential environmental (ecological) risks were identified for terrestrial invertebrates, aquatic non-vascular plants, and chronic effects to birds, mammals, fish and aquatic invertebrates, the ecological exposure potential is expected to be low, for the following reasons:

- When applied as intended, mainly in the residential setting, a limited environmental footprint is expected.
- Outdoor broadcast application is expected to occur less than 4 times per year in residential settings. The supplier of Maxforce® Ant and Cockroach Bait has confirmed that the product is not of interest to the agricultural market.
- Granular baits are designed to be highly attractive to target insects (primarily ants and cockroaches) and granules are expected to be rapidly and extensively removed from the application site to their nests, where it is not available for consumption by non-target organisms. Thus, the exposure potential and risk to non-target insects or other animals is reduced due to the behaviour of the primary target pest.

It is concluded that potential risks are outweighed by the benefits of hydramethylnon use in ant and cockroach baits. Potential risks are mitigated by measures to ensure that hydramethylnon is used as intended.

**Restricted use applied for**

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

- For outdoor use on ants and indoor use on cockroaches.
- Ants: the bait is suitable for ant nest/mound, cracks and crevices, broadcast and perimeter treatments, directly from the shaker can in which the product is provided.
- Cockroaches: granules are sprinkled directly from the shaker can into cracks and crevices where the cockroaches are active.
- A warning “very toxic to aquatic life with long lasting effects” appears on the label.

**Mitigation measures**

The following mitigatory label and/or leaflet instructions should be included:

- Specifying the maximum number of applications and minimum retreatment intervals if not already provided – these should not exceed the expected 4 times per year residential application frequency.
- Advisory statements to emphasise proper use, such as avoiding excessive bait application.
- To reduce the potential for runoff into urban waters/sewerage systems:
    - Applications to impervious surfaces are to be avoided, e.g., broadcast application on paving and horizontal concrete surfaces.
    - Applying the ant bait to specific cracks and crevices in paving or concrete, rather than a general broadcast application, is anticipated to reduce surface runoff, particularly in urban settings.
    - Avoiding application on impervious surfaces should be recommended in conjunction with a rain advisory, that is, "avoid making applications if it is likely to rain within 24 hours of application".
    - This may be supplemented with a warning to prevent contamination of fish ponds, streams, or rivers.

Wearing of gloves

The finding of acceptable health risks, even while not wearing gloves, does not mean that gloves need not be worn. As recommended on the product label, gloves should be used while applying the bait.

Other measures

The following measures include those generally proposed by international regulatory agencies to protect man, animals and the environment:

- Where possible, prior to the application inform possible bystanders (users of the treated area and their surroundings) about the application event.
- Precautions, e.g., keeping children away from the applied product, and directions for use on the product label must be followed.

**Support for the restricted use application**

The restricted use application is supported because the health risk assessment of hydramethylnon in Maxforce® Ant and Cockroach Bait indicates that:

- A risk to health of occupational or residential handlers is not expected.
- It also does not pose a risk to those exposed after application, such as:
    - Groundskeepers or workers responsible for golf course maintenance.
    - Adults and older children mowing a treated lawn.
    - Adults and children playing or spending time in contact with a treated lawn.
    - Adults or children playing golf on a treated golf course.
    - Toddlers incidentally ingesting hydramethylnon residues through hand-to-mouth transfer.

The balance of risks versus benefits is always to be considered in connection with regulatory decisions regarding access to pesticides. It is concluded that potential environmental risks are outweighed by the benefits of hydramethylnon use in ant and cockroach baits. The environmental footprint is expected to be limited if correct application procedures are followed and potential risks are mitigated by measures proposed in this report.

In conclusion, 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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# List of Abbreviations

| | |
|---|---|
| AEL | Acceptable exposure level |
| ACR | Acute-to-chronic ratio |
| a.i. | Active ingredient |
| BCFs | Bioconcentration factors |
| 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 |
| ECETOC | European Centre for Ecotoxicology and Toxicology of Chemical's |
| ECHA | European Chemicals Agency |
| EEC | Environmental Exposure concentration |
| ErC50 | The aqueous concentration of a test substance resulting in a 50% reduction in growth rate of aquatic organisms |
| EU | European Union |
| FQPA SF | Food Quality Protection Act Safety Factor |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |
| HHRA | Human health risk assessment |
| 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 |
| LOAECs | Lowest-observed-adverse-effect concentrations |
| LOC | Level of concern |
| MOE | Margin of exposure |
| NOAELs | No-observed-adverse-effect levels |
| NOAECs | No-observed-adverse-effect concentrations |
| NRC | US National Research Council |
| OECD | Organisation for Economic Co-operation and Development |
| OPPT | USEPA Office for Pollution Prevention and Toxics |
| PCOs | Pest control operators |
| PNECs | Predicted no-effect concentrations |
| POD | Point of departure |
| PPDB | Pesticide Properties Database |
| PPE | Personal protective equipment |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RQ | Risk quotient |
| 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 Product identification

This document is a risk assessment report supporting an application for derogation for the restricted use of the registered ant and cockroach bait granule product listed below.

| **Report prepared for:** | | |
|---|---|---|
| **Name** | 2022 Environmental Science ZA (Pty) Ltd (Envu) | |
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| | E-mail address | ncumisa.madubela@envu.com |
| **Sponsor** | Envu Environmental Science U.S., LLC<br>5000 CentreGreen Way, Suite 400<br>Cary, NC 27513<br>United States | |
| **Registered product** | Maxforce® Ant and Cockroach Bait Granules. Act 36 of 1947 registration number: L5658. | |

## 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

Maxforce® Ant and Cockroach bait. 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."*

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.

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

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

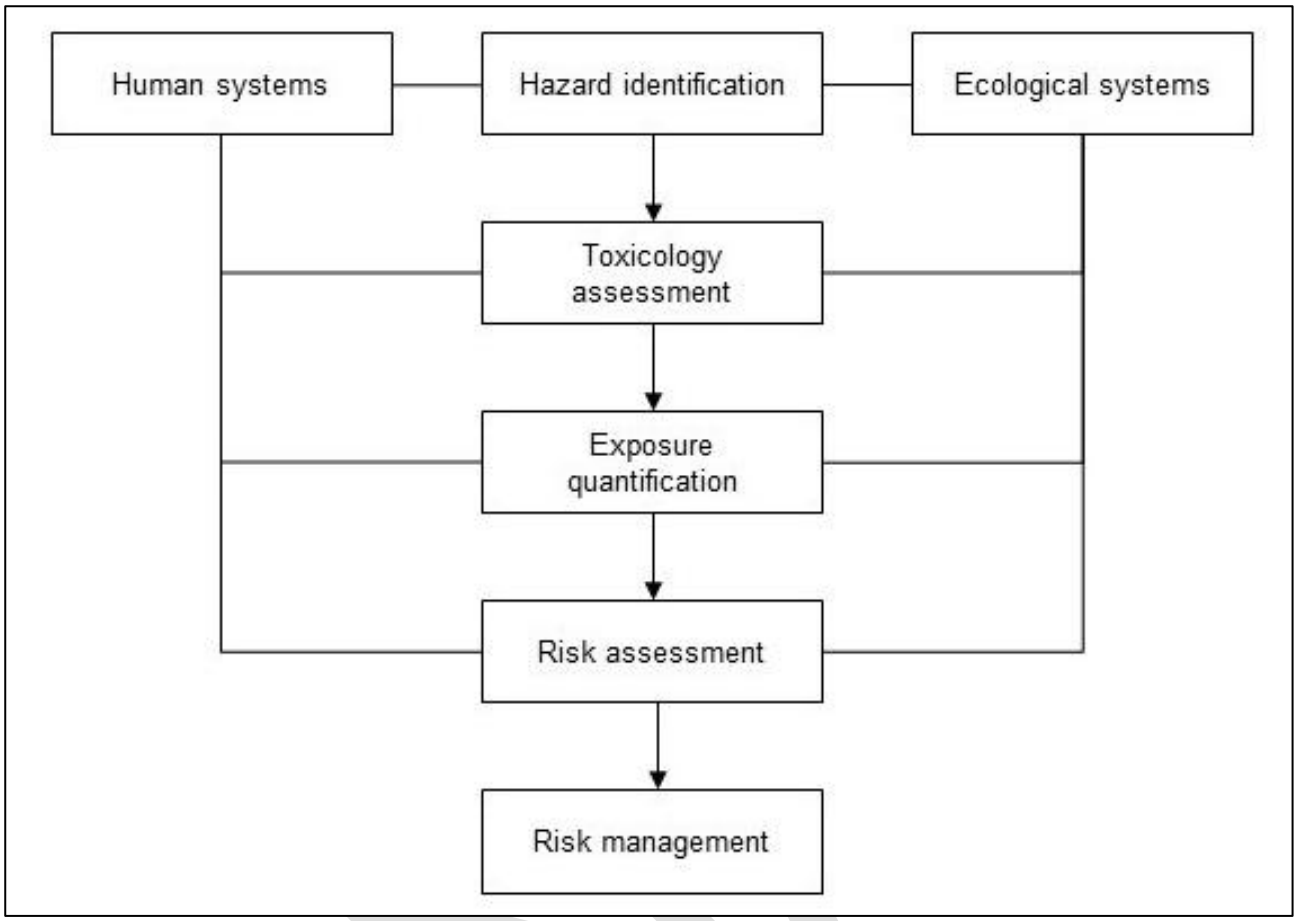



**Figure 2.1.1: The holistic health risk assessment paradigm.**

## 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:

- **Hazard assessment** is the identification of the chemical constituent of concern and the hazard it poses, in this case reproductive/developmental toxicity hazards of hydramethylnon. 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") or acceptable exposure level ("AEL"), and level of concern ("LOC") for the HHRA purposes, by applying appropriate uncertainty factors and safety factors for infants and children, referring to dose through the routes of exposure. 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. Health risks may also be assessed following the margin of exposure ("MOE") approach. The MOE approach is basically a comparison of the calculated

exposure dose and the toxicity limit value for a specific health effect, referred to as the health effect endpoint.

- The calculated MOE is compared to the LOC, also referred to as a benchmark MOE. The LOC is the margin of exposure between the calculated exposure and the POD that indicates a risk of health effects associated with the calculated exposure. Each POD is associated with a specific numerical LOC value. Therefore, if a calculated MOE is higher in value than the LOC associated with the POD used for the MOE calculation, a risk to health under the assessed exposure conditions is highly unlikely and excluded for all practical purposes. However, if the calculated MOE is lower than the associated LOC, a risk to health cannot be excluded.

- **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 focuses on the following occupational user exposure scenarios:
  - The potential oral, dermal and inhalation routes of exposure of pesticide handlers.
  - The potential oral, dermal and inhalation routes of exposure of post-application re-entry workers, e.g., golf course maintenance personnel.

  Residential exposure scenarios are also assessed, because the pesticides are also intended for the residential/domestic market:
  - Assuming that non-professionals might not be diligent users of personal protective equipment ("PPE"), the exposure of domestic/residential users handling the product without gloves, resulting in dermal exposure, is assessed.
  - The product label hazard statements advise: "*Keep out of reach children, uninformed persons and animals. Store in a cool, dry place, away from food, feedstuffs and other insecticides. Keep container closed when not in use"*.
  - Nonetheless, incidental ingestion of bait by infants/toddlers is assessed in the hand-to-mouth transfer scenario.

- **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.

## 2.3 International regulatory documents used in this report

- The US Environmental Protection Agency ("USEPA") Proposed Interim Registration Review Decision of hydramethylnon (USEPA 2019).
- The USEPA Preliminary Environmental Fate and Ecological Risk Assessment in Support of the Registration Review for Hydramethylnon (USEPA 2018a).
- The USEPA document: Hydramethylnon. Draft Human Health Risk Assessment for Registration Review (USEPA 2018b).
- The USEPA document: Hydramethylnon. Occupational and Residential Exposure Assessment for Registration Review (USEPA 2018c).

# 3 Hazard identification

## 3.1 The need for GHS classification

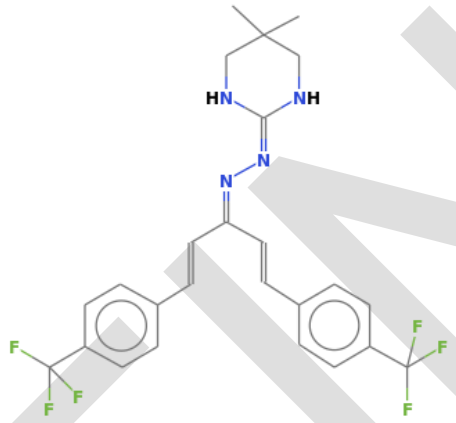
Internationally, there is a demand for safer chemicals and technologies, and it is appropriate to utilise information in the GHS as a starting point. This INFOTOX report relates specifically to active ingredients and their formulations that meet the criteria of CMR categories 1A or 1B in the GHS. Information in the GHS represents hazard data, not information on risk.

## 3.2 Hydramethylnon CMR hazard classification

**Mode of action**

Hydramethylnon is a slow-acting stomach toxicant insecticide and is the active ingredient in Maxforce® Ant and Cockroach Bait Granules. The Insecticide Resistance Action Committee classifies hydramethylnon in Mode of Action Group 20. This group acts by disrupting mitochondrial electron transport, thus interfering with energy metabolism (USEPA 2019).

