

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance methyl nonyl ketone ¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Methyl nonyl ketone is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004³, as amended by Commission Regulation (EC) No 1095/2007⁴.

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 1107/2009⁵, in accordance with Commission Implementing Regulation (EU) No 540/2011⁶, as amended by Commission Implementing Regulation (EU) No 541/2011⁷. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010⁸, 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.

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

² Correspondence: pesticides.peerreview@efsa.europa.eu

³ OJ L 379, 24.12.2004, p.13

⁴ OJ L 246, 21.9.2007, p.19

⁵ OJ L 309, 24.11.2009, p.1

⁶ OJ L 153, 11.6.2011, p.1

⁷ OJ L 153, 11.6.2011, p.187

⁸ OJ L 37, 10.2.2010, p.12

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance methyl nonyl ketone. EFSA Journal 2012;10(1):2495. [36 pp.] doi:10.2903/j.efsa.2012.2495. Available online: www.efsa.europa.eu/efsajournal



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 c	ontents	3					
Backgrou	nd	4					
The active	e substance and the formulated product	6					
Conclusio	ns of the evaluation	6					
1. Iden	tity, physical/chemical/technical properties and methods of analysis	6					
2. Man	nmalian toxicity	6					
3. Resi	dues	7					
4. Envi	ronmental fate and behaviour	7					
5. Ecot	oxicology	7					
6. Over	rview of the risk assessment of compounds listed in residue definitions triggering assess	sment					
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. Parti	cular conditions proposed to be taken into account to manage the risk(s) identified	12					
9. Cond	cerns	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					
Reference	s	14					
Appendic	Appendices 1						
Abbreviat	ions	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 2229/2004⁹, as amended by Commission Regulation (EC) No 1095/2007¹⁰.

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 1107/2009¹¹, in accordance with Commission Implementing Regulation (EU) No 540/2011¹², as amended by Commission Implementing Regulation (EU) No 541/2011¹³. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010¹⁴ 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 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

⁹ OJ L 379, 24.12.2004, p.13

¹⁰ OJ L 246, 21.9.2007, p.19

¹¹ OJ L 309, 24.11.2009, p.1

¹² OJ L 153, 11.6.2011, p.1

¹³ OJ L 153, 11.6.2011, p.187

¹⁴ 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 LD50 >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 approach¹⁵ (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 (Koc = 2480 mL/g) and an unacceptable DT_{50} soil (=6.54 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 3.3.3¹⁶, based on a conservative DT_{50} soil (= 1000 days) and on an unacceptable adsorption value (Koc = 2480 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 LD50/m². The LD₅₀ 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 LD50/m² 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

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

¹⁶ 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* (EC₅₀ = 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 microorganisms 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 ^(a)	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 ^(a)	Data not available, data required	Data not available, data required ^(b)	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 $0.1\mu g/L$ 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 ^(a)	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 PECsw 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 us	e	Animal repellent for the protection of home garden and amenity grass, ornamentals and vegetable patches
	Risk identified	
Operator risk	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	Risk identified	
vertebrates	Assessment not finalised	
Risk to wild non	Risk identified	
target terrestrial organisms other than vertebrates	Assessment not finalised	X ³
Risk to aquatic	Risk identified	
organisms	Assessment not finalised	X^2
Groundwater exposure active	Legal parametric value breached	
substance	Assessment not finalised	X^1
	Legal parametric value breached	
Groundwater exposure metabolites	Parametric value of 10µg/L ^(a) breached	
	Assessment not finalised	X^1
Comments/Reman	·ks	

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



REFERENCES

- Belgium, 2006. Draft Assessment Report (DAR) on the active substance methyl nonyl ketone prepared by the rapporteur Member State Belgium in the framework of Directive 91/414/EEC, September 2006.
- Belgium, 2011. Final Addendum to Draft Assessment Report on methyl nonyl ketone, compiled by EFSA, May 2011.
- EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models comparability and the consistency of this risk assessment of groundwater contamination. The EFSA Journal (2004) 93, 1-20.
- EFSA (European Food Safety Authority), 2007. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.
- EFSA (European Food Safety Authority), 2008.Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals, Adopted on 17 June 2008, *The EFSA Journal* (2008) 734: 1-181.
- EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438.
- EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance methyl nonyl ketone.
- European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.
- European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.
- European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.
- European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.
- European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.
- European Commission, 2004. Guidance document on Dermal Absorption. SANCO/22/200 rev. 7, 19 March 2004.
- European Commission, 2008. Review Report for the active substance methyl nonyl ketone finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of methyl nonyl ketone in Annex I of Directive 91/414/EEC SANCO/2619/08 rev. 1, 6 August 2008.
- FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.



