

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance methyl nonyl ketone<sup>1</sup>

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#### SUMMARY

Methyl nonyl ketone is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>3</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>4</sup>.

Methyl nonyl ketone was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>5</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>7</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>8</sup>, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Belgium being the designated rapporteur Member State submitted the DAR on methyl nonyl ketone in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 18 September 2006. The peer review was initiated on 12 June 2008 by dispatching the DAR for consultation of the original notifier Pet and Gardening Manufacturing Ltd (the notifier is now Spotless Punch Ltd). Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on methyl nonyl ketone.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of methyl nonyl ketone as an animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2009-00259, issued on 2 December 2011.

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<sup>3</sup> OJ L 379, 24.12.2004, p.13

<sup>4</sup> OJ L 246, 21.9.2007, p.19

<sup>5</sup> OJ L 309, 24.11.2009, p.1

<sup>6</sup> OJ L 153, 11.6.2011, p.1

<sup>7</sup> OJ L 153, 11.6.2011, p.187

<sup>8</sup> OJ L 37, 10.2.2010, p.12

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Numerous data gaps have been identified for the physical and chemical properties of the active substance and the formulation. The technical specification for this compound is open because the 5-batch analysis was not conducted according to GLP. Data gaps for methods for the technical material, formulation, soil, water and air have been identified.

A critical area of concern was identified for methyl nonyl ketone in the mammalian toxicology section, as it was not possible to assess the compliance of the batches tested with the proposed specification (both missing). Based on the outcome of the vapour pressure study (data gap identified by physical chemical properties section), an acute inhalation toxicity study might be required.

No significant residues in plant or animal matrices were expected based on the representative use, and a quantitative consumer risk assessment is therefore not required.

The information on the environmental fate and behaviour of methyl nonyl ketone in relation to the representative uses assessed was insufficient to complete the necessary environmental exposure assessment at the EU level. The fate and behaviour in soil and natural sediment water systems has not been addressed. Consequently the environmental exposure assessment for soil, surface water and groundwater for any transformation products that might be formed from methyl nonyl ketone could not be finalised. A data gap was also identified for the adsorption/desorption properties of the active substance, and therefore the available predicted environmental concentrations in surface water can not be considered valid. Because of the lack of relevant end points for methyl nonyl ketone the groundwater exposure assessment could not be finalised.

A critical area of concern was identified for methyl nonyl ketone in the ecotoxicology section, as it was not possible to assess the compliance of the batches tested with the proposed specification (both missing). A data gap was identified to provide acute toxicity studies for fish to fulfil the Annex II data requirements. Data gaps were also identified for a new risk assessment for aquatic organisms, and to further address the risk to soil-living organisms (i.e. earthworms, other soil macro- and micro-organisms, soil non-target arthropods).

## KEY WORDS

Methyl nonyl ketone, peer review, risk assessment, pesticide, repellent

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	3
Background .....	4
The active substance and the formulated product .....	6
Conclusions of the evaluation .....	6
1. Identity, physical/chemical/technical properties and methods of analysis .....	6
2. Mammalian toxicity .....	6
3. Residues .....	7
4. Environmental fate and behaviour .....	7
5. Ecotoxicology .....	7
6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments .....	9
6.1. Soil .....	9
6.2. Ground water .....	9
6.3. Surface water and sediment .....	10
6.4. Air .....	10
7. List of studies to be generated, still ongoing or available but not peer reviewed .....	11
8. Particular conditions proposed to be taken into account to manage the risk(s) identified .....	12
9. Concerns .....	12
9.1. Issues that could not be finalised .....	12
9.2. Critical areas of concern .....	12
9.3. Overview of the concerns for each representative use considered .....	13
References .....	14
Appendices .....	15
Abbreviations .....	34

## BACKGROUND

Methyl nonyl ketone is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>9</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>10</sup>.