**Active ingredient identification**




Hydramethylnon

**CAS # 67485-29-4**

**Mol. formula:** $C_{14}H_{13}F_3N_2O_4$

**Molecular weight:** 330.26 g/mol

**ISO common name:** Hydramethylnon

**Table 3.2.1: CMR GHS classification of hydramethylnon.**

| 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 | H360 | May damage fertility or 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 animal studies.

- 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.

Maxforce® Ant and Cockroach bait is a mixture of more than one chemical substance. None of the other constituent substances have been classified as CMR hazards. The complete composition is not provided here, in order to protect proprietary information, but has been made available to the Registrar of Act 36 of 1947, in confidence, at the time of the application for registration. The hazard classification of Maxforce® has been dealt with in the existing product registration documents.

The hydramethylnon 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) on the GHS classification of chemical mixtures containing hydramethylnon, and also the GHS as presented in the latest revised edition of the UN "Purple Book". The Purple Book concentration limit for the classification of a mixture is 0.1%, and the concentration of hydramethylnon in Maxforce® Ant and Cockroach bait is sufficient (see Table 3.2.2) to classify the product in reproductive toxicity category 1B.

**Table 3.2.2: Concentration of hydramethylnon in Maxforce® Ant and Cockroach bait.**

| g/kg | Weight % |
|---|---|
| 10 g/kg | 1.0 |

# 4 Environmental fate and behaviour

## 4.1 Hydramethylnon in air

The University of Hertfordshire Pesticide Properties DataBase ("PPDB") lists the volatility of hydramethylnon as moderate to low (Lewis et al. 2016). Therefore, hydramethylnon in solution or on the soil surface is not expected to partition into the atmosphere to a significant extent.

Relevant physical-chemical indicators predicting low to moderate volatility are:
- Vapour pressure far less than $1 \times 10^{-6}$ Pa ($2.7 \times 10^{-9}$ Pa at 20°C).
- Henry's law constant of $7.81 \times 10^{-1}$ $Pa.m^3.mol^{-1}$.

Hydramethylnon is expected to rapidly photolyse in the atmosphere (half-life = 0.14 days) (USEPA 2018a).

## 4.2 Hydramethylnon in water

Hydramethylnon is of low solubility in water, that is, 0.006 mg/litre at 20°C (Lewis et al. 2016).

The substance photodegrades with a half-life ($DT_{50}$) of 1 hour or less in water (NPIC 2002 and USEPA 2018a), while Lewis et al. (2016) lists an aqueous photolysis $DT_{50}$ of 7 days at pH 7.

The aqueous hydrolysis $DT_{50}$ at 20°C and pH 7 listed in the PPDB is 10 days, interpreted as indicating non-persistence (Lewis et al. 2016).

The log of the octanol/water partition coefficient (log $K_{ow}$) at pH 7 and 20°C is variably listed as:

- 4.44 (USEPA 2018a), and
- 2.31 (Lewis et al. 2016).

The log $K_{ow}$ values indicate a relatively propensity to solubilise in lipid-like environments as opposed to a watery environment, that is, hydramethylnon is lipophilic and hydrophobic. Hydramethylnon will thus be able to penetrate cell walls and may accumulate in the fatty deposits of exposed organisms.

Bioconcentration factors ("BCFs") in fish, found in the literature are 34 900 litre/kg (PPDB, Lewis et al. 2016) and 1 300 (unitless factor) (USEPA 2018a), both reflecting a relatively high potential to bioconcentrate.

The USEPA (2018a) lists half-lives for anaerobic aquatic metabolism from 504 days to stable and for aerobic aquatic metabolism from 4.6 d to 529 days.

Hydramethylnon is not expected to be persistent in the water compartment of the aquatic environment, but will partition to and strongly absorb to sediment (USEPA 2018a).

## 4.3 Hydramethylnon 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.

Lewis et al. (2016) presents a $K_{oc}$ range of 3 300 to 8 677 ml/g. The USEPA (2018a) describes the mobility of hydramethylnon in soil in terms of the soil adsorption coefficient ($K_d$), which indicates the amount of chemical substance adsorbed onto soil per amount of water. The $K_d$ is preferred because the coefficient of variation of the $K_d$ was lower than that of the $K_{oc}$. The reported $K_d$ values ranged from 1 039 to 1 782 ml/g soil.

Both sorption parameters indicate that hydramethylnon is not mobile in soil, that once adsorbed to soil its availability in the environment is expected to be low, that it will not easily leach through soil and is thus unlikely to contaminate groundwater (NPIC 2002, Lewis et al. 2016 and USEPA 2018a).

Plants do not absorb hydramethylnon from soil (NPIC 2002) and it is reasoned that any residues on plant surfaces typically come from direct contact during application. The USEPA (2018a) has also concluded that dissolved hydramethylnon in soil might be taken up by plants and transported into foliage, but that it is generally expected to be minor and limited. Therefore, crop uptake of hydramethylnon used in agriculatural applications was not considered as part of the human health risk assessment.

The USEPA (2018a) presents a soil half-life of 1 149 days at 25°C, probably for anaerobic soils, in which hydramethylnon is described as "stable". The National Pesticide Information Center ("NPIC") of the Oregon State University (NPIC 2002) lists a range in aerobic soil of 375 to 391 days, the USEPA (2018a) quotes a half-life of 383 days and Lewis et al. (2016) a "typical" soil degradation DT50 of 10 days at 20°C, also in aerobic soil. It is not immediately clear why the range of reported values is so wide, but different soil types and field versus experimental observations might be plausible explanations.

## 4.4 Summary

In summary, the USEPA (2019a) concluded that the major degradation and dissipation routes of hydramethylnon applied outdoors are abiotic photolysis, soil binding, and aerobic aquatic metabolism.

Hydramethylnon is stable in anaerobic soil and degrades very slowly in aerobic soil. It is immobile in soil and not expected to leach to groundwater.

The compound shows low solubility in water, is not expected to persist for long in the aquatic environment, but has a high potential for accumulating in fish tissues.

# 5 Environmental assessment

## 5.1 Summary of international assessments

The USEPA (2018a and 2019) assessed registered granular insecticides with a range of percent hydramethylnon, the active ingredient ("a.i."), of 0.036% to 1%. Since the hydramethylnon content of Maxforce® Ant and Cockroach Bait is 1% (Table 3.2.2), the environmental assessment of the USEPA is directly applicable to Maxforce® bait.

The USEPA (2019) concluded that the outdoor broadcast application of hydramethylnon granules, that is, uniform scattering of the granules on lawns and other areas, as recommended on the Maxforce® label, is expected to expose non-target organisms. Potential risk concerns were found to be limited to terrestrial invertebrates, aquatic non-vascular plants, and chronic effects to birds, mammals, fish and aquatic invertebrates. Details are presented in the following sections.

## 5.2 Hydramethylnon toxicity to terrestrial species

### 5.2.1 Hydramethylnon toxicity to terrestrial plants

The USEPA (2019) conducted a series of risk assessments from which it was concluded that there are no risks of concern for terrestrial plants. Hydramethylnon no-observed-adverse-effect-concentration ("NOAEC") values were derived for a number of agricultural crops and compared to modelled post-application hydramethylnon concentrations, based on application in such crops. Maxforce® is intended for use around the home and other buildings, and for application to lawns. The size of the product packaging (225 g) is also probably not amenable to agricultural application. Therefore, crop applications are not relevant to the assessment of environmental impacts of Maxforce®. However, considering that hydamethylnon was found not to pose a risk of decreased growth or production to monocots such as corn, oat, onion, and ryegrass (USEPA 2019a), it can be concluded that hydramethylnon will also not pose a risk to lawn gras (all grasses are monocots).

### 5.2.2 Hydramethylnon toxicity to birds

Regarding acute toxicity to birds (USEPA 2018a):

- Hydramethylnon is practically non-toxic to slightly toxic to birds, with the following single oral dose LD50s:
  - Northern Bobwhite Quail LD50 = 1 828 mg active ingredient ("a.i.")/kg-bw (slight toxicity).
  - Mallard Duck LD50 > 2 510 mg a.i./kg-bw (practically non-toxic).
  - Canary LD50 > 2000 mg a.i./kg-bw (practically non-toxic).

Short-term dietary exposure in birds indicated slight toxicity (USEPA 2018a):

- Northern Bobwhite Quail LC50 = 1 136 mg a.i /kg-diet.
- Mallard Duck LC50 = 4 355 mg a.i /kg-diet.

One generation reproduction studies (USEPA 2018a):

- Northern Bobwhite Quail:
  - NOAEC ≥ 57 mg a.i /kg diet.
  - Lowest-observed-adverse-effect-concentration ("LOAEC") > 57 mg a.i /kg-diet.
  - No treatment-related effects were observed.
- Mallard Duck:
  - NOAEC = 28.5 mg a.i /kg diet.
  - LOAEC = 57 mg a.i /kg-diet.
  - LOAEC based on an 11% reduction in body weight of 14-day old survivors.

### 5.2.3 Hydramethylnon toxicity to mammals

The following acute toxicity data for hydramethylnon are summarised from the USEPA (2018b) and the NPIC (2002):

- Oral:
  - Low in toxicity when ingested.
  - LD50 in rats ranged from 817 to 1 131 mg/kg in males and 1 300 to 1 502 mg/kg in females.
- Inhalation:
  - Very low in toxicity when inhaled by rats.
  - LC50 of 2.9 mg/litre air.
- Dermal:
  - No observed signs of toxicity after dermal exposure.
  - LD50 in rabbits exceeded the test limit of 2 000 mg/kg.

The available long-term (chronic) toxicity data for hydramethylnon summarised from the USEPA (2018b) and the NPIC (2002) are:

- 2-Generation reproduction:
  - NOAEC = 50 mg a.i./kg diet (3.3 mg a.i./kg bw).
  - LOAEC = 75 mg a.i./kg diet (5.05 mg a.i./kg diet).
  - Based on lower impregnation rates, longer precoital intervals, reduced gestation weight gain, and smaller litters.
- 3-Generation reproduction:
  - NOAEC = 50 mg a.i./kg diet (2.4 mg a.i./kg bw).
  - LOAEC = 100 mg a.i./kg diet (4.9 mg a.i./kg diet).
  - Based on male infertility.

### 5.2.4 Hydramethylnon toxicity to bees (invertebrates)

Hydramethylnon is practically non-toxic to bees, with an acute contact LD50 = 68 µg a.i./bee, measured in adult bees (USEPA 2018a).

## 5.3 Hydramethylnon toxicity to aquatic species

Toxicity to fish (USEPA 2018a):

- Hydramethylnon is moderately to very highly toxic to fish on an acute basis:
  - Channel catfish was the most sensitive species tested (96-hr LC50 = 70.7 µg a.i./litre).
  - This endpoint was used by the USEPA for environmental risk calculations.
- Hydramethylnon inhibited the growth of sheepshead minnow in an early life stage study:
  - NOAEC = 3.4 µg a.i./litre.
  - LOAEC = 7.65 µg a.i./litre.
- A chronic study is not available for freshwater fish, but a chronic NOAEC < 0.25 µg a.i./litre was extrapolated from a database of acute toxicity values (USEPA 218a).

Toxicity to aquatic invertebrates (water column species) (USEPA 2018a):

- Acute toxicity:
  - Hydramethylnon is moderately to very highly toxic on an acute basis.
  - EC50s range from >21 to 1 140 µg a.i./litre for three tested species, of which the eastern oyster was least sensitive, daphnia intermediate and mysid shrimp the most sensitive species.
  - Mysid shrimp LC50 = 55.4 µg a.i./litre, used for aquatic invertebrate risk assessment (USEPA 2018a).
- Chronic toxicity:
  - The most sensitive endpoint was reproduction (decreased numbers of young produced in treatment groups).
  - The daphnia NOAEC = 0.218 µg a.i./litre.
  - LOAEC = 0.410 µg a.i./litre.

Toxicity to aquatic invertebrates (benthic species) (USEPA 2018a):

- Effects observed after 10-day exposure were reported.
- Most sensitive species was *Chironomus dilutes*:
  - NOAEC = 50 400 µg a.i./kg OC.
  - LOAEC = 91 400 µg a.i./kg OC.
  - Based on mortality and reduced growth (dry weight).
  - The unit µg a.i./kg OC indicates normalisation of the hydramethylnon concentration in sediment according to the amount of organic carbon (“OC”) present.
- The 10-day toxicity studies suggest low to moderate toxicity, but uncertainty remains because 10-day studies do not capture potential effects on reproduction (USEPA 2018a).

Toxicity to aquatic plants (USEPA 2018a):

- Hydramethylnon inhibited the growth of non-vascular aquatic plant species (e.g., cyanobacteria and diatoms):
  - IC50s (concentration needed to inhibit growth by 50%) were 0.029 to >7.28 µg a.i./litre.
  - The two tested diatom species were the most sensitive aquatic plants.
  - Most sensitive IC50 = 0.029 µg a.i./litre (reduced biomass yield).
  - Associated IC05 = 0.012 µg a.i./litre.
  - Statistically defined NOAEC is < 0.0184 µg a.i./litre.
- Vascular aquatic plant toxicity is measured in terms of the inhibition of biomass yield:
  - Duckweed (*Lemna*), was inhibited most:
  - IC50 = 11 µg a.i./litre.
  - NOAEC = 0.22 µg a.i./litre.

## 5.4 Hydramethylnon environmental risk assessment

### 5.4.1 USEPA environmental risk assessment methods

The USEPA (2018a and 2019) used two risk assessment approaches, both based on the comparison of non-target organism exposure to the toxicity LOCs. The USEPA's risk LOC criteria are established according to the "*interpretive policy such that when acute or chronic risk LOCs are exceeded, the need for regulatory action may be considered*" (USEPA 2018a).