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

Function (*e.g.* fungicide)

Rapporteur Member State

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

Belgium

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

Chemical name (IUPAC) ‡

Chemical name (CA) ‡

CIPAC No ‡

CAS No ‡

EEC No (EINECS or ELINCS) ‡

FAO Specification (including year of publication):

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

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

Molecular formula ‡

Molecular mass ‡

Structural formula ‡

Undecan-2-one2-Undecanonenot applicable112-12-9203-937-5no FAO specification existsOpenOpenOpenC11H22O170.29 u H_3C OH<



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

Physical-chemical properties (Annex IIA, point 2)



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

Crop and/ or situation	Product name	F G or I	Pests or Group of pests controlled	Form	ılation		AI	oplication		Applicatio	on rate per	treatment	PHI (days)	Remarks:
(a)		(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	min max	interval between applications (min)	U U	water L/ha min max	0	(1)	(m)

Animal repellent for	EU	Get Off My	Cats, dogs, foxes and rabbits.	17.0 g/l	Spreading	Not applicable	Several 10/year	2-3 days	Not applicable	Not applicable	1.5 kg as/ha	Not applica	application only around lawns or around plant beds; application to
plant		Garden		C			,					ble	food crop should be avoided.
protection		Scatter											
purposes.		Crystals											
Protection of													
home garden													
and amenity													
grass,													
ornamentals													
and vegetable													
patches													

(a)	For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the	(i)	g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for
	use situation should be described (e.g. fumigation of a structure)		the variant in order to compare the rate for same active substances used in different variants (e.g.
(b)	Outdoor or field use (F), greenhouse application (G) or indoor application (I)		fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to
(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		3-8263-3152-4), including where relevant, information on season at time of application
(f)	All abbreviations used must be explained	(k)	Indicate the minimum and maximum number of application possible under practical conditions of use
(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(1)	The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha
(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of		instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
	equipment used must be indicated	(m)	PHI - minimum pre-harvest interval



Methods of Analysis

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

Technical as (principle of method)
Impurities in technical as (principle of method)

Open			
Open			
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)

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)

Soil (principle of method and LOQ)

Water (principle of method and LOQ)

Air (principle of method and LOQ)

Body fluids and tissues (principle of method and LOQ)

No data available, no data required
No data available, no data required
Open
Open
Open
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



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 othe 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 ₅₀ oral	> 2000 mg/kg bw	
Rat LD ₅₀ dermal	>2000 mg/kg bw	
Rat LC_{50} inhalation	No data, possible data gap based on the outcome of vapour pressure study (data gap in phys-chem)	
Skin irritation	Irritating Xi, R38	
Eye irritation	Not irritating	

Skin sensitization (test method used and result)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect

Lowest relevant oral NOAEL / NOEL Lowest relevant dermal NOAEL / NOEL

Genotoxicity (Annex IIA, point 5.4)

Not sensitiser (M&K test not sensitiser)

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)

50 mg/kg bw/day ; 90 day rat study

No data, not necessary

No genotoxic potential



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 ‡

Relevant parental NOAEL ‡

Relevant reproductive NOAEL ‡

Relevant offspring NOAEL **‡**

Developmental toxicity

Developmental target / critical effect ‡

Relevant maternal NOAEL ‡

Relevant developmental NOAEL ‡

No specific data for methyl nonyl ketone; data with other ketones show no reproductive/developmental potential	
-	
-	
-	

No specific data for methyl nonyl ketone; data	
with other ketones show no	
reproductive/developmental potential	
-	
-	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Not neurotoxic.

Other toxicological studies (Annex IIA, point 5.8)

None

Medical data (Annex IIA, point 5.9)

No incidents of poisoning have been reported in employees



Summary (Annex IIA, point 5.10) Value Study

			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.

Assessment

Acceptable exposure scenarios (including method of calculation)

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

<u>*</u>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

Xi, R38 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 <u>around</u> lawns and <u>around</u> 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

.....

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

Not available

Ruminant:

Poultry:

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:

Yes/noYes/noYes/noMuscleNot availableNot availableNot availableLiverKidney---Fat----Milk----Eggs----

Pig:



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

Сгор		Trials results relevant to the critical GAP (a)	Recommendation/comments	STMR (mg/kg) (b)
Not availa	ıble			

(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



on soil surface)

Data gap

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

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 ‡

Rate of degradation in soil (Annex IIA, point 7.1.1.2,

Method of calculation

Laboratory studies (range or median, with n value, with r^2 value) \ddagger

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} ‡

 $K_d \ddagger$ pH dependence (yes / no) (if yes type of dependence) ‡

Mobility in	soil (Annex	IIA, point	7.1.3, Annex	IIIA, point 9.1	.2)
	``	/ 1	,	/ 1	

Column leaching ‡

Aged residues leaching ‡

Lysimeter/ field leaching studies ‡

, Annex IIIA, point 9.1.1)	

Data gap

EFSA Journal 2012;10(1):2495

Not required Not required

Not required

Not required. It is not expected that the a.s. would be exposed to anaerobic conditions (spreading of granules



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 _(s) mg a.s./kg soil		Single application Time weighted	Multiple application Actual	Multiple application Time weighted	
Initial	20.0000	average -		average	