Methyl nonyl ketone was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>11</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>12</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>13</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>14</sup> the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Belgium being the designated rapporteur Member State submitted the DAR on methyl nonyl ketone in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 18 September 2006 (Belgium, 2006). The peer review was initiated on 12 June 2008 by dispatching the DAR for consultation of the original notifier Pet and Gardening Manufacturing Ltd (the notifier is now Spotless Punch Ltd). The DAR was later dispatched to Member States for consultation and comments on 20 October 2010. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifier's response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the Commission on 15 February 2011. On the basis of the comments received and the RMS's evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including points for additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in May/June 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion

<sup>9</sup> OJ L 379, 24.12.2004, p.13

<sup>10</sup> OJ L 246, 21.9.2007, p.19

<sup>11</sup> OJ L 309, 24.11.2009, p.1

<sup>12</sup> OJ L 153, 11.6.2011, p.1

<sup>13</sup> OJ L 153, 11.6.2011, p.187

<sup>14</sup> OJ L 37, 10.2.2010, p.12

is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (10 February 2011),
- the Evaluation Table (26 May 2011),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of May 2011 containing all individually submitted addenda (Belgium, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Methyl nonyl ketone is the used name for undecan-2-one (IUPAC), there is no ISO common name for this compound.

The representative formulated product for the evaluation is 'Get Off My Garden Scatter Crystals' a gel like formulation containing 17 g/l methyl nonyl ketone.

The representative uses evaluated are as an animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

### 1. Identity, physical/chemical/technical properties and methods of analysis

No supporting batch analysis conducted according to GLP is currently available and the specification of technical methyl nonyl ketone is open. Therefore, a data gap has been identified. A data gap has also been identified for further information/data on the method of manufacture and the starting materials used.

Data gaps identified for the active substance are: flash point, surface tension, vapour pressure, Henry's law constant, appearance, spectra, water solubility, solubility in organic solvents, octanol water partition co-efficient, hydrolysis, photolysis, auto-flammability, and surface tension.

For the formulated product the following data gaps are identified: data to demonstrate that the product can be applied successfully, flash point, accelerated storage and shelf-life.

No acceptable methods of analysis are available for the technical material or the formulated product, and therefore a data gap has been identified. Methods for food of plant and animal origin are not required as the formulation is not for use on edible crops and no MRLs are proposed. Data gaps have been identified for methods of analysis for soil, water and air. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

### 2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: European Commission, 2004.

Based on the available data it was not possible to assess the compliance of the batches tested with the proposed specification (both missing).

Methyl nonyl ketone is not acutely toxic via the oral and dermal route (both LD<sub>50</sub> >2000 mg/kg bw); no studies are available for acute inhalation toxicity (depending on the outcome of the data gap for vapour pressure an acute inhalation study might be required). It is a skin irritant (classification as **Xi, R38 "Irritating to skin"** was proposed). It is neither an eye irritant nor a skin sensitiser. The relevant short-term No Observed Adverse Effect Level (NOAEL) is 50 mg/kg bw/day based on a general deterioration in health in a 90-day study in rats (reduced grip strength, increase in serum phosphorus and calcium, increased liver weight and kidney effects at 1000 mg/kg bw/day). Methyl nonyl ketone did not show any genotoxic potential in two *in vitro* tests. As for long-term toxicity and carcinogenicity, no original studies were submitted, however, based on data from the open literature the only relevant effect recorded is nephropathy in male rats (including adenomas and adenocarcinomas), whose non-relevance for humans is known. No specific data were submitted for reproductive toxicity, however, based on the available information no concern was raised. Based on the representative uses, there is no need to set an Acceptable Daily Intake (ADI) or an Acute Reference Dose (ARfD). The Acceptable Operator Exposure Level (AOEL) of 0.5 mg/kg bw/day was based on the relevant short-term toxicity NOAEL with the application of an uncertainty factor of 100.



Operator exposure was below the AOEL (about 1%) with the use of gloves (which is a default in the PHED model used) however, even without the use of Personal Protective Equipment (PPE) the estimated exposure is likely to be below the AOEL. Amateur and bystander exposure is below the AOEL (about 10%).

### 3. Residues

The representative use of methyl nonyl ketone is as a dog and cat repellent in home and amateur gardens on concrete, paving, around lawns and around plant beds and vegetable patches. Contact to food or feed crops must be avoided. Therefore no significant residues in plant or animal matrices are expected when applied under the defined conditions. Data to address the nature and magnitude of residues in food of plant and animal origin are not required for this use, and a quantitative consumer risk assessment is not required.