The USEPA risk assessment approach entails:

- The USEPA (2018a) sometimes uses imperial measurement units (e.g., lb weight), which are converted to metric units (e.g., 1 lb = 0.454 kg).
- Estimates of the number of granules that a bird or mammal would need to consume to exceed the LOC.
- Calculation of active ingredient ("a.i.") application quantities per acre according to registered uses of insecticides with hydramethylnon in the USA.
- The maximum registered single field broadcast application rate was 0.0219 lb a.i./acre for agricultural uses and 0.0176 lb a.i./acre for non-agricultural uses. The converted values are 0.025 kg/hectare for agricultural and 0.020 kg/hectare for non-agricultural uses, such as on grass and turf, on ornamental plants, and in residential and commercial areas.
- A.i. application rates were used to calculate expected environmental exposure concentrations ("EECs") due to application.
- EECs were subsequently compared to toxicity endpoints ([3]NOAELs/[4]NOAECs, [5]LOAELs, etc.) to calculate risk quotients ("RQs"); with RQ = EEC/toxicity endpoint.
- The resulting RQs are compared to LOCs.

The LOCs sometimes vary according to whether the relevant specie is "listed" or "non-listed". Listed species are either on the US Endangered Species Act ("ESA") list as threatened or endangered, or on other lists reflecting "*conservation concern*".

The LOCs are:

- Acute LOC of 0.5 for:
  - Non-listed birds and mammals.
  - Listed and non-listed fish and aquatic invertebrates.
- Acute LOC of 0.1 for:
  - Listed birds and mammals.
- Chronic LOC of 1 for:
  - Listed and non-listed birds, mammals, fish, and aquatic invertebrates.
- Terrestrial and aquatic plants: LOC of 1 for:
  - Non-listed species (based on RQ = EEC/[6]IC25).
  - Listed species (based on RQ = EEC/IC05 or EEC/NOAEC).
- For honeybees:
  - Acute LOC = 0.4.
  - Chronic LOC = 1.0.

[3] No-observed-adverse-effect level

[4] No-observed-adverse-effect concentration

[5] Lowest-observed-adverse-effect level

[6] IC25 = concentration at which 25% inhibition of growth/yield is achieved, vs. the untreated control.

## 5.4.2 Risks to terrestrial species

Terrestrial exposure estimates were not impacted by the assumed application interval of 30 days; thus, a cumulative impact is not expected (USEPA 2018a).

**Terrestrial plants**

EECs for terrestrial plants were calculated by the USEPA (2018a) based on a single hydramethylnon application. EEC calculations were based on a hydramethylnon run-off scenario. Spray drift was not considered because none of the assessed products are applied as a spray, and this is also applicable to Maxforce® Ant Bait. Exposure from applications within bait boxes was presumed negligible.

Listed plants:

- RQs were < 0.1 (less than the LOC of 1.0) for broadcast applications.

Non-listed plants:

- No risk concern for non-listed species because there were no treatment-related adverse effects in the available toxicity study and the EECs were below the NOAEC values.

Overall, the USEPA (2018a) concluded that the weight-of-evidence assessment suggested that there is no risk concern for terrestrial plants, based on the above RQs and since no adverse incidents had been reported for terrestrial plants exposed to hydramethylnon.

**Birds**

Exposure to animals (birds and mammals) was based on the consumption of granules or contaminated aquatic prey (USEPA 2018a).

Primary exposure (consumption of granules): acute exposure

Based on the acute toxicity values presented in Section 5.2, the USEPA (2018a) concluded that there is not an acute risk concern for birds consuming granules containing hydramethylnon after broadcast applications. Acute RQs calculated for the assessed products were all ≤ 0.01, that is, less than the non-listed species LOC of 0.5 and less than the listed species LOC (0.1). The calculated RQs and the associated conclusions regarding toxicity to birds are also applicable to Maxforce® Ant and Cockroach Bait, because the hydramethylnon content of Maxforce® bait (1%) is within the range of percent a.i. assessed by the USEPA. The USEPA also did not find reported environmental hydamethylnon incidents involving birds.

Primary exposure (consumption of granules): chronic exposure

Chronic risk estimates by the USEPA (2019) were based on the consumption of pesticide granules, which are presumed to be an attractive food item for birds. Overall, the weight-of-evidence suggests that the likelihood of a chronic risk concern will vary widely depending in large part on the percentage of active ingredient in the granules.

The conclusions of the USEPA (2019) were:

- A mallard duck (the most sensitive species tested) would need to consume a large quantity of about 244 to 6 769 granules (range represents different products, with 244 being applicable to Maxforce® Ant and Cockroach Bait) to exceed the chronic LOC, based on the NOAEL, and double the number of granules to exceed the LOAEL. The risk to bigger birds thus appears rather low.

- Smaller birds would need to consume fewer granules to exceed the LOC, and are thus at a greater risk of harm.
- The likelihood of a risk of concern will vary widely depending to a large extent on the amount of active ingredient.
- The potential for risk is plausible in some situations, especially considering that the bait is likely attractive to animals and may be broadcast onto the landscape.

Secondary exposure (consumption of contaminated aquatic organisms)
The USEPA (2018a) concluded that there is not a risk concern for birds that consume hydramethylnon-contaminated aquatic organisms:
- Acute RQs were all < 0.01, that is, less than the listed and non-listed species acute LOCs of 0.1 and 0.5, respectively.
- Chronic RQs were all ≤ 0.05, which are less than the listed and non-listed species chronic LOC of 1.0.

**Mammals**
Exposure to mammals was based on the consumption of granules or contaminated aquatic prey (USEPA 2018a).

Primary exposure (consumption of granules): acute exposure
There is not an acute risk concern for mammals consuming the broadcasted pesticide granules. Acute RQs calculated by the USEPA (2018a) were all ≤ 0.01 and thus lower than the non-listed species LOC of 0.5, and lower than the listed species LOC of 0.1. In addition, the USEPA did not find reported environmental incidents involving hydramethylnon and mammals.

Primary exposure (consumption of granules): chronic exposure
The USEAP (2018a) assumed that, given that the bait is designed to be attractive to insects, it is reasonable that mammals may also actively forage for the bait. Based on risk calculations, the USEPA concluded that the likelihood of a chronic risk concern will depend mostly on the percentage of active ingredient in the granules:

The conclusions of the USEPA (2019) were:
- A rat (mammalian species tested) would need to consume about 49 to 1 348 granules (range represents different products, with 49 being applicable to Maxforce® Ant and Cockroach Bait) to exceed the chronic LOC of 1.0, based on the NOAEL, and double the number to exceed the LOC based on the LOAEL.
- Baits with a higher percentage of active ingredient and higher application rates are more likely to be a potential risk concern for mammals.

Secondary exposure (consumption of contaminated aquatic organisms)
Based on risk calculations, the USEPA (2018a) concluded that there is not a risk concern for mammals that consume hydramethylnon-contaminated aquatic organisms:
- Acute RQs were all < 0.01, that is, less than the listed and non-listed species acute LOCs of 0.1 and 0.5, respectively.
- All chronic RQs were ≤ 0.2; less than the chronic LOC of 1.0 for listed and non-listed species.

**Non-target terrestrial invertebrates**
In the case of honeybees:
- The USEPA (2018a) does not expect acute contact risks if spray applications are not recommended. This is directly relevant to Maxforce® Ant and Cockroach Bait, that is also not sprayed.

- The USEPA did not find reported environmental incidents involving hydramethylnon and honeybees.
- Dietary risks to honeybees were uncertain or could not be precluded, given:
  - The lack of honeybee toxicity data.
  - The known mode of action, that is, disruption of energy metabolism by interference with mitochondrial electron transport, which implies the same effect in bees.
  - The registered use sites for the products assessed by the USEPA, which included orchards, considered bee attracting plants.

In the case of other invertebrates:
The USEPA (2018a) concluded:
- There is not currently a quantitative method to assess risk to terrestrial invertebrates other than honeybees.
- However, a risk is qualitatively assumed for sensitive non-target terrestrial invertebrates, given that hydramethylnon is toxic to ants, a member of the invertebrate family.

### 5.4.3 Risks to aquatic organisms

Exposure potential is greatest from run-off of hydramethylnon to aquatic and semi-aquatic areas following granule broadcast applications. EECs were calculated and compared to toxicity endpoints (NOAECs, LOAECs, etc.) to calculate RQs as described in Section 5.4.1. The USEPA (2018a) found only negligible differences in the EECs for single applications applied in different seasons; therefore, RQs are presented only for a single season.

**Fish**
The USEPA (2018a) concluded:
- There is not an acute risk concern for fish: all calculated acute RQs are ≤ 0.01, which are less than the listed and non-listed species acute LOCs of 0.05 and 0.5, respectively.
- There is not a chronic risk concern for estuarine/marine fish: all calculated chronic RQs were less than 0.09, and thus less than the listed and non-listed species chronic LOC of 1.0.
- There is uncertainty about the chronic risk to freshwater fish given that:
  - There is a lack of chronic toxicity data.
  - The 4 tested freshwater fish species are more sensitive in acute toxicity tests than are the tested estuarine-marine fish, which probably indicate that freshwater fish may also be more sensitive in chronic toxicity tests.
- The USEPA (2018a) conducted a qualitative assessment, which suggested that it is possible and reasonable to assume that the chronic LOC for freshwater fish would be exceeded for at least some hydramethylnon use scenarios.
- Overall, a risk concern cannot be precluded for freshwater fish given the uncertainty about chronic toxicity.

**Aquatic invertebrates**
An acute risk concern is not foreseen for aquatic invertebrates, based on the weight of the evidence (USEPA 2018a):
- All acute RQs were ≤ 0.01, which are less than the listed and non-listed species acute LOCs of 0.05 and 0.5, respectively.
- No environmental hydramethylnon incidents were reported for aquatic invertebrates.

Regarding benthic invertebrates, risks associated with sub-chronic exposure (10 days) are not indicated. All available NOAEC values (for sediment organic carbon, for pore water and for overlying

water in the water column) are much greater than respective EECs for all relevant uses, calculated by the USEPA (2018a).

There is a potential chronic risk concern for aquatic invertebrates (USEPA 2018a):

- The NOAEC-based RQs for several broadcast scenarios exceed the chronic LOC (1.0) for estuarine-marine invertebrates after a single application and also after about two to three applications.
- RQs based on the LOAEC also exceed the LOC for some scenarios after a single application.

A chronic risk concern cannot be precluded for sensitive sediment-dwelling aquatic invertebrates. Chronic toxicity data are not available for benthic invertebrates. The available 10-day toxicity studies do not suggest a risk concern, which is consistent with the lack of an acute risk concern for water column species. However, the usefulness of 10-day toxicity studies as a point of departure to extrapolate chronic risks is limited, because these studies are not carried though the reproductive stage. The USEPA (2018a) concluded that, given the reproductive effects observed in daphnia (water column species), it is reasonable to expect that benthic species may also exhibit reproductive effects as hydramethylnon is likely to partition to the sediment.

**Aquatic plants**

Vascular plants (e.g., duckweed (*Lemna*))

Based on calculated EECs and RQs, the USEPA (2018a) concluded:

- There is not a potential risk concern for aquatic vascular plants, except for listed species after about 3 or more sequential broadcast applications made every 30 days, when the calculated EEC would exceed the NOAEC (LOC > 1.0).
- The EEC would also exceed the LOAEC in a few scenarios, but only after about 6 or more sequential applications made every 30 days.

Non-vascular plants (e.g., cyanobacteria and diatoms)

- There is a potential risk concern for both listed and non-listed plants.
- The non-listed species RQs (range from 0.3 to 30) would exceed the LOC (1.0) for:
  - All broadcast scenarios with 12 applications per year (the reasonable-use-assumption).
  - Half of the scenarios at the estimated maximum single application rate of 0.0219 lb ai/acre (0.020 kg/ha).
  - Most scenarios after about two applications.
- The listed species RQs are higher, ranging from 0.6 to 70 and exceeding the LOC for most uses after a single application.

## 5.5 Maxforce® Ant and Cockroach Bait environmental assessment

The environmental risk assessment of the USEPA, presented in Section 5.4, was conducted for granular insecticides with a range of 0.036% to 1% a.i. Since the hydramethylnon content of Maxforce® Ant and Cockroach Bait is 1% (Table 3.2.2), the environmental assessment of the USEPA is directly applicable to the Maxforce® bait.

Maxforce® Ant and Cockroach Bait is not intended for the agricultural market, and it is clearly stated on the label that it is for outdoor ant control and indoor control of cockroaches. The USEPA based non-agricultural risk calculations on an application rate of 0.020 kg hydramethylnon/hectare, for use on grass, sod and turf, ornamental plants, and in residential and commercial areas. This was the

maximum application rate from the USEPA (2018a) review of products registered in the USA, and was applicable to outdoor premises, including manufacturing, processing, industrial, institutional, residential, recreational and retail areas.

Maxforce® label-recommended application rates, and rates converted to kg/hectare, are presented in Table 5.5.1, for comparison with the application rate used by the USEPA. The broadcast application rate for lawns and other areas is equal to the USEPA (2018a) value of 0.020 kg hydramethylnon/hectare.