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡ Photolytic degradation of active substance and Relevant metabolites ‡	Data gap Data gap
Readily biodegradable (yes/no) ‡	Not readily biodegradable.
Degradation in $-DT_{50}$ water ‡ water/sediment $-DT_{90}$ water ‡	Data gap
 DT₅₀ whole system ‡ DT₉₀ 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 ‡	Not required
Quantum yield of direct phototransformation	Not available
Photochemical oxidative degradation in air ‡	The photochemical oxidative degradation of MNK was estimated using the computer program AOP (method based on SAR as developed by Atkinson): → 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 1.5 x 10 ⁶ OH/cm ³ during daylight) The only significant reaction is the abstraction of H- atoms. Reaction rate of MNK with ozone was not estimated, as
	no double or triple bonds are present in the chemical structure of MNK.
Volatilization ‡	$\Rightarrow MNK \text{ is not persistent in the atmosphere.}$ from plant surfaces: \ddagger not relevant
	from soil: ‡not available
PEC (air)	
Method of calculation	Not required
PEC _(a)	

Maximum concentration

Not required

Definition of the Residue (Annex IIA, point 7.3)

Residues requiring further assessment Soil : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in soil compartment) Environmental occurring residues requiring further assessment by other disciplines (toxicology and Surface water : methyl nonyl ketone (provisional, as a ecotoxicology) and or requiring consideration for data gap has been set for the route of degradation in soil groundwater exposure. and in water compartments) Sediment : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in water compartment) Groundwater : methyl nonyl ketone (provisional, as a data gap has been set for the route of degradation in soil compartment) Air : methyl nonyl ketone



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



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 ‡

Reproductive toxicity to mammals ‡

Acute toxicity to birds ‡

Dietary toxicity to birds ‡

Reproductive toxicity to birds ‡

No reliable data available. No further data re	equired.
No reliable data available. No further data re	equired.
No reliable data available. No further data re	equired.
No reliable data available. No further data re	equired.
Not required.	

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

Application rate (kg a.s./ha)	Сгор	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, poir	nt 10.2) ‡
------------------	------------

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
‡ Oncorhynchus mykiss	Active substance			No reliable data available. Data gap.
‡ Lepomis macrochirus	Active substance			No reliable data available. Data gap.
‡ Daphnia magna	Active substance	48 hours	EC ₅₀	0.23 mg a.s./L (mm)
Pseudokirchneriella subcapitata	Active substance	48 hours	$\begin{array}{c} E_b C_{50} \\ E_r C_{50} \end{array}$	< 0.25 mg a.s./L (mm) 0.73 mg a.s./L (mm)
		72 hours	$\begin{array}{c} E_b C_{50} \\ E_r C_{50} \end{array}$	0.29 mg a.s./L (mm) 0.143 mg a.s./L (mm)

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 _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
Methyl nonyl	Daphnia magna	0.23	48 h				100
ketone	Pseudokirchneriella subcapitata	< 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)	PECsw (µg/L)	TER	Trigger
D1	ditch						100
	stream						100
D2	ditch						100
	stream						100
D3	ditch						100
D4	pond	Daphnia magna	48 h	0.23			100
	stream						100
D5	pond						100
	stream						100
R2	stream						100
R3	stream						100
D1	ditch						10
	stream						10
D2	ditch						10
	stream						10
D3	ditch	Pseudokirchneriella subcapitata	48 h	< 0.25			10
D4	pond						10
	stream						10
D5	pond						10
	stream						10



.2	stream			
R3	stream			

Bioconcentration

Bioconcentration factor (BCF) ‡

Annex VI Trigger for the bioconcentration factor

Clearance time (CT_{50})

 (CT_{90})

Level of residues (%) in organisms after the 14 day depuration phase

Not required.	
Not required.	
Not required. Not required.	
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	Crop	Route	Hazard quotient	Annex VI
(kg as/ha)				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	Dose	Endpoint	Effect	Annex VI
1	C	Substance	(kg as/ha)	Ĩ		Trigger
Laboratory test	S					
around lawns a product is app negligible and	and plant beds blied on limited the risk to non-	to protect plant d surface areas	s from damage. . Therefore, it ds is concluded	It is not applie is considered t	attered on concrete, pa ed directly onto plants hat the actual expose pt for soil-living non-t	. The tre is

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)	Сгор	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 ‡	Data gap
Carbon mineralization ‡	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)

EC₅₀ (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

ABBREVIATIONS

1 /	
1/n	slope of Freundlich isotherm
3	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	
u -	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC_{50}	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_{50}	emergence rate/effective rate, median
ErC_{50}	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

efsa European Food Safety Authority	Peer Review of the pesticide risk assessment of the active substance methyl nonyl ketone
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 _{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K _{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	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 NOEL	no observed effect concentration no observed effect level
NULL	

efsa III European Food Safety Authority	Peer Review of the pesticide risk assessment of the active substance methyl nonyl ketone
ОМ	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in ground water
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pKa	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
\mathbf{r}^2	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 _{1/2}	half-life (define method of estimation)
TER	toxicity exposure ratio
TERA	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	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 UDS	time weighted average
UV	unscheduled DNA synthesis ultraviolet
W/S	water/sediment
w/v	weight per volume
w/v w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
vr yr	year
J =	y