### 4. Environmental fate and behaviour

The information available was not sufficient to permit an appropriate assessment of the fate and behaviour of methyl nonyl ketone in the environment. Part of the data provided were based on studies which were not included in the submission dossier but were derived from conclusions of other organisations (i.e. US EPA RED document or EU biocide assessment report). Consequently data gaps were identified for the route and rate of degradation in soil and the aquatic environment and predicted environmental concentrations (PEC) in surface water and groundwater for the active substance and any potentially formed degradation products. A data gap was also identified for the adsorption/desorption properties of the active substance. The active substance is not readily biodegradable. Initial PECs in soil for methyl nonyl ketone were appropriately calculated by the RMS assuming no degradation of the active substance. Surface water and sediment exposure assessments were carried out for methyl nonyl ketone using the FOCUS (FOCUS, 2001) steps 1-3 approach<sup>15</sup> (refer to Addendum to Vol. 3 section B8, dated April 2011 (Belgium, 2011)). Although the results can not be considered valid because of the use of an unacceptable adsorption value ( $K_{oc} = 2480 \text{ mL/g}$ ) and an unacceptable  $DT_{50\text{soil}}$  ( $=6.54 \text{ days}$ ), there are indications that there is a risk for aquatic organisms in some scenarios (refer to section 5). Similarly, PEC groundwater calculations with the model PEARL 3.3.3<sup>16</sup>, based on a conservative  $DT_{50\text{soil}}$  ( $=1000 \text{ days}$ ) and on an unacceptable adsorption value ( $K_{oc} = 2480 \text{ mL/g}$ ), indicated that there is a potential for groundwater exposure in some FOCUS groundwater scenarios.

### 5. Ecotoxicology

The representative use of methyl nonyl ketone is as an animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches, where the product is scattered on concrete and on paving around lawns and plant beds to protect plants.

Based on the available data it was not possible to assess the compliance of the batches tested with the proposed specification (both missing).

No studies have been carried out to test the toxicity of methyl nonyl ketone to birds. According to the representative uses, the treated area is limited and as a consequence the exposure to birds and mammals may be considered negligible. Therefore, further data are not required. The RMS provided an evaluation of the risk for birds and mammals based on the calculation of  $LD_{50}/m^2$ . The  $LD_{50}$  values were derived from EPA reports. The original studies were not available in the dossier, therefore it was not possible to validate these endpoints. The  $LD_{50}/m^2$  approach, although proposed as an alternative approach for the first tier risk assessment in the opinion of EFSA 2008a, was not retained in the guidance document EFSA 2009. The lack of Annex VI trigger values for such an approach makes the interpretation of the results difficult. Overall, taking into account the limited treated area and the

<sup>15</sup> Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

<sup>16</sup> Simulations complied with EFSA (EFSA, 2004) and correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

repellent properties of methyl nonyl ketone against terrestrial vertebrates, it can be concluded that the risk to birds and mammals is low for the representative uses. The risk to birds and mammals would need to be further addressed if the active substance is applied in a more extensive way.

Toxicity studies on aquatic organisms were not submitted in the dossier, except for *Daphnia* and algae. The RMS proposed some endpoints for fish based on EPA reports, however the original studies were not available in the dossier, and therefore it was not possible to validate the endpoints. A data gap was identified to provide acute toxicity studies for fish to fulfil the Annex II data requirements. Based on the available toxicity data, methyl nonyl ketone is very toxic to aquatic organisms. The lower endpoint was observed in the study on *Daphnia magna* ( $EC_{50} = 0.23$  mg a.s. /L). The  $PEC_{sw}$  values were not considered valid in the fate and behaviour section (see section 4), and therefore, a data gap was identified for a new aquatic risk assessment.

No studies on the toxicity of methyl nonyl ketone to earthworms and other soil macro- and micro-organisms are available. Since methyl nonyl ketone is applied to the soil surface, even if only in limited areas, the exposure to soil-living organisms could not be excluded (see section 4). Therefore, a data gap has been identified to further address the risk to soil-living organisms.

No studies with bees, non-target arthropods, non-target plants and biological methods for sewage treatment, were available. According to the GAP, methyl nonyl ketone is not applied directly onto plants and the treated areas are limited, therefore the exposure to those non-target organisms (except soil non-target arthropods) can be deemed negligible and no further data are required. Overall, it can be concluded that the risk to bees, non-target arthropods (except soil non-target arthropods), non-target plants and biological methods for sewage treatment, is low for the representative uses.



## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
methyl nonyl ketone <sup>(a)</sup>	Data not available, data required	Data gap identified to further address the risk to soil-living organisms.

(a): Provisional only as a data gap has been identified for the route of degradation in the soil compartment.

### 6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
methyl nonyl ketone <sup>(a)</sup>	Data not available, data required	Data not available, data required <sup>(b)</sup>	Yes	Yes	Methyl nonyl ketone is very toxic to aquatic organisms. Acute effects on <i>Daphnia magna</i> (EC50 = 0.23 mg a.s. /L) were driving the risk assessment. The risk assessment could not be finalised for aquatic organisms.

(a): Provisional only as a data gap has been identified for the route of degradation in the soil compartment.

(b): EFSA's reading of the Council Directive 98/83/EC on the quality of drinking water intended for human consumption is, that as a repellent, methyl nonyl ketone is not considered a pesticide under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision making criteria regarding groundwater exposure, does not apply. However a consumer risk assessment would need to be carried out if in the future groundwater exposure is not excluded. Currently an ADI is not set.

### 6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
methyl nonyl ketone <sup>(a)</sup>	Methyl nonyl ketone is very toxic to aquatic organisms. Acute effects on <i>Daphnia magna</i> (EC50 = 0.23 mg a.s. /L) were driving the risk assessment. The risk assessment could not be finalised for aquatic organisms.

(a): Provisional only as a data gap has been identified for the route of degradation in the soil and water compartments.

### 6.4. Air

Compound (name and/or code)	Toxicology
Methyl nonyl ketone	No data available on inhalation toxicity

## 7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Revised specification with supporting batch data and validated methods of analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown, new data are stated to be available; see section 1).
- Further information/data on the method of manufacture and the starting materials (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Flash point, surface tension, vapour pressure, Henry's law constant, appearance, spectra, hydrolysis, photolysis, auto-flammability and surface tension of the active substance (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Water solubility, solubility in organic solvents and octanol water partition co-efficient (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown, data are stated to be available; see section 1).
- Data to demonstrate that the product can be applied successfully such that it can be applied evenly and the correct application rate can be achieved (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Flash point, accelerated storage and shelf-life for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Methods of analysis for the active substance in the technical material and formulated product (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Methods of analysis for soil, water and air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Satisfactory information to address the route and potential transformation product formation in soil (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Rate of degradation of the active substance under aerobic conditions in four soil types and for potential transformation products in three soil types (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Satisfactory information to address the soil photolysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Satisfactory information to address the soil adsorption/desorption of the active substance and the potential transformation products (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Satisfactory information to address the fate and behaviour of the active substance in water: hydrolytic degradation, photochemical degradation and degradation in the water/sediment system (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).

- Assessments of the potential for surface and groundwater exposure from the active substance and the potential degradation products (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Acute toxicity studies for fish to fulfil the Annex II data requirements (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- A new risk assessment for the aquatic organisms based on valid PEC<sub>sw</sub> values (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Further data are needed to address the risk to soil-living organisms (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).

## 8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- The product should not be placed where food or feed could become contaminated, i.e. only around vegetable patches and at a safe distance from the plants.

## 9. Concerns

### 9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. Information on the fate and behaviour of the active substance in soil and natural sediment water systems such that the route of degradation can be determined is not available. Consequently the environmental risk assessment and groundwater exposure assessment for the active substance as well as for any degradation products potentially formed could not be finalised.
2. The aquatic risk assessment could not be finalised.
3. The risk assessment for soil-living organisms could not be finalised.

### 9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

4. There is no information available on the specification of the material tested in the mammalian toxicology and ecotoxicology studies. Furthermore, the technical specification is currently open.

### 9.3. Overview of the concerns for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

In addition to the concerns indicated, all columns are grey as there is no information available on the specification of the material tested in the mammalian toxicology and ecotoxicology studies, and the technical specification is currently open.