For perimeter treatment, the hydramethylnon application rate (kg/hectare) for South African conditions was estimated as follows, based on South African housing parameters, sourced from the internet (various websites[7]):

- Average number of houses/ha = 20; given "Residential 2 (cluster housing or townhouses)" = 10 to 20 dwellings/ha; "Residential 3 (estates and larger complexes)" = 21 to 40 dwellings/ha.
- Average home circumference = 40 m, given:
  - Average-sized 3-bedroom home = 120 to 150 $m^2$; new sectional title units = 90 $m^2$.
  - Square roots of 120 $m^2$ = 11 m, of 90 $m^2$ = 9.5 m (average approximately 10 m per side of a square house).
- Maxforce® label describes width of perimeter = 0.5 m; perimeter area/house = 40 m x 0.5 m = 20 $m^2$.
- Perimeter area/ha = 20 $m^2$/house x 20 houses/ha = 400 $m^2$/ha.
- Hydramethylnon application rate = 0.06 g/$m^2$ x 400 $m^2$/ha x 0.001 kg/g = 0.024 kg/ha.

This is a very conservative residential parameter assessment, since calculations assume that all houses (per hectare) are treated, and that all houses are treated around the entire perimeter. Furthermore, the perimeter application area/ha will be significantly smaller for larger non-residential buildings. A lower application rate is reasonably possible; therefore, the USEPA estimate of 0.020 kg hydramethylnon/ha is accepted for Maxforce® Ant and Cockroach Bait applications (see Table 5.5.1).

**Table 5.5.1: Maxforce® Ant and Cockroach Bait and converted hydramethylnon outdoor application rates.**

| Application scenario | Product application rate (product label) | *Converted hydramethylnon application rate | Hydramethylnon application rate (kg/ha) |
|---|---|---|---|
| Perimeter treatment (around buildings) | 6 g/$m^2$ | 0.06 g/$m^2$ | 0.024 kg/ha (see notes in text) |
| Broadcast application (lawns and other areas) | 20 g/100 $m^2$ | 0.20 g/100 $m^2$ | 0.020 kg/ha |
| Accepted for South African conditions (see notes in text) | | | 0.020 kg/ha |
| Ant nests: spot treatment | 30 g around nest | 0.30 g around nest | 0.0003 kg/nest |
| *Hydramethylnon content of Maxforce® Ant and Cockroach Bait is 1% (w/w). | | | |

The USEPA application rate for non-agricultural use is accepted as applicable to Maxforce® bait granules and the hydramethylnon content of the granules (1% w/w) is the upper end of the range

[7] Businesstech Staff Writer, 3 Aug 2017. The size of your home in South Africa is shrinking: here's why. https://businesstech.co.za/news/trending/190002/the-size-of-your-home-in-south-africa-is-shrinking-heres-why/ Property24, 14 Jun 2024. How do zoning laws impact property use and value. https://www.property24.com/articles/advice/home-owners

assessed by the USEPA (2018a and 2019). Therefore, it is reasonable to extrapolate the following findings of the USEPA assessment to Maxforce® Ant and Cockroach Bait granules:

Regarding terrestrial organisms:

- No risk concern for terrestrial plants.
- No acute risk concern for birds consuming granules after broadcast applications.
- A potential risk associated with chronic exposure of birds is plausible in some situations.
- No risk concern (acute or chronic) for birds that consume hydramethylnon-contaminated aquatic organisms.
- No acute risk concern for mammals consuming the broadcasted pesticide granules.
- A potential risk associated with chronic exposure of mammals is plausible in some situations.
- No risk concern (acute or chronic) for mammals that consume hydramethylnon-contaminated aquatic organisms.
- No contact risks to bees, since spray applications are not applicable.
- Dietary risks to honeybees are not likely for Maxforce® Ant and Cockroach Bait, since it is mainly intended for non-agricultural use (perimeter applications around homes and on lawns, according to the label). It is not intended primarily for the agricultural market, where application might be to flowering crops, and thus a direct dietary hazard to bees.
- Nonetheless, a dietary risk to honeybees cannot be excluded, because pollen and nectar may receive hydramethylnon residues from any dust generated during broadcast applications of granules; however, the extent of this exposure pathway is highly uncertain (USEPA 2018a).
- A risk is qualitatively assumed for sensitive non-target terrestrial invertebrates, but cannot be quantitatively confirmed or refuted, because methods to assess risk to terrestrial invertebrates other than honeybees are not currently available.

Regarding aquatic organisms:

- No acute risk concern for fish.
- No chronic risk concern for estuarine/marine fish.
- Concern cannot be precluded for chronically exposed freshwater fish.
- No acute risk concern for aquatic and benthic invertebrates.
- A potential risk concern exists for chronic exposure of aquatic invertebrates.
- Concern cannot be precluded for chronically exposed sensitive sediment-dwelling aquatic invertebrates.
- Not a potential risk for aquatic vascular plants.
- A potential risk concern exists for non-vascular aquatic plants.

In conclusion, environmental risks cannot be excluded for:

- Birds and mammals chronically exposed to the bait.
- Honeybees and sensitive non-target terrestrial invertebrates (acute and chronic exposure).
- Chronically exposed freshwater fish, aquatic invertebrates, sensitive sediment-dwelling aquatic invertebrates and non-vascular aquatic plants.

It must be noted that calculations are based on an assumed 12 applications of granules at a 30-day interval. These assumptions might represent the worst-case for Maxforce® Ant and Cockroach Bait, but are nonetheless relevant for plausible application scenarios, such as lawns, sod and turf.

# 6 Human health and toxicological review

## 6.1 Toxicological studies

In acute lethality studies, technical hydramethylnon (a crystalline solid) is of low toxicity via the oral, dermal, and inhalation routes. It is moderately irritating to the eye, not irritating to the skin, and is not a dermal sensitiser (USEPA 2018b).

The primary target of toxicity is the male reproductive system (USEPA 2018b):

- Effects to the testes occurred after subchronic and chronic oral exposure in rats, mice, and dogs.
- Noted effects were primarily decreased testicular weight, testicular atrophy (wasting away or reduction in size of the testis) and testicular degeneration.
- These effects occurred at similar doses for all species and durations (5.0 to 6.93 mg/kg-day).
- In the rat two-generation reproductive toxicity study, the following were observed:
    - At the parental/reproductive LOAEL of 3.32 mg/kg/-day: testicular degeneration and the absence of sperm generation in the testes.
    - The NOAEL for testicular effects was 1.66 mg/kg-day.
    - At 5.05 mg/kg-day, the highest dose tested: smaller litter sizes and decreased male reproduction performance.

No evidence of female reproductive effects was observed in the rat and rabbit developmental toxicity studies or the rat two-generation reproductive toxicity study, except late-term abortions in the rabbit at the mid-dose (10 mg/kg-day) (USEPA 2018b). The toxicological implications are uncertain, since the effect was not observed at the higher dose, excluding a dose-related response, implying that the observed effect is not necessarily a valid toxicological endpoint useful for health risk calculations.

Regarding developmental toxicity (USEPA 2018b):

- All developmental effects were observed in the presence of comparably severe maternal toxicity, which resulted in the conclusion that there is no actual evidence of increased foetal susceptibility in the rat and rabbit developmental toxicity and rat reproduction studies.
- Observed effects (at maternal toxicity levels) are:
    - Decreased mean foetal weights in the rat and rabbit developmental toxicity studies.
    - Developmental effects observed in rats included increased incidence of rudimentary structures and incompletely ossified supraoccipital bones. These bones form the most posterior part of the skull base.
- There were no offspring effects in the two-generation reproduction toxicity study in rats.

Other effects commonly observed at the LOAELs in subchronic and chronic studies in rats and dogs were changes in clinical chemistry parameters, decreased body weights, and other clinical signs, including nasal mucus, soft stools and weakness/wasting of the body across all species and exposure durations (USEPA 2018b).

## 6.2 Pertinent health effects

Neurotoxicity is not indicated (USEPA 2018b). Clear descriptions of health effects in humans are lacking, due to the absence of occupational studies or medical reports on the effects of hydramethylnon on humans (NPIC 2002) but it appears that general symptoms such as nausea and vomiting are possible. Hydramethylnon is under consideration for endocrine disruption, but is not yet conclusively classified, since the required battery of tests has not yet been completed (USEPA 2019).

Hydramethylnon has not been classified as carcinogenic by the World Health Organization ("WHO") International Agency for Research on Cancer ("IARC" online). The USEPA Office of Pesticide Programs has classified hydramethylnon as a Group C Possible Human Carcinogen, indicating limited evidence of carcinogenicity in animals in the absence of human data (USEPA 2023). Due to the limited evidence, a carcinogenicity hazard classification according to the GHS (see Section 3.2) is not justified.

Skin and eye corrosion/irritation, summarised from the USEPA (2018b) and the NPIC (2002):

- No skin irritation observed in rabbits and guinea pigs.
- Not a skin sensitizer in guinea pigs.
- Caused transient eye irritation in rabbits.

Acute and subchronic neurotoxicity studies, subchronic inhalation toxicity and immunotoxicity studies for hydramethylnon were not available for review by the USEPA (2018b).

## 6.3 Hydramethylnon health incident data

The USEPA (2019) studied pesticide incident data on hydramethylnon (not necessarily ingestion, and not necessarily resulting in death) in the USEPA Office of Pesticide Programs ("OPP") incident Data System ("IDS") and the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health Sentinel Event Notification System for Occupational Risk-Pesticides ("SENSOR"-Pesticides) databases.

Cases reported in the OPP IDS between 1 January 2013 and 8 January 2018 are:

- 11 cases reported to Main IDS, of which:
  - 9 involved only the active ingredient hydramethylnon:
    - 1 of major severity.
    - 8 of moderate severity.
  - 2 involved multiple active ingredients.
- 86 cases reported to Aggregate IDS, classified as minor severity.

A query of SENSOR-Pesticides from 1998 to 2014 identified a total of 36 cases:

- Most cases (78%) were residential exposures to ant and cockroach bait.
- 1 case was high in severity
- 6 cases were moderate in severity:
  - 2 were intentional ingestions.
- 29 cases were low in severity.

Similar data are not available for South Africa, but the USEPA data show that incident numbers can be described as low to moderate, with the majority of cases being of low or minor severity.

## 6.4 Routes of absorption

**Oral absorption and subsequent excretion**

The USEPA (2018b) studied the absorption, distribution, metabolism, and elimination ("ADME") of radio-activity marked hydramethylnon following a single low and high dose as well as repeated low dose oral exposure in rats and reported:

- Most radioactivity (85 to 98% of the administered dose) was eliminated in the faeces by 36 hours post dosing, while minimal quantities were recovered in the urine (1 to 2%) and less than 10% was retained in the treated animal.

- Most of the radiolabeled material recovered in the faeces (94-99%) was unchanged hydramethylnon (not metabolised or biotransformed).
- Less than 10 % of the administered dose was retained in the body of the treated test animal; of the retained 10%, most accumulated in the carcass and least in the blood.
- The elimination percentages and -times suggest that hydramethylnon taken in by the oral route was mostly not systemically absorbed, but directly excreted.
- The relative contributions of urinary or faecal elimination were not influenced by the size of the dose.

No detectable residues were found in either the tissue or milk of:
- Goats fed hydramethylnon at 0.2 mg/kg for 8 days.
- Cattle fed hydramethylnon at 0.05 mg/kg for 21 days (NPIC 2002).

The above ADME information indicates that very little of hydramethynon taken in by the oral route will remain in the body. Therefore, repeated oral exposure at 30-day intervals (the usual application-interval for ant and cockroach bait) is unlikely to cause significant accumulation of hydramethylnon in the body.

**Dermal absorption**

A dermal absorption study on technical (solid crystalline) hydramethylnon was not available to the USEPA (2018a), but in vivo (living animal) studies with gel formulations indicated less than 1% absorption after 10 hours. Therefore, a dermal absorption factor of 1% is used by the USEPA for human health risk calculations.

**Inhalation**

The USEPA (2018b) assumed that toxicity from inhalation would be equivalent to oral toxicity. The default inhalation absorption factor assumed by the USEPA is 100%, in the absence of a route-specific inhalation study.

## 6.5 Toxicity values for risk assessment

The USEPA (2018b) concluded that the primary target of toxicity for hydramethylnon is the reproductive system:
- Effects to the testes occurred after subchronic and chronic oral exposure in rats, mice and dogs, at similar doses for all species and durations (5.0 to 6.93 mg/kg-day).
- No evidence of developmental toxicity in rat and rabbit studies.
- Foetal and offspring effects were observed only in the presence of maternal toxicity.

The NOAEL of 1.66 mg/kg-day, based on testicular effects in the two-generation reproductive toxicity study in rats (see Section 6.1) was identified by the USEPA (2018b) as the most suitable POD for the development of toxicity values for human health risk assessment calculations (Table 6.5.1). The oral point of departure was selected for the dermal and inhalation risk assessments, in the absence of acceptable dermal or inhalation toxicity studies.

The LOC for all subpopulations is an MOE of 100, based on combined uncertainty factors of 10 for interspecies extrapolation and 10 for intra-species variability (Table 6.5.1).

Non-occupational health risk assessments take account of the vulnerability of children and infants, and of potential dietary exposure through the ingestion of treated crops (not crops treated with the pesticide product of interest, but with other pesticide products containing hydramethylnon). This is

achieved for by incorporating a required Food Quality Protection Act Safety Factor ("FQPA SF"), an additional margin of safety applied in human health risk assessments by the USEPA to account for potential harm to infants and children from pesticide residues in food.

The default FQPA SF is 10, but the USEPA (2018b) reduced the default to 1 for hydramethylnon, based on the following considerations, with reference to toxicity presented in Section 6.1:

- The completeness of the toxicity database including adequate studies to assess the potential pre- and post-natal susceptibility in the young.
- The absence of quantitative or qualitative susceptibility in the rat or rabbit core guideline developmental or reproduction toxicity studies.
- The absence of adverse developmental/offspring effects observed in the rat two-generation reproduction study.
- The POD selected for risk assessment is protective of all other effects observed in the toxicology data base.
- No neurotoxicity was observed in the database, and neurotoxicity studies, including a developmental neurotoxicity study are not required.
- Chronic dietary risks associated with hydramethylnon residues in food and drinking water are not of concern, based on reliable data and conservative assumptions, including modelled drinking water residue estimates, upper bound residue estimates in food commodities and an assumption of 100% crop treated.
- Lastly, the residential assessment was based on the best available data and professional judgment; therefore, it was concluded that the dietary and residential assessments will not underestimate exposure.

**Table 6.5.1: Summary of toxicological doses and endpoints for hydramethylnon human health risk assessments.**

| Exposure/ Scenario | *Point of departure (POD) | Uncertainty Factors | Level of concern |
|---|---|---|---|
| **Residential (domestic) exposure** | | | |
| Incidental oral (children 1 to 2 years), short-term (1-30 days) | NOAEL = 1.66 mg/kg-day | $UF_A$= 10<br>$UF_H$= 10<br>FQPA SF = 1<br>Total UF= 100 | LOC = 100 |
| Dermal (short-term) | NOAEL = 1.66 mg/kg-day | $UF_A$= 10<br>$UF_H$= 10<br>FQPA SF = 1<br>Total UF= 100 | LOC = 100 |
| Inhalation (short- and intermediate term) | NOAEL = 1.66 mg/kg-day | $UF_A$= 10<br>$UF_H$= 10<br>FQPA SF = 1<br>Total UF= 100 | LOC = 100 |
| **Occupational exposure** | | | |
| Dermal (short-term) | NOAEL = 1.66 mg/kg-day | $UF_A$= 10<br>$UF_H$= 10<br>Total UF= 100 | LOC = 100 |
| Inhalation (short- and intermediate term) | NOAEL = 1.66 mg/kg-day | $UF_A$= 10<br>$UF_H$= 10<br>Total UF= 100 | LOC = 100 |
| Cancer (oral, dermal, inhalation) | Classification: Group C (see Section 6.2) – possible human carcinogen based on increased lung adenomas in female mice. The reference dose approach should be used for quantification of human cancer risk (USEPA 2018b). | | |

| Exposure/ Scenario | *Point of departure (POD) | Uncertainty Factors | Level of concern |
|---|---|---|---|
| **Residential (domestic) exposure** | | | |
| *Point of Departure (POD): Data point derived from dose-response data, used to extrapolate risks associated with lower environmentally relevant human exposures.<br>Study and toxicological effects: Two-generation reproductive toxicity (rats), with LOAEL = 3.32 mg/kg-day, based on testicular effects.<br>UF: uncertainty factor. UFA: extrapolation from animal to human (interspecies). UFH: potential variation in sensitivity among members of the human population (intraspecies).<br>LOC: level of concern. | | | |

# 7 Occupational exposure and risk characterization

## 7.1 Occupational handler exposure parameters

**Description**

The USEPA (2018b) uses the term “handlers” to describe those individuals who are involved in the pesticide application process. Handlers may have distinct job functions or tasks related to applications, and exposures can vary depending on the specifics of each task. Examples are “mixers” who have to prepare spray solutions or the application mixture, “loaders” who load the mixture into the application equipment, e.g., a hand-held spray applicator for spot-applications, and the ”applicator” who walks through the crops, spraying the crops as needed. Job requirements, the quantity of product used in each application, the kinds of equipment used, the target being treated, and the level of personal protective equipment (“PPE”) used by a handler can cause exposure levels to differ in a manner specific to each application event.

In the case of Maxforce® Ant and Cockroach Bait, mixers and loaders are not involved, because the product is supplied ready-for-use in a suitable shaker container. Thus, the only relevant handler is the applicator.

**Occupational handler exposure data and assumptions**

The USEPA (2018b) uses a series of assumptions and exposure factors to conduct the occupational handler risk assessment and these will be followed here for the Maxforce® bait:

Application rate: The calculation of Maxforce® Ant and Cockroach Bait and converted hydramethylnon outdoor application rates are fully explained in Section 5.5 and Table 5.5.1, and summarised with other application parameters in Table 7.3.1. Indoor application rates are presented in Table 7.1.1, with the outdoor application rates for easy comparison. Indoor cockroach spot treatment application rates are lower than outdoor application rates by a factor of at least 30; therefore, the exposure dose of an occupational handler applying the product indoors is reasonably expected to be lower than when application is to outdoors crack and crevices, e.g., during perimeter treatments.

**Table 7.1.1: Maxforce® Bait and converted hydramethylnon application rates.**

| Application scenario | Product application rate (product label) | *Converted hydramethylnon application rate | Hydramethylnon application rate (kg/ha) |
|---|---|---|---|
| Perimeter treatment (around buildings) | 6 g/m$^2$ | 0.06 g/m$^2$ | 0.024 kg/ha (see notes in text) |
| Broadcast application (lawns and other areas) | 20 g/100 m$^2$ | 0.20 g/100 m$^2$ | 0.020 kg/ha |
| Accepted for South African conditions (see notes in Section 5.5) | | | 0.020 kg/ha |
| Ant nests: spot treatment | 30 g around nest | 0.30 g around nest | 0.0003 kg/nest |
| Cockroach spot treatment: cracks and crevices | 0.2 g/m$^2$ | 0.002 g/m$^2$ | Not applicable |
| *Hydramethylnon content of Maxforce® Ant and Cockroach Bait is 1% (w/w). | | | |

Unit exposures:

- Are standard generic values recommended for use in predicting handler exposure.
- The "unit exposure" is the mass of pesticide ingredient exposure per unit mass of ingredient handled, in units of µg a.i. to which the handler is exposed, per kg a.i. handled (Table 7.3.1).
- Unit exposures are provided for specific combinations of exposure scenario (activity, equipment, formulation, site, etc.), exposure route, and PPE levels.
- The USEPA (2018b) uses various sources of such data; those applicable to Maxforce® bait applications were from the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table", cited by the USEPA and presented in Table 7.3.1.

Area treated, application rate and amount handled:

- The USEPA (2018b) sometimes uses imperial measurement units (e.g., lb weight), which are converted to metric units (e.g., 1 lb = 0.454 kg).
- USEPA (2018b) assumptions of "per event" values are based on ExpoSAC Policy 9.1 (reference not provided in the USEPA document) or other reasonable assumptions if applicable data were not available in the policy document:
    - 1 000 feet squared (93 m$^2$) for sites treated with granule end-use products using shaker cans, as in the case of Maxforce® Ant and Cockroach Bait.
    - 100 mounds/nests treated with a granule end-use product using shaker cans.
    - 25 lbs (13.2 kg) of bait applied to voids/cracks/crevices/ant trails using shaker cans. This was the largest shaker can size submitted to the USEPA.

The application of the USEPA values to the Maxforce® bait, with a container size of 225 g, is adjusted as follows:

- 93 m$^2$ for sites treated is reasonable for a handler assisting groundskeepers of golf courses of other sports facilities, or for a general factotum looking after public utility buildings or grounds. According to Table 5.5.1, the product application rate for broadcast application on lawns and other areas is 20 g/100 m$^2$; therefore, the contents of one can (225 g) is sufficient for an application event covering 93 m$^2$.
- 93 m$^2$ for sites treated is also reasonable for a general worker maintaining a residential complex or industrial/public utility:
    - Given label instructions to apply 6 g product/m$^2$ for perimeter treatment around a house, one can (225 g) of Maxforce® bait is sufficient for treating 37.5 m$^2$ (225 g/6 g) around a house.
    - Thus, 1 can is sufficient to treat at least 1 average house perimeter, given the estimated 20 m$^2$ perimeter area of the average house, described in Section 5.5.

- The treatment of 93 $m^2$ of residential perimeter area thus requires 2.5 cans [93 $m^2$/(37.5 $m^2$ per can) = 2.5 cans], which appears a reasonable estimate of the number of cans that can be managed per day.

- 100 ant mounds/nests treated with a granular end-use product supplied in shaker cans is a likely overestimation in the case of Maxforce® bait, because the product label instructions are to use 30 g around nests, while the total contents of the can is only 225 g. Assuming that 3 cans (equal to 675 g of product) can be managed by 1 applicator per day, it is reasonable to conclude that approximately 23 nests may be treated per day (675 g/30 g per nest = 23 nests). The equivalent amount of hydramethylnon is 6.75 g (0.00675 kg).
- 25 lbs (13.2 kg) of bait applied to voids/cracks/crevices/ant trails using shaker cans, based on the largest size shaker can found by the USEPA, is not applicable to the Maxforce® bait container size of 225 g (0.225 kg). Assuming, as for ant nests, that 3 cans can be managed per applicator per day, amount handled daily is approximately 675 g product. The equivalent amount of hydramethylnon is 6.75 g (0.00675 kg) and this is assumed sufficient to include indoor applications for cockroach treatment.
- Areas treated, application rates and amounts of handled Maxforce® Ant and Cockroach Bait are summarised in Table 7.1.2.

**Table 7.1.2: Summary of occupational handler areas treated, application rates and amounts of bait handled.**

| Term | Term symbol | Units | Value |
|---|---|---|---|
| **Area treated per day** | | | |
| Perimeter application - around buildings | A | ha/day | 93 $m^2$ = 0.0093 ha |
| Broadcast application - turf, lawns, public utility areas | A | ha/day | |
| **Application rates (estimated maximum, hydramethylnon/ha)** | | | |
| Perimeter application - around buildings | AR | kg a.i./ha | 0.020 kg a.i./ha (Section 5.5 and Table 5.5.1, calculated from product label) |
| Broadcast application - turf, lawns, public utility areas | AR | kg a.i./ha | |
| **Amount of hydramethylnon handled per day** | | | |
| Spot treatment - ant nests | AR | kg a.i./day | 3 cans/day = 675 g product @ 1% a.i. = 6.75 g a.i. = 0.00675 kg a.i. |
| Spot treatment – ant trails, cockroaches and ants in cracks/crevices. | AR | kg a.i./day | |

Exposure duration:

- USEPA classifies exposures from 1 to 30 days as short-term and 30 days to six months as intermediate-term.
- For hydramethylnon, based on the registered uses, short- and intermediate-term exposures were expected by the USEPA (2018b), as multiple applications might be needed under conditions of high pest pressure.
- Since the short and intermediate-term PODs are the same (See Section 6.5), the short-term risk assessment is applicable to the intermediate-term as well, and a separate intermediate-term assessment is not required (USEPA 218b).
- The Maxforce® bait short-term assessment is thus applicable to the intermediate term.

PPE use:

- The USEPA (2018b) assumes “baseline” clothing defined as a single layer of clothing consisting of a long-sleeved shirt, long pants, shoes plus socks, no protective gloves, and no respirator.

Risks while using gloves are not included in the first round of calculations, because the USEPA (2018b and 2019) found acceptable occupational exposures without the use of gloves. However, should occupational risks without wearing gloves be unacceptable, calculations will be repeated with gloves, because the Maxforce® Ant and Cockroach Bait product label calls for the use of "protective gloves/protective clothing/eye protection/face protection".

- Exposure and risk calculations for the Maxforce® bait assessment are done assuming basic (single-layer) protective clothing.

Body weight:

- The USEPA (2018b) used a standard adult body weight of 80 kg.
- The value might overestimate the general South African body weight; therefore, a value of 60 kg is assumed, as used by European Union regulators.

## 7.2 Exposure and risk equations

Exposure and risk equations proposed by the USEPA (2018c) for the assessment of occupational and residential handlers are presented in this section. Exposure of bystanders is considered negligible, because spray drift is not applicable at all, and because the amount of airborne material generated during application of the granules is expected to be too small to impact bystanders. Unaware bystanders might accidentally, or through curiosity, touch the dispersed granules. Dermal exposure in this case is likely to be less than occupational handlers applying the product without wearing gloves (assessed in this section); therefore, the risks associated with dermal exposure of occupational users are viewed as a surrogate exposure for accidental bystander exposure.

**Occupational handler equations**

Potential daily dermal and inhalation exposures of handlers are calculated using the following equations:

$$E = UE * AR * A * 0.001\ mg/ug$$

Equation 7.2.1

where:

| | |
|---|---|
| *E* | hydramethylnon exposure (mg/day) |
| *UE* | unit exposure (µg hydramethylnon/kg hydramethylnon handled) |
| *AR* | maximum application rate according to product label (kg hydramethylnon/ha) |
| *A* | area treated or amount handled (e.g., ha/day, kg/day) |

The daily doses are calculated using the following equation:

$$ADD = \frac{E * AF}{BW}$$

Equation 7.2.2

where:

| | |
|---|---|
| *ADD* | average daily dose absorbed in a given scenario (mg a.i./kg-day) |
| *E* | exposure (mg a.i./day) |
| *AF* | absorption factor (dermal and/or inhalation) |
| *BW* | body weight (kg) |

Non-cancer risk estimates for each scenario are calculated using the Margin of Exposure (MOE) approach, which is a ratio of the POD to the daily dose of concern.