Representative use		Animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X <sup>3</sup>
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X <sup>2</sup>
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	X <sup>1</sup>
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L <sup>(a)</sup> breached	
	Assessment not finalised	X <sup>1</sup>
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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## APPENDICES

### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

#### Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

##### Identity, Physical and Chemical Properties

Active substance (ISO Common Name) ‡

methyl nonyl ketone (there is no ISO common name for this active substance)

Function (*e.g.* fungicide)

Repellent

Rapporteur Member State

Belgium

##### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡

Undecan-2-one

Chemical name (CA) ‡

2-Undecanone

CIPAC No ‡

not applicable

CAS No ‡

112-12-9

EEC No (EINECS or ELINCS) ‡

203-937-5

FAO Specification (including year of publication)‡

no FAO specification exists

Minimum purity of the active substance as manufactured (g/kg) ‡

Open

Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)

Open

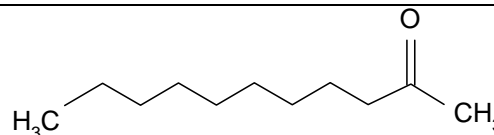
Molecular formula ‡

C<sub>11</sub>H<sub>22</sub>O

Molecular mass ‡

170.29 u

Structural formula ‡





**Physical-chemical properties** (Annex IIA, point 2)

Melting point (state purity) ‡	freezing point : 12.2°C (99.5%)
Boiling point (state purity) ‡	235.5°C (99.5%)
Temperature of decomposition	not applicable
Appearance (state purity) ‡	Open
Vapour pressure (in Pa, state temperature) ‡	Open
Henry's law constant (Pa m <sup>3</sup> mol <sup>-1</sup> ) ‡	Open
Solubility in water (g/l or mg/l, state temperature) ‡	Open
Solubility in organic solvents (in g/l or mg/l, state temperature) ‡	Open
Surface tension ‡	Open
Partition co-efficient (log P <sub>OW</sub> ) (state pH and temperature) ‡	Open
Dissociation constant ‡	Not applicable (no dissociation in water occurs)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡	Open
Flammability ‡	Open
Explosive properties ‡	No explosive properties
Oxidising properties ‡	No oxidising properties

### Summary of uses supported by available data (methyl nonyl ketone)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Animal repellent for plant protection purposes. Protection of home garden and amenity grass, ornamentals and vegetable patches	EU	Get Off My Garden Scatter Crystals	F/G/I	Cats, dogs, foxes and rabbits.	GW	17.0 g/l	Spreading	Not applicable	Several 10/year	2–3 days	Not applicable	Not applicable	1.5 kg as/ha	Not applicable	application only around lawns or around plant beds; application to food crop should be avoided.
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<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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## Methods of Analysis

### Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	Open
Impurities in technical as (principle of method)	Open
Plant protection product (principle of method)	Open

### Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	No data available, no data required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No data available, no data required
Soil (principle of method and LOQ)	Open
Water (principle of method and LOQ)	Open
Air (principle of method and LOQ)	Open
Body fluids and tissues (principle of method and LOQ)	no method required : a.s. is not classified as T or T+

### Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None
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## Impact on Human and Animal Health

### Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption:	Kinetic parameters in human and data from other ketones in rats suggest that absorption of ketones is important and rapid (peak blood level within 1-2 h after dosing)
Distribution:	No specific data for methyl nonyl ketone; data with other ketones show a distribution reaching liver and lung
Potential for accumulation:	No data provided
Rate and extent of excretion:	No specific data for methyl nonyl ketone; data with other ketones show urinary and biliary excretion as glucuronic acid ; exhalation plays also a role for excretion of unchanged compound
Metabolism in animals	General info for aliphatic linear ketones: efficient metabolic detoxification via reduction to the corresponding secondary alcohol which is further glucuronoconjugated. Omega-oxidation is important at high concentrations.
Toxicologically significant compounds (animals, plants and environment)	Parent compound

### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral	> 2000 mg/kg bw
Rat LD <sub>50</sub> dermal	>2000 mg/kg bw
Rat LC <sub>50</sub> inhalation	No data, possible data gap based on the outcome of vapour pressure study (data gap in phys-chem)
Skin irritation	Irritating <b>Xi, R38</b>
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Not sensitiser ( M&K test not sensitiser )

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	General deterioration in health (reduced grip strength, increase in serum P and Ca, increased liver weight and kidney effects at 1000 mg/kg bw/day)
Lowest relevant oral NOAEL / NOEL	50 mg/kg bw/day ; 90 day rat study
Lowest relevant dermal NOAEL / NOEL	No data, not necessary

### Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential
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### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	-
Lowest relevant NOAEL / NOEL	-
Carcinogenicity	No specific data for methyl nonyl ketone; data with other ketones show no carcinogenic potential relevant to humans

### Reproductive toxicity (Annex IIA, point 5.6)

#### Reproductive toxicity

Reproduction target / critical effect ‡	No specific data for methyl nonyl ketone; data with other ketones show no reproductive/developmental potential	
Relevant parental NOAEL ‡	-	
Relevant reproductive NOAEL ‡	-	
Relevant offspring NOAEL ‡	-	

#### Developmental toxicity

Developmental target / critical effect ‡	No specific data for methyl nonyl ketone; data with other ketones show no reproductive/developmental potential	
Relevant maternal NOAEL ‡	-	
Relevant developmental NOAEL ‡	-	

### Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Not neurotoxic.
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### Other toxicological studies (Annex IIA, point 5.8)

None
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### Medical data (Annex IIA, point 5.9)

No incidents of poisoning have been reported in employees
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**Summary** (Annex IIA, point 5.10)

	Value	Study	Assessment factor
ADI	Not necessary		
AOEL	0.5 mg/kg bw/day	90 day rat study	100
ARfD (acute reference dose)	Not necessary		

**Dermal absorption** (Annex IIIA, point 7.3)

No data, default value of 100% proposed by the notifier.

**Acceptable exposure scenarios** (including method of calculation)

Operator	Puffer pack model (UK, amateurs): <b>8.5%</b> of the AOEL PHED (operators): 1.05% (95 <sup>th</sup> percentile, use of gloves*)
Workers	Not relevant
Bystanders	S. Martin et al., (June 2008 ) : <b>1.27%</b> of the AOEL
Residents	Adults: <b>1.27%</b> of the AOEL Children: <b>9.5%</b> of the AOEL

\*the use of gloves is a default in the PHED model used; however, even without the use of PPE the estimated exposure is likely to be below the AOEL

**Classification and proposed labelling with regard to toxicological data** (Annex IIA, point 10)

RMS/peer review proposal
<b>Xi, R38</b> Irritating to skin



## Residues

Based on the representative use pattern, residues on food and feed are not expected. A quantitative risk assessment for consumer is not required.

### Justification:

The formulation is a dog and cat repellent for plant protection purposes. The compound should only be used in home and in amateur gardens on concrete, paving and around lawns and around plant beds and vegetable patches. Direct and indirect contact to food or feed crops should be avoided. No residues on food or feed are expected when the product is applied under these restrictive conditions.

### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Not available
Rotational crops	Not available
Plant residue definition for monitoring	Not available
Plant residue definition for risk assessment	Not available
Conversion factor (monitoring to risk assessment)	Not available

### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not available
Animal residue definition for monitoring	Not available
Animal residue definition for risk assessment	Not available
Conversion factor (monitoring to risk assessment)	Not available
Metabolism in rat and ruminant similar (yes/no)	Not available
Fat soluble residue: (yes/no)	Not available

### Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Not available
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### Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Not available
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### Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock $\geq 0.1$ mg/kg diet/day:	Ruminant: Yes/no	Poultry: Yes/no	Pig: Yes/no
Muscle	Not available	Not available	Not available
Liver			
Kidney			
Fat			
Milk			
Eggs			

**Summary of critical residues data** (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern Europe	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL (mg/kg)	STMR (mg/kg) (b)
Not available					

(a) : Number of trials in which particular residue levels were reported.

(b) : Supervised Trials Median Residue : The median residue level estimated on the basis of supervised trials relating to the critical GAP

**Consumer risk assessment** (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not necessary
TMDI (European Diet) (% ADI)	Not available
NEDI (% ADI)	Not available
Factors included in NEDI	Not available
ARfD	Not necessary
Acute exposure (% ARfD)	Not available

**Processing factors** (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not available			

**Proposed MRLs** (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Not available
---------------

## Fate and Behaviour in the Environment

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡

Non-extractable residues after 100 days ‡

Relevant metabolites - name and/or code, % of applied (range and maximum) ‡


### Data gap on the route of degradation (aerobic) in soil

#### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Soil photolysis ‡

Not required. It is not expected that the a.s. would be exposed to anaerobic conditions (spreading of granules on soil surface)
Data gap

#### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation

Laboratory studies (range or median, with n value, with  $r^2$  value) ‡

Field studies (state location, range or median with n value) ‡

Soil accumulation and plateau concentration ‡


### Data gap on the rate of degradation in soil

#### Soil adsorption/desorption (Annex IIA, point 7.1.2)

$K_f / K_{oc}$  ‡

$K_d$  ‡

pH dependence (yes / no) (if yes type of dependence) ‡

Data gap
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#### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡

Aged residues leaching ‡

Lysimeter/ field leaching studies ‡

Not required
Not required
Not required

**PEC (soil)** (Annex IIIA, point 9.1.3)

Method of calculation

No degradation assumed

Application rate

Crop: home and in amateur gardens on concrete, paving and around lawns and plant beds  
Application to bare soil; no plant interception  
Number of applications: 10 (exaggerated worst case)  
Interval (d): 10 applications at the same time  
Application rate(s): 1.5 kg as/ha

**PEC<sub>(s)</sub>**  
mg a.s./kg soil

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
20.0000	-		

**Route and rate of degradation in water** (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT<sub>50</sub>) (state pH and temperature) ‡

Data gap

Photolytic degradation of active substance and Relevant metabolites ‡

Data gap

Readily biodegradable (yes/no) ‡

Not readily biodegradable.

Degradation in - DT<sub>50</sub> water ‡  
water/sediment - DT<sub>90</sub> water ‡

Data gap

- DT<sub>50</sub> whole system ‡  
- DT<sub>90</sub> whole system ‡

Mineralization

Data gap

Non-extractable residues

Data gap

Distribution in water / sediment systems (active substance) ‡

Data gap

Distribution in water / sediment systems (metabolites) ‡

Data gap

**PEC (surface water and sediment)** (Annex IIIA, point 9.2.3)

**Data gap**

Method of calculation

Application rate

Main routes of entry


**PEC (ground water)** (Annex IIIA, point 9.2.1)

**Data gap**

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter )

Application rate


**Fate and behaviour in air** (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡

Quantum yield of direct phototransformation

Photochemical oxidative degradation in air ‡

Volatilization ‡

Not required
Not available
<p>The photochemical oxidative degradation of MNK was estimated using the computer program AOP (method based on SAR as developed by Atkinson):</p> <p>→ estimated photochemical-oxidative half-life with respect to bimolecular reaction with OH-radicals = 9.284 hours (12-hrs-day) (based on an average OH-concentration of <math>1.5 \times 10^6</math> OH/cm<sup>3</sup> during daylight)</p> <p>The only significant reaction is the abstraction of H-atoms.</p> <p>Reaction rate of MNK with ozone was not estimated, as no double or triple bonds are present in the chemical structure of MNK.</p> <p>⇒ MNK is not persistent in the atmosphere.</p> <p>from plant surfaces: ‡ not relevant</p> <p>from soil: ‡ not available</p>

**PEC (air)**

Method of calculation

Not required
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**PEC<sub>(a)</sub>**

Maximum concentration

Not required
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**Definition of the Residue** (Annex IIA, point 7.3)

Residues requiring further assessment  
Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.

<p>Soil : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in soil compartment)</p> <p>Surface water : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in soil and in water compartments)</p> <p>Sediment : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in water compartment)</p> <p>Groundwater : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in soil compartment)</p> <p>Air : methyl nonyl ketone</p>
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**Monitoring data, if available** (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

**Classification and proposed labelling** (Annex IIA, point 10)

with regard to fate and behaviour data	R53
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## Effects on Non-target Species

### Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	No reliable data available. No further data required.
Reproductive toxicity to mammals ‡	No reliable data available. No further data required.
Acute toxicity to birds ‡	No reliable data available. No further data required.
Dietary toxicity to birds ‡	No reliable data available. No further data required.
Reproductive toxicity to birds ‡	Not required.

### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger

### Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2) ‡

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
‡ <i>Oncorhynchus mykiss</i>	Active substance			No reliable data available. Data gap.
‡ <i>Lepomis macrochirus</i>	Active substance			No reliable data available. Data gap.
‡ <i>Daphnia magna</i>	Active substance	48 hours	EC <sub>50</sub>	<b>0.23 mg a.s./L</b> (mm)
<i>Pseudokirchneriella subcapitata</i>	Active substance	48 hours	E <sub>b</sub> C <sub>50</sub> E <sub>r</sub> C <sub>50</sub>	< <b>0.25 mg a.s./L</b> (mm) 0.73 mg a.s./L (mm)
		72 hours	E <sub>b</sub> C <sub>50</sub> E <sub>r</sub> C <sub>50</sub>	0.29 mg a.s./L (mm) 0.143 mg a.s./L (mm)
Microcosm or mesocosm tests				
Not required.				

## Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

### FOCUS step 2

Toxicity Exposure Ratios (TERs) for aquatic organisms exposed to methyl nonyl ketone in surface water for use in garden (10 x 1.5 kg a.s./ha) based on FOCUS step 2 calculations

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC <sub>ini</sub> (µg/L)	PEC <sub>twa</sub> (µg/L)	TER	Annex VI Trigger
Methyl nonyl ketone							
	<i>Daphnia magna</i>	0.23	48 h				100
	<i>Pseudokirchneriella subcapitata</i>	< 0.25	48 h				10

### FOCUS step 3

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to methyl nonyl ketone in surface water for use in garden (10 x 1.5 kg a.s./ha) based on FOCUS step 3 calculations. Data gap.

Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC <sub>sw</sub> (µg/L)	TER	Trigger
D1	ditch	<i>Daphnia magna</i>	48 h	0.23			100
	stream						100
D2	ditch						100
	stream						100
D3	ditch						100
D4	pond						100
	stream						100
D5	pond						100
	stream						100
R2	stream						100
R3	stream						100
D1	ditch	<i>Pseudokirchneriella subcapitata</i>	48 h	< 0.25			10
	stream						10
D2	ditch						10
	stream						10
D3	ditch						10
D4	pond						10
	stream						10
D5	pond						10
	stream						10

R2	stream						10
R3	stream						10

### Bioconcentration

Bioconcentration factor (BCF) ‡	Not required.
Annex VI Trigger for the bioconcentration factor	Not required.
Clearance time (CT <sub>50</sub> )	Not required.
(CT <sub>90</sub> )	Not required.
Level of residues (%) in organisms after the 14 day depuration phase	Not required.

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	Not required.
Acute contact toxicity ‡	Not required.

### Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
Get Off My Garden Scatter Crystals is an animal repellent and is generally scattered on concrete, paving, around lawns and plant beds to protect plants from damage. It is not applied directly onto plants where bees are likely to be foraging. Therefore, potential exposure of bees to methyl nonyl ketone is expected to be low and the risk to bees is concluded to be low.				
Field or semi-field tests				
Not required.				

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5) ‡

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
Get Off My Garden Scatter Crystals is an animal repellent and is generally scattered on concrete, paving, around lawns and plant beds to protect plants from damage. It is not applied directly onto plants. The product is applied on limited surface areas. Therefore, it is considered that the actual exposure is negligible and the risk to non-target arthropods is concluded to be low, except for soil-living non-target arthropods where a data gap has been identified..						
Field or semi-field tests						
Not required.						

### Effects on earthworms and other soil macro-organisms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡

Reproductive toxicity ‡


### Toxicity/exposure ratios for earthworms and other soil macro-organisms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
Data gap				

### Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡

Carbon mineralization ‡

Data gap
Data gap

### Effects on other non-target organisms (flora and fauna) (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Get Off My Garden Scatter Crystals is an animal repellent and is generally scattered on concrete, paving, around lawns and plant beds to protect plants from damage. It is not applied directly onto plants. The product is applied on limited surface areas. Therefore, it is considered that the actual exposure is negligible and the risk to non-target plants is concluded to be low.

### Effects on biological methods for sewage treatment (Annex IIA, point 8.7)

EC<sub>50</sub> (3 h) = 379.49 mg a.s./L

### Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data

N, R50 for the active substance R52 for the formulation
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## ABBREVIATIONS

1/n	slope of Freundlich isotherm
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EPA RED	Environmental Protection Agency Reregistration Eligibility Decision
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography

GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GLP	Good laboratory practice
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K <sub>doc</sub>	organic carbon linear adsorption coefficient
kg	kilogram
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC <sub>50</sub>	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level

OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year