All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$ Equation 7.2.3

where:

| | |
|---|---|
| *MOE* | margin of exposure: value used by the USEPA to represent risk estimates (unitless) |
| *POD* | point of departure (mg/kg-day) |
| ADD | average daily dose absorbed in a given scenario (mg ai/kg-day) |

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for these exposure routes were similar (USEPA 2018b), using the following equation:

Total MOE = 1 ÷ (1/Dermal MOE) + (1/Inhalation MOE) Equation 7.2.4

**Occupational post-application (re-entry) equations**

The USEPA (2018b) assumed the use of bulb dusters for application of granular baits in "residential living spaces" but this method is not applicable to Maxforce® Ant and Cockroach Bait, which is sprinkled directly from the shaker can into cracks and crevices where the cockroaches are active. Therefore, indoor residential handler applications of Maxforce® bait are assessed based on the approach for outdoor use. This will not underestimate exposure, since the quantity applied for cockroach treatment is less than applied for outdoor ant treatment of cracks and crevices (Table 7.1.1).

Potential daily hydramethylnon exposures of outdoor occupational post-application re-entry workers, due to the transfer of residues from treated turf to the skin of workers, are calculated by the USEPA (2018b) using the concept of the dislodgeable foliar residue ("DFR") and the transfer coefficient ("TC").

The TC is the expected foliar surface with which a worker may have dermal contact during one hour of a specific activity, in units of $cm^2$/hr. The TC used for granule application calculations is based on standard clothing worn by occupational field workers: shoes, socks, long-legged pants, and long-sleeved shirts. The TC associated with a specific activity, e.g., weeding by hand, presents an estimate of the fraction of foliar residues (in this assessment, residues of hydramethylnon) transferred to the skin of re-entry workers during that activity. The TC is dependent on the foliage properties (in this case grass) and the specific activity undertaken in the treated lawn/turf.

The DFR is an estimate of the quantity of foliar hydramethylnon residue that is available for transfer to the skins of outdoor post-application workers. In the case of turf/lawns/sod, the turf transferable residue ("TTR"), a similar concept, in units of µg a.i./$cm^2$ of turf/lawn/sod is used instead of the DFR (Equation 7.2.5). While the equation for the calculation of the DFR includes a term for the number of days after application (e.g., 2 days post-application), which is used to account for active ingredient dissipation after application. In the case of the TTR, it is assumed that contact can take place immediately after application, and the dissipation factor is not considered. The number of days after application of the ant and cockroach bait is thus assumed to be zero.

Dermal exposure during outdoor activities is calculated with Equation 7.2.5:

$$E = TC * DFR_t * ET * 0.001 \frac{mg}{ug}$$ Equation 7.2.5

where:

| | |
|---|---|
| *E* | exposure (mg a.i./day) |
| *TC* | transfer coefficient for adults after granule applications<br>= 3 700 $cm^2$/hr for golf course maintenance<br>= 2 500 $cm^2$/hr for greens only maintenance (USEPA 2018b) |
| $TTR_t$ is used instead of $DFR_t$ | turf transferable residue on day "t" = 0.2% of the application rate (AR) (µg/$cm^2$) and day "t" = day 0 (USEPA 2018c) |
| *ET* | exposure time (hours/day) |

The daily doses are calculated using Equation 7.2.2 and the MOE with Equation 7.2.3.

## 7.3 Occupational exposure: risk calculations and results

A summary of terms and values used in the risk calculations for occupational handlers and post-application re-entry workers are presented in Table 7.3.1. The indoor application rates are less than the outdoor application rates by a factor of at least 30 (Table 7.1.1). Therefore, exposures and risks associated with indoor applications are not calculated separately, but are expected to be significantly less than calculated for outdoor applications. Outdoor exposure and risks are thus a conservative approximation of indoor applications.

Outdoor re-entry activities are supposed to involve manual labour, assumed to present a risk of dermal contact with granule residues on grass/turf/sod. Non-manual or mechanised activities, such as mechanised mowing with a tractor-mower, does not present a risk of dermal contact, and are thus not assessed. The occupational post-application outdoor re-entry activity presenting the greatest opportunity for potential exposure is golf course maintenance. Golf course maintenance exposure is expected to exceed exposures (and risks) associated with other occupational maintenance activities on lawns or on sods.

Indoor re-entry activities are likely to involve cleaning of residential living spaces where the bait was applied. The USEPA (2018b) did not assess this scenario. It is fair to conclude that occupational outdoor re-entry activities, e.g., golf course maintenance, involve higher exposure doses than indoor cleaning activities, for the following reasons:

- Firstly, indoor application rates are lower than outdoor application rates by at least an order of magnitude (presented in Table 7.1.1).
- Secondly, spot treatments indoors involve far smaller areas of application than outdoors golf course greens, freeways or tees.
- Thirdly, golf course maintenance of treated turf is likely to involve more manual contact than indoor cleaning, which is expected to be done with a broom, rag or other household appliance, offering less opportunity for incidental dermal contact with the bait.

Outdoor post-application exposure and risks can thus be accepted as a worst-case representation of indoor post application exposure and risks. Therefore, indoor post-application exposure and risks are not assessed separately.

Post-application inhalation exposure assessment was not conducted by the USEPA (2018b and c). Considering hydramethylnon's low vapour pressure, the USEPA expected inhalation exposure to be negligible and not of concern. Given the small amounts of bait to be applied indoors (Table 7.1.1), indoor clean-up is not expected to generate significant amounts of airborne hydramethylnon residues and indoor post-application inhalation exposure is also not assessed.

**Table 7.3.1: Terms and values for occupational exposure and risk calculations.**

| Term | Symbol | Units | Value |
|---|---|---|---|
| **Shaker can broadcast application of foundations/perimeter/turf/lawns/sod. Shaker can spot applications of cockroaches and ant mounds/nests/cracks/crevices/ant trails. Sprinkling of granules in indoor cracks and crevices where cockroaches are active.** | | | |
| **Unit exposure values** | | | |
| Dermal unit exposure (PPE = SL/no-G: single layer clothing, no gloves) | UE | µg/kg a.i. handled | 112 µg/lb a.i. (USEPA 2018b) = 247 µg/kg hydramethylnon handled |
| Inhalation unit exposure (PPE = No-R: no respirator) | UE | µg/kg a.i. handled | 12.5 µg/lb a.i. (USEPA 2018b) = 27.6 µg/kg hydramethylnon |
| Conversion factor | CF | mg/µg | 0.001 mg/µg |
| **Application rates (kg hydramethylnon/ha)** | | | |
| Perimeter application - around buildings | AR | kg a.i./ha | 0.020 kg a.i./ha (Table 7.1.1) |
| Broadcast application - turf, lawns, other public utility areas | AR | kg a.i./ha | |
| **Amount of hydramethylnon handled per day** | | | |
| Spot treatment - ant nests | AR | kg a.i./day | 0.00675 kg a.i./day (Table 7.1.1) |
| Spot treatment - cracks/crevices/ant trails | AR | kg a.i./day | |
| **Area treated per day** | | | |
| All applications except spot treatments | A | ha/day | 93 $m^2$ = 0.0093 ha (Table 7.1.1) |
| **Post-application (re-entry) exposure factors** | | | |
| Transfer coefficient (adults) (USEPA 2018c) | TC | $cm^2$/hr | 3 700 (golf course maintenance) 2 500 (greens only maintenance) |
| Turf transferable residue | TTR | µg/$cm^2$ | 0.2% x ($AR_{turf/lawn}$) = 0.2% x 0.020 kg a.i./ha =0.0004 µg/$cm^2$ |
| Exposure time | ET | hours/day | 8 |
| **Absorption factors, body weight and toxicity values** | | | |
| Absorption factor (Section 6.4) | AF | unitless | Dermal: 1% Inhalation: 100% |
| Adult body weight | BW | kg | 60 (see ***Body weight,*** Section 7.1) |
| Point of departure | POD | mg/kg-day | NOAEL = 1.66 mg/kg-day (Table 6.5.1) |
| Level of concern | LOC | unitless | MOE ≤ 100 (Table 6.5.1) |

Results of risk calculations for occupational handler exposure to Maxforce® Ant and Cockroach Bait hydramethylnon are presented in Table 7.3.2 for perimeter-, broadcast grass/turf and spot-treatment (cockroaches, ant nests, ant trails, cracks and crevices) application.

Results of risk calculations for occupational re-entry workers post-application exposure to Maxforce® bait hydramethylnon are presented in Table 7.3.3.

**Table 7.3.2: Occupational handler exposure and MOEs.**

| Treatment scenario | Dermal exposure | | | Inhalation exposure | | | Combined exposure | |
|---|---|---|---|---|---|---|---|---|
| | Dose (mg/kg-day) | LOC = 100 | | Dose (mg/kg-day) | LOC = 100 | | LOC = 100 | |
| | | MOE | MOE > LOC? | | MOE | MOE > LOC? | MOE | MOE > LOC? |
| Perimeter | $7.7 \times 10^{-9}$ | > 1 000 000 | Yes | $8.5 \times 10^{-8}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| Lawn/turf | $7.7 \times 10^{-9}$ | > 1 000 000 | Yes | $8.5 \times 10^{-8}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| Ant nests | $2.8 \times 10^{-7}$ | > 1 000 000 | Yes | $3.1 \times 10^{-6}$ | 535 350 | Yes | 491 300 | Yes |
| Cracks and crevices | $2.8 \times 10^{-7}$ | > 1 000 000 | Yes | $3.1 \times 10^{-6}$ | 535 350 | Yes | 491 300 | Yes |
| POD = 1.66 mg/kg-day (Table 6.5.1) | | | | | | | | |

**Table 7.3.3: Post-application occupational exposure and risks of re-entry workers.**

| Activity | Dermal exposure | | |
|---|---|---|---|
| | Dose (mg/kg-day) | LOC = 100 | |
| | | MOE | MOE > LOC? |
| Golf course maintenance - greens, tees, and fairways | $2.0 \times 10^{-6}$ | 841 200 | Yes |
| Greens only maintenance | $1.3 \times 10^{-6}$ | 1 245 000 | Yes |
| Notes to table:<br>POD = 1.66 mg/kg-day (Table 6.5.1).<br>Inhalation risk is not calculated, because inhalation exposure is likely to be negligible (see Section 7.3). | | | |

**Summary of risk results**

The risk calculation results presented in Tables 7.3.2 and 7.3.3 clearly indicate that handling of Maxforce® Ant and Cockroach Bait by professional applicators does not present a risk of health effects related to hydramethylnon exposure. There is also not a risk to the health of post-application re-entry workers. The assessment represents indoor and outdoor applications.

Acceptable risks were found with calculations not accounting for the use of protective gloves in occupational scenarios (not considering gloves is motivated in Section 7.1). Therefore, it was not necessary to calculate occupational risks with the use of gloves, but this should not be viewed as implying that the use of gloves is not necessary. The use of gloves is recommended on the Maxforce® bait label and is always an additional protective measure, which should remain on the label.

It should be noted that male fertility effects are the only health endpoints (aside from mortality) for which dose-response values are available in toxicological studies (see Section 6.5). Thus, there is no other choice but to base acceptable occupational exposure levels of females on this health endpoint as well. Therefore, the absence of a risk to health in general, and specifically the absence of a risk to male fertility, is implied by a finding of “acceptable exposures or risks”.

# 8 Residential and recreational exposure and risk characterization

## 8.1 Residential handler

**Description**

The USEPA (2018b) approach residential handler exposure and risk assessment differently than occupational handlers, as residential/domestic non-professional users are assumed not to use protective equipment. This is not strictly applicable to Maxforce® Ant and Cockroach Bait, since label instructions include "*Wear protective gloves/protective clothing/eye protection/face protection."* However, considering that non-professional users might not always adhere to these, residential handler exposure is calculated assuming that protective clothing and gloves are not used.

The residential handler scenarios relevant to Maxforce® bait addressed by the USEPA (2018b) are:

- Granules applied to lawns/turf using shaker cans;
- Granules applied to ornamental plants using a shaker can; and
- Applying granules to outdoor perimeters, using shaker cans.

The USEPA (2018b) assumed the use of bulb dusters for application of granular baits in "residential living spaces". This is not relevant to Maxforce® bait, which is sprinkled directly from the shaker can into cracks and crevices where the cockroaches are active. Therefore, indoor residential handler applications of Maxforce® bait are assessed based on the approach for outdoor use. This will not underestimate exposure, since the quantity applied for cockroach treatment is less than applied for outdoor ant treatment (Table 7.1.1). Outdoor exposure and risks are thus a conservative approximation of indoor applications.

**Residential handler exposure data and assumptions**

The assumptions and exposure factors used by the USEPA (2018b) to conduct the residential handler risk assessment are used here for Maxforce® bait, with some adjustments of the areas treated, as indicated below.

The application rates, unit exposures, assessed exposure periods and adult body weight are as for occupational handlers (Section 7.1). The USEPA (2018b) sometimes uses imperial measurement units (e.g., lb weight), which are converted to metric units (e.g., 1 lb = 0.454 kg).

The area treated or amount handled by residential users are adjusted from the occupational handlers' values (Section 7.1), considering that the Maxforce® bait container size is 225 g:

- 93 $m^2$ for sites treated is reasonable for a residential user with a large garden. According to Table 5.5.1, the product application rate for broadcast application on lawns and other areas is 20 g/100 $m^2$; therefore, the contents of one can (225 g) is sufficient for an application event covering 93 $m^2$. The value is likely to overestimate use in a housing complex with small gardens.
- 93 $m^2$ for sites treated is a likely overestimation for a residential user applying the product to the perimeter of a home, given that:
    - The perimeter area of the average house is estimated at 20 $m^2$, described in Section 5.5.
    - Given label instructions to apply 6 g product/$m^2$ for perimeter treatment around a house, one can (225 g) of Maxforce® bait is sufficient for treating 37.5 $m^2$ (225 g/6 g) around a house.
    - Thus, the assumed area for perimeter treatment should be 37 $m^2$. In order to avoid the generation of redundant numbers, residential user exposure and risk calculations are based

on the larger treated area of 93 $m^2$ (for lawns), which is more than adequate for perimeter treatment exposure and risks.

- 23 ant mounds/nests treated with a shaker can by occupational handlers is a likely overestimation for residential handlers. A more likely number is 5 mounds/nests on a residential property. Given the product label instructions to apply 30 g around nests, 5 nests would require 150 g of Maxforce® bait, for which one can of 225 g would be more than enough. The equivalent amount of hydramethylnon is 1.5 g (0.0015 kg).
- 25 lbs (13.2 kg) of bait applied to voids/cracks/crevices/ant trails using shaker cans, based on the largest size shaker can found by the USEPA, is not applicable to the Maxforce® bait container size of 225 g (0.225 kg), which will instead be used in calculations presented in this report. The equivalent amount of hydramethylnon is 2.25 g (0.00225 kg).
- Areas treated, application rates and amounts of handled Maxforce® bait are summarised in Table 8.1.1.

**Table 8.1.1: Summary of residential handler areas treated, application rates and amounts of bait handled.**

| Term | Symbol | Units | Value |
|---|---|---|---|
| **Area treated per day** | | | |
| Perimeter application - around buildings | A | ha/day | 93 $m^2$ = 0.0093 ha |
| Broadcast application – lawns, open areas | A | ha/day | |
| **Application rates (estimated maximum, hydramethylnon/ha)** | | | |
| Perimeter application - around buildings | AR | kg a.i./ha | 0.020 kg a.i./ha (Section 5.5 and Table 5.5.1, from product label) |
| Broadcast application - lawns, open areas | AR | kg a.i./ha | |
| **Amount of hydramethylnon handled per day** | | | |
| Spot treatment - ant nests | AR | kg a.i./day | 150 g product @ 1% a.i. = 1.5 g a.i. = 0.0015 kg a.i. |
| Spot treatment - cracks/crevices/ant trails | AR | kg a.i./day | 1 can/day = 225 g product @ 1% a.i. = 2.25 g a.i. = 0.00225 kg a.i. |

# 8.2 Residential and recreational post-application exposure

**Scenarios**

Residential post-application exposure scenarios are (USEPA 2018b):

- Adults:
  - Dermal exposure from any physical “high contact” lawn activities on treated residential turf/lawns, including lawn care and maintenance.
  - Post-application inhalation exposure assessment was not conducted since hydramethylnon has a low vapour pressure, causing the USEPA to expect negligible inhalation exposure that is not of concern.
  - Oral exposure is highly unlikely and is not assessed.
- Children’s life stages selected by the USEPA (2018b):
  - Incidental oral exposure (hand-to-mouth, children 1 to < 2 years) from “high contact” lawn activities on turf treated with a granular-bait formulation.
  - Dermal exposure from any physical activities, e.g., playing on treated residential turf/lawns, children 6 to < 11 years.
  - Dermal exposure from contact with residues on treated turf while mowing after application of a granular-bait formulation, children 11 to < 16 years.
- Non-occupational dermal exposure is calculated for the post-application recreational activity of

golfing on treated turf, calculated for adults and/or children aged 6 to < 11 years, and/or 11 to < 16 years.
- According to the USEPA (2018b) life stages other than the selected are potentially exposed, but exposure and risks of the selected lifestages are indicative of the exposure and risk estimates of other potentially-exposed lifestages.

The USEPA (2018b) did not assess indoor post-application activities such as cleaning residential living spaces where the bait was applied. This scenario should not exceed exposure doses calculated for adults and children in the above residential and recreational post-application scenarios. Therefore, the scenarios detailed above can be viewed as conservative high-end representations of indoor post-application activities, such as cleaning. Incidental dermal and oral (hand-to-mouth contact) of toddlers in the home is unlikely to exceed the exposure doses calculated for incidental contact on treated grass, which thus accounts for potential indoor contact.

Accidental ingestion of granules is considered an episodic event and not a routine behaviour occurring on a regular basis. Concern for human health is then related to acute poisoning rather than short-term exposure to hydramethylnon residues. The USEPA (2018b) assessed risks resulting from episodic ingestion of granules as equivalent to an acute dietary dose and, given that it had been determined that hydramethylnon possesses no acute dietary toxicity, episodic ingestion was not assessed by the USEPA, and is also not assessed for Maxforce® Ant and Cockroach Bait in this report.

**Exposure data and assumptions**

The USEPA (2018b) assumptions and exposure factors for the residential and recreational post-application exposure- and risk assessment are used for the Maxforce® bait assessment.

The application rates and adult body weight are as for residential handlers (Section 8.1).

Body weights for infants, younger and older children, used by the USEPA (2018b), are adopted for the Maxforce® Ant and Cockroach Bait calculations:
- 11 kg for children 1 to <2 years old.
- 32 kg for children 6 to <11 years old.
- 57 kg for children 11 to <16 years old.

Turf transferable residue (USEPA 2018b) for post-application activities on golf courses and lawns/turf:
- 0.2% of the applied granules are available for transfer after the last application.
- 10% residue dissipation per day.

The USEPA (2018b) expects exposure to be short-term in duration (hours, see Table 8.4.1).

## 8.3 Exposure and risk equations

Exposure and risk equations proposed by the USEPA (2018c) for the assessment of residential and recreational exposures and risks are presented in this section.

**Residential handler equations**

Potential exposures for residential handlers are calculated with some equations used for occupational exposure calculations, but with exposure factor values applicable to residential handlers, as explained in the previous sections, and summarised in Table 8.4.1:

- Hydramethylnon exposure (mg/day) of residential handlers: Equation 7.2.1.
- Hydramethylnon exposure doses (mg/kg-day) of residential handlers: Equation 7.2.2.
- All MOEs according to Equation 7.2.3.
- Dermal and inhalation risk estimates are combined using Equation 7.2.4.

**Residential post-application exposure equations**

Potential residential post-application exposures of adults and children are calculated using some equations for residential handlers, but with exposure factor values applicable to post-application activities (e.g., playing on or mowing treated grass), as explained in the previous sections, and summarised in Table 8.4.1:

- Post-application residential exposure (mg a.i./day): Equation 7.2.5.
- Post-application residential exposure doses (mg/kg-day): Equation 7.2.2.
- All MOEs according to Equation 7.2.3.
- Dermal and inhalation risk estimates are combined using Equation 7.2.4.

The USEPA (2018b) considered the combination of dermal and hand-to-mouth post-application exposure scenarios for children 1 to < 2 years old as a protective estimate of children's exposure, and concluded that object-to-mouth activities would be covered by the estimates for hand-to-mouth scenarios.

The USEPA (2018c) developed the following equations for post-application hand-to-mouth exposure of a young child (1 to <2 years) associated with physical activities on grass/turf:

$$E = [HR * (FM * SAH) * (ET * N\_Replen) * (1- (1- SE)^{(Freq\_HtM/N\text{-}Replen)})]$$ Equation 8.3.1.

where:

| | |
|---|---|
| $E$ | oral exposure (mg a.i./day) |
| $HR$ | hand residue loading (mg/cm$^2$) |
| $FM$ | fraction hand surface area mouthed / event (fraction/event) |
| $SAH$ | typical surface area of one hand (cm$^2$) |
| $ET$ | exposure time (hours/day) |
| $N\_Replen$ | number of replenishment intervals per hour (intervals/hour) |
| $SE$ | saliva extraction factor (i.e., mouthing removal efficiency) |
| $Freq\_HtM$ | number of hand-to-mouth contact events per hour (events/hour) |

and

$$HR = \frac{Fa.i._{hands} \times DE}{SA_H \times 2}$$ Equation 8.3.2

Where:

| | |
|---|---|
| $HR$ | hand residue loading (mg/cm$^2$) |
| $Fa.i._{hands}$ | fraction ai on hands compared to total surface residue from dermal transfer coefficient study (unitless) |
| $DE$ | dermal exposure (mg), calculated with Equation 7.2.5, but using exposure factors for children aged 1 to <2 (Table 8.4.1) |
| $SA_H$ | typical surface area of one hand (cm$^2$) |

The exposure dose (mg/kg-day) is calculated with Equation 7.2.2, and the MOE with Equation 7.2.3.

The values used by the USEPA (2018c) are presented in Table 8.4.2.

Dermal and oral risk estimates of the young child (1 to <2 years) associated with physical activities on grass/turf were combined in this assessment, since the toxicological effects for these exposure routes were similar (USEPA 2018b), using the following equation:

Total MOE = 1 ÷ (1/Dermal MOE) + (1/Oral MOE) Equation 8.3.3

**Recreational post-application exposure equations**

Potential exposures during post-application recreational activities are calculated using some equations for post-application residential exposure, but with exposure factor values applicable to recreational activities (golfing, etc.) as explained in the previous sections, and summarised in Table 8.4.1:

- Post-application recreational exposure (mg a.i./day): Equation 7.2.5.
- Post-application recreational exposure doses (mg/kg-day): Equation 7.2.2.
- All MOEs according to Equation 7.2.3.

## 8.4 Residential and recreational exposure: risk calculations and results

Terms and values used in the risk calculations for residential handlers and for residential and recreational post-application exposures to Maxforce® Ant and Cockroach Bait hydramethylnon are summarised in Tables 8.4.1 and 8.4.2.

Post-application exposure and activities assessed in the residential setting are related to residential lawns:

- Dermal exposure during any physical activity on residential lawns, e.g.:
  - Playing/running/sitting/reclining on the grass: adults and children. Children 1 to <2 years of age are expected to be most exposed, and their risks are assumed to account for other age groups.
  - Mowing the lawn. Adults and children aged 11 to <16 years are supposed to be involved.
- Oral exposure of children 1 to <2 years of age via hand-to-mouth transfer while active on residential lawns.

Public recreational post-application exposure is associated with activities on golf courses. Adults and children aged 6 to <16 years of age are supposed to take part. The USEPA (20199c) actually distinguishes between exposures if the ant bait had been applied on the greens, tees and fairways (4 hours activity contact assumed) or only on grees and tees (1 hour of contact). The calculations for Maxforce® bait were done assuming 4 hours of contact (see “Exposure time” in Table 8.4.1) and are thus conservatively protective of both application scenarios.

Post-application inhalation exposure assessment was not conducted by the USEPA (2018b and c). Given hydramethylnon’s low vapour pressure, the USEPA expected inhalation exposure to be negligible and not of concern.

**Table 8.4.1: Terms and values for residential handler, post-application and recreational activities exposure.**

| Term | Symbol | Units | Value |
|---|---|---|---|
| **Shaker can broadcast application of foundations/perimeter/lawns. Shaker can spot applications of ant mounds/nests/cracks/crevices/ant trails.** | | | |
| **Unit exposure default values** | | | |
| Dermal unit exposure (PPE = SL/no-G: single layer clothing, no gloves) | UE | µg/kg a.i. handled | 112 µg/lb a.i. (USEPA 2018b) = 247 µg/kg hydramethylnon handled |
| Inhalation unit exposure (PPE = No-R: no respirator) | UE | µg/kg a.i. handled | 12.5 µg/lb a.i. (USEPA 2018b) = 27.6 µg/kg hydramethylnon handled |
| Conversion factor | CF | mg/µg | 0.001 mg/µg |
| **Application rates (kg hydramethylnon/ha)** | | | |
| Perimeter application - around buildings | AR | kg a.i./ha | 0.020 kg/ha (Section 5.5 and Table 5.5.1, from product label) |
| Broadcast application - turf, lawns, other open areas | AR | kg a.i./ha | |
| **Amount of hydramethylnon handled per day** | | | |
| Spot treatment - ant nests | AR | kg a.i./day | 0.0015 kg a.i. (Table 8.1.1) |
| Spot treatment - cracks/crevices/ant trails | AR | kg a.i./day | 0.00225 kg a.i. (Table 8.1.1) |
| **Area treated per day** | | | |
| All applications except spot treatments | A | ha/day | 93 $m^2$ = 0.0093 ha (Table 8.1.1) |
| **Post-application and recreational exposure factors** | | | |
| Turf transferable residue | TTR | µg/$cm^2$ | 0.2% x ($AR_{turf/lawn}$) = 0.2% x 0.020 kg a.i./ha =0.0004 µg/$cm^2$ |
| **Transfer coefficients (USEPA 2018c)** | | | |
| Physical activities (e.g., sitting on, playing on, running on turf/lawn). | TC | $cm^2$/hr | Adults: 200 000<br>Children 1 to <2 years: 54 000 |
| Mowing lawn | TC | $cm^2$/hr | Adults: 5 500<br>Children 11 to <16 years: 4 500 |
| Golfing on golf course | TC | $cm^2$/hr | Adults: 5 300<br>Children 11 to <16 years: 4 400<br>Children 6 to <11 years: 2 900 |
| **Exposure time (USEPA 2018c)** | | | |
| Physical activities (e.g., sitting on, playing on, running on turf/lawn). | ET | hours/day | 1.5 (adults and children) |
| Mowing turf | ET | hours/day | 1.0 (adults and children) |
| Golfing | ET | hours/day | 4 (granules on greens, tees and fairways) |
| **Body weight (see *Body weight,* Section 8.1)** | | | |
| Adults | BW | kg | 60 |
| Children 11 < 16 years | BW | kg | 57 |
| Children 6 < 11 years | BW | kg | 32 |
| Children 1 < 2 years: | BW | kg | 11 |
| **Absorption factors, body weight and toxicity values** | | | |
| Absorption factor (Section 6.4) | AF | unitless | Dermal: 1%<br>Inhalation: 100%<br>Oral: 100% |
| Point of departure | POD | mg/kg-day | NOAEL = 1.66 mg/kg-day (Table 6.5.1) |
| Level of concern | LOC | unitless | MOE ≤ 100 (Table 6.5.1) |

**Table 8.4.2: Summary of terms and values for hand-to-mouth calculations, children aged 1 to <2 years, playing on treated grass.**

| Term | Term symbol | Units | Value |
|---|---|---|---|
| **For hand residue loading (HR) calculation (Equation 8.3.2)** | | | |
| Fraction a.i. on hands compared to total surface residue from USEPA dermal transfer coefficient study (unitless) | $Fa.i._{hands}$, granular formulations | unitless | 0.027 (USEPA 2018c) |
| Dermal exposure | DE | mg | Calculated with Equation 7.2.5 and values from Table 8.4.1. |
| Surface area one hand children 1 to <2 | $SA_H$ | $cm^2$ | 150 (USEPA 2018c) |
| **For exposure (E) calculation (Equation 8.3.1)** | | | |
| Fraction hand surface area mouthed / event | FM | fraction/event | 0.127 (USEPA 2018c) |
| Exposure time | ET | hours/day | 1.5 (USEPA 2018c) |
| Number of replenishment intervals per hour | N_Replen | intervals/hour | 4 (USEPA 2018c) |
| Saliva extraction factor (i.e., mouthing removal efficiency) | SE | unitless | 0.48 (USEPA 2018c) |
| Number of hand-to-mouth contact events per hour | Freq_HtM | events/hour | 13.9 (USEPA 2018c) |
| Body weight children 1 to <2 | BW | kg | 11 (Table 8.4.1) |

Results of risk calculations for residential handler exposure to Maxforce® Ant and Cockroach Bait hydramethylnon are presented in Table 8.4.3 for perimeter-, broadcast grass and spot-treatment (ant nests, ant trails, cracks and crevices) application.

Results of risk calculations for residential and recreational post-application exposure to Maxforce® bait hydramethylnon are presented in Table 8.4.4.

**Table 8.4.3: Residential handler exposure and MOEs.**

| Treatment scenario | Dermal exposure | | | Inhalation exposure | | | Combined exposure | |
|---|---|---|---|---|---|---|---|---|
| | Dose (mg/kg-day) | LOC = 100 | | Dose (mg/kg-day) | LOC = 100 | | LOC = 100 | |
| | | MOE | MOE > LOC? | | MOE | MOE > LOC? | MOE | MOE > LOC? |
| Perimeter | $7.7 \times 10^{-9}$ | > 1 000 000 | Yes | $8.5 \times 10^{-8}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| Lawn/turf | $7.7 \times 10^{-9}$ | > 1 000 000 | Yes | $8.5 \times 10^{-8}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| Ant nests | $6.2 \times 10^{-8}$ | > 1 000 000 | Yes | $7.0 \times 10^{-7}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| Cracks and crevices | $9.3 \times 10^{-8}$ | > 1 000 000 | Yes | $1.0 \times 10^{-6}$ | > 1 000 000 | Yes | > 1 000 000 | Yes |
| POD = 1.66 mg/kg-day (Table 6.5.1) | | | | | | | | |

**Table 8.4.4: Residential and recreational post-application exposure and risks of re-entry workers.**

| Activity | Dermal exposure | | |
|---|---|---|---|
| | Dose (mg/kg-day) | LOC = 100 | |
| | | MOE | MOE > LOC? |
| Physical activities - Adults | $2.0 \times 10^{-5}$ | 83 000 | Yes |
| Physical activities - Children 1 < 2 years | $3.0 \times 10^{-5}$ | 56 000 | Yes |
| Mowing turf - Adults | $3.7 \times 10^{-7}$ | > 1 000 000 | Yes |
| Mowing turf - Children 11 < 16 years | $3.2 \times 10^{-7}$ | > 1 000 000 | Yes |
| Golfing - Adults | $1.4 \times 10^{-6}$ | > 1 000 000 | Yes |
| Golfing - Children 11 < 16 years | $1.2 \times 10^{-6}$ | > 1 000 000 | Yes |
| Golfing - Children 6 < 11 years | $1.5 \times 10^{-6}$ | > 1 000 000 | Yes |
| Hand-to-mouth exposure: young child (1 to <2 years) associated with physical activities on grass/turf | $2.7 \times 10^{-5}$ | 61 000 | Yes |
| Aggregate exposure: young child (1 to <2 years) dermal and oral exposure | | 29 312 | Yes |
| Notes to table:<br>POD = 1.66 mg/kg-day (Table 6.5.1).<br>Inhalation risk is not calculated, because inhalation exposure is likely to be negligible (see text in this section). | | | |

**Summary of risk results**

The results presented in Tables 8.4.3 and 8.4.4 clearly indicate that handling of Maxforce® Ant and Cockroach Bait by adults applying the product in the residential environment does not present a risk of health effects related to hydramethylnon exposure. There is also not a risk to the health of adults and children in contact with treated lawns after application, even if immediately after application. In the recreational (golf course) exposure scenario, a risk is not shown for any of the relevant age groups. These scenarios more than account for potential indoor application and post-application exposures and risks, as explained in Section 8.3. Therefore, unacceptable risks are also not indicated for indoor use.

Since young children/toddlers playing on treated lawns are regarded as the most vulnerable exposed group, the result of aggregate dermal and oral (hand-to-mouth) exposure is of particular importance (Table 8 4.4). It is noted that the aggregate exposure of children 1 to <2 years of age also does not present a risk of health effects related to hydramethylnon exposure. These conclusions are also applicable to indoor exposure of children and infants, as explained in Section 8.3.

As noted in Section 7.3, male fertility effects are the only health endpoints (aside from mortality) for which dose-response values are available from toxicological studies (see Section 6.5). Thus, there is no other choice but to base acceptable exposure levels of females 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 male fertility, is implied by a finding of “acceptable exposures or risks”.

It is stated in the description of residential handler exposure assumptions in Section 8.1 that residential handler exposure is calculated assuming that protective clothing and gloves are not used. These calculations indicated an acceptable health risk if gloves are not used (Table 8.4.3); therefore, it is not necessary to calculate occupational risks with the use of gloves. However, this should not be viewed as implying that the use of gloves is not necessary. The use of gloves is recommended on the Maxforce® Ant and Cockroach Bait label and is always an additional protective measure and should remain on the label.

# 9 Discussion

## 9.1 Risk/benefit review

The USEPA (2019) has reviewed the risks, benefits, and uses of hydramethylnon. Hydramethylnon has broad spectrum effects on a variety of insect pests, but it is particularly effective as a bait toxin against ants and cockroaches. It has a unique mode of action compared to other available alternative ant and cockroach control products, and thus occupies a particular niche in the market.

While potential ecological risks were identified for terrestrial invertebrates, aquatic non-vascular plants, and chronic effects to birds, mammals, fish and aquatic invertebrates, the USEPA expects the ecological exposure potential to be low, for several reasons:

- When applied as intended, a limited environmental footprint is expected.
- Outdoor broadcast application is expected to pose the greatest exposure potential, but are expected to occur less than 4 times per year in residential settings. Hydramethylnon has very limited usage in agriculture and the supplier of Maxforce® Ant and Cockroach Bait has confirmed that the product is not of interest to the agricultural market.
- Granular baits are designed to be highly attractive to target insects (ants and cockroaches) and granules are expected to be rapidly and extensively removed from the application site to their nests, where it is not available for consumption by non-target organisms. Thus, the exposure potential and risk to non-target insects or other animals is reduced due to the behaviour of the primary target pest.

Although there are potential ecological risks, the USEPA (2019) has determined that any potential risks are outweighed by the benefits of hydramethylnon. Potential risks are mitigated by measures to ensure that hydramethylnon is used as intended (Section 9.2).

## 9.2 Proposed mitigation measures

Proposed USEPA (2019) label clarifications to promote use as intended are:

- Advisory statements to emphasise proper use, such as avoiding excessive bait application.
- To reduce the potential for runoff into urban waters/sewerage systems, the USEPA proposes:
  - Applications to impervious surfaces are to be avoided, e.g., broadcast application on paving and horizontal concrete surfaces.
  - Applying the bait to specific cracks and crevices in paving or concrete, rather than a general broadcast application, is anticipated to reduce surface runoff, particularly in urban settings.
  - Avoiding application on impervious surfaces should be recommended in conjunction with a rain advisory, that is, “avoid making applications if it is likely to rain within 24 hours of application”.
- The USEPA proposed that environmental hazard statements for fish toxicity should include a warning for aquatic invertebrates as well. The Maxforce® label already conforms, with a statement “very toxic to aquatic life with long lasting effects”. This may be supplemented with a warning to prevent contamination of fish ponds, streams or rivers.

<u>Wearing of gloves</u>

The finding of acceptable health risks, even while not wearing gloves, does not mean that gloves need not be worn. As recommended on the product label, gloves should be used while applying the bait.

Other measures

The following measures include those generally proposed by international regulatory agencies to protect man, animals and the environment:

- Where possible, prior to the application inform possible bystanders (users of the treated area and their surroundings) about the application event.
- Precautions, e.g., keeping children away from the applied product, and directions for use on the product label must be followed.

# 10 Conclusions

Since male fertility effects are the only health endpoint (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 females 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 male fertility, is implied by a finding of “acceptable exposures or risks”. Vice versa, unacceptable risks indicate unacceptable risks of male fertility effects.

In support of the application for derogation regarding the restricted use of the registered product Maxforce® Ant and Cockroach Bait, identified as substances of concern due to the reproductive toxicant properties of the insecticide active ingredient hydramethylnon, the human health risk assessment results lead to the following conclusions:

- Adult pesticide handlers, whether in the occupational of residential setting, are not at risk of a health effect when applying the product according to label instructions. This was found in scenarios where handlers are assumed not to wear gloves, although the use of gloves is required on the product label.

- Acceptable levels of exposure without wearing gloves cannot be used to negate the need for glove use recommendations on product labels. Recommending the use of gloves is a protective measure for all pesticide users and should remain on the Maxforce® Ant and Cockroach Bait label.

- The occupational post-application re-entry activity presenting the greatest opportunity for potential exposure is golf course maintenance. Golf course maintenance exposure is expected to exceed exposures (and risks) associated with other occupational maintenance activities on lawns or on sods. Associated exposure without using gloves did not result in unacceptable risks.

- Residential post-application outdoors activities on treated lawns, such as physical activities on lawns, and mowing of grass were assessed. Indoor activities, such as cleaning living spaces where the bait was applied, were accounted for with the outdoor assessments. Such activities, even on the day of application, entailed levels of exposure associated with acceptable risks, for adults or for children. This conclusion is also applicable to toddlers assumed to inadvertently ingest hydramethylnon residues via incidental hand-to-mouth activity.

- Recreational post-application outdoors activities were assessed for children and adults playing golf on treated greens, tees and fairways, assuming that the golf course was accessed even on the day of application. The calculated levels of exposure indicated acceptable risks to health of adults and children.

- A risk of detrimental environmental effects is indicated for aquatic non-vascular plants (algae), and for scenarios of chronic exposure to fish, aquatic and sensitive sediment-dwelling invertebrates. Acute risks are not of concern in the aquatic environment.

- A risk of detrimental environmental effects cannot be excluded in the case of chronic consumption of the bait by birds or mammals. However, since the Maxforce® bait is mainly intended for non-agricultural use, the opportunity for exposure of birds and mammals in the residential scenario should be limited. Thus, the environmental risk in the residential setting is expected to be low.

- A risk is qualitatively assumed for sensitive non-target terrestrial invertebrates, but cannot be quantitatively confirmed or refuted, because methods to assess risk to terrestrial invertebrates other than honeybees are not currently available.

- It is important to note that environmental risks to birds, small mammals and terrestrial invertebrates are reduced due to the behaviour of the primary targets (ants and cockroaches). Granular baits are designed to be highly attractive to the targets and granules are expected to be rapidly and extensively removed from the application site to their nests, as indicated on the Maxforce® bait label. Once relocated to the nest, the bait is not available for consumption by non-target organisms and the exposure potential and risk to non-target insects or other animals is reduced.

- In conclusion, limited environmental risks are expected if Maxforce® Ant and Cockroach Bait is deployed as intended, and if excessive application is discouraged.

- Dietary risks to honeybees are not likely for Maxforce® bait, since it is mainly intended for non-agricultural use. Nonetheless, a dietary risk to honeybees cannot be excluded, because pollen and nectar may receive hydramethylnon residues from any dust generated during broadcast applications of granules. Therefore, it is important to follow product application instructions on the label and to discourage excessive application of the product.

- The restricted use applied for by the suppliers of Maxforce® Ant and Cockroach Bait with the active hydramethylnon is according to the intended product use:
  - For outdoor use on ants and indoor use on cockroaches.
  - Ants: the bait is suitable for ant nest/mound, cracks and crevices, broadcast and perimeter treatments, directly from the shaker can in which the product is provided.
  - Cockroaches: granules are sprinkled directly from the shaker can into cracks and crevices where the cockroaches are active.
  - A warning “very toxic to aquatic life with long lasting effects” appears on the label.

- When the recommended mitigation measures (Section 9.2) are applied, accidental exposure of children, pets, non-target animals and the environment can be effectively limited.

- The application for derogation of Maxforce® Ant and Cockroach Bait is supported by the assessment presented in this report, provided that recommended mitigation measures are effectively implemented.

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