

# **Decision on amending the MRLs for**

# **1,4-dimethylnaphthalene in products of animal origin**

**MRLs evaluated to support a new use in GB**

■ GB MRL Decision Number: GB MRL 2022/011

■ Date of entry into force: 3 August 2022



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# Background

## Competent authority

The risk assessment associated with amending the MRLs for Great Britain has been conducted by the Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE).

## Application

1,4-dimethylnaphthalene (1,4-DMN) is an approved active substance in Great Britain.

In accordance with Article 6 of Regulation (EC) No 396/2005,<sup>1</sup> HSE received an application from ERM on behalf of DormFresh Ltd to set new MRLs for 1,4-DMN in products of animal origin to accommodate a new authorisation on potatoes.

HSE as the competent authority drew up an Evaluation Report (ER) that included its Reasoned Opinion (RO) on the risk to consumers associated with amending the MRLs.

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<sup>1</sup> Retained [Regulation \(EC\) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales.

## Conclusion of the competent authority on the risk assessment

The competent authority concluded that the proposed use of 1,4-DMN on potatoes and the resulting residue levels in products of animal origin will not result in consumer exposures exceeding the toxicological reference value and therefore is unlikely to have harmful effects on human health.

Full details of the assessment, including the dietary exposure estimates and the list of endpoints, are outlined in the ER-RO (Application Reference Number COP 2020/00459): [Published new and raised GB MRLs list](#).

# Decision on the application to amend the MRLs

## Adoption of new endpoints for the residues assessment

In the course of evaluating the MRL application the competent authority recommended amending or establishing new endpoints, including the residue definitions for plants and animals. The endpoints outlined in Appendix D of the ER/RO, along with those established for the approval of the active substance, are now applicable in GB for the residues assessments when granting PPP authorisations and setting MRLs. Specifically for animals the residue definition for enforcement and risk assessment is:

- Sum of 1,4-dimethylnaphthalene, M23 (free and conjugated), expressed as 1,4-dimethylnaphthalene

(The molecular weight conversion to express M23 as 1,4-DMN is 0.84)

## Adoption of new MRLs

In accordance with Article 14 of Regulation (EC) No 396/2005, the MRLs outlined in Table 1 will be amended in the GB MRL Statutory Register.

## Supplementary information

The competent authority identified data gaps in the analytical method submitted for the enforcement and monitoring of residues in products of animal origin. The following points have been taken into account in deciding to set a data requirement for further information:

- The consumer risk assessment is complete and supports the new MRLs recommended for products of animal origin
- The data gaps do not relate to any data that has been generated or is required for the risk assessment
- The additional data will not impact the consumer risk assessment or impact the numerical levels of the MRLs calculated for products of animal origin
- The additional data is required for the analytical method that may be used by laboratories to check compliance of products of animal origin with the MRLs, and not the method required for the treated crop

- The additional data is not required to address a complete absence of data, it is to provide re-assurance/ confirmation on the analytical methods for monitoring residues in products of animal origin
- There is sufficient information/ data to be confident that laboratories will be able to analyse products of animal origin for 1,4-DMN and its metabolites
- In terms of monitoring and ensuring compliance with MRLs, the monitoring method for plants is fully validated and provided that residues in potatoes remain within the MRL there will be no concern that residues will exceed the new MRLs set for products of animal origin

Taking into account all the above points, in accordance with the provision of Article 14 of Regulation (EC) No 396/2005, it is appropriate in this specific case to allow supplementary information to be submitted after the MRLs are set in the GB MRL Statutory Register.

The following supplementary information must be provided to the competent authority:

- Validation data in accordance with SANTE/2020/12830 rev.1 for the method of analysis proposed as a monitoring method for the determination of residues in products of animal origin must be submitted. Validation data must be provided for milk, eggs, liver or kidney, muscle and fat matrices. The method should be validated for the agreed residue definition of 'Sum of 1,4-dimethylnaphthalene and M23 (free and conjugated) expressed as 1,4-dimethylnaphthalene'. The validation data should include the efficiency of the hydrolysis step and extraction efficiency. Suitable ILV data should be provided.

If it is not possible to address the above data requirement then the following additional data would be required to support the existing proposed monitoring methods:

1. A confirmatory method is required to support the monitoring method for the determination of 1,4-DMN and M23 in all relevant products of animal origin and for conjugated M23 in egg as the current proposed method utilising HPLC-FLD is not highly specific.

Validation data for the confirmatory method should be generated in accordance with the guidance SANTE/2020/12830, Rev 1.

2. The ILV for the determination of M23 in liver and kidney matrices is not considered satisfactorily validated as significant matrix interference was noted. In the report it is stated that for these matrices the average control response was subtracted from the fortification samples response; this is not considered acceptable as part of the ILV validation and as such HSE considers the ILV inconclusive for this metabolite/matrix combination. Further validation data to address this must be provided.

**The data must be provided by 31 August 2023.**



**Table 1 MRLs to be amended in the GB MRL Statutory Register**

| Product code   | Product   | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments   |
|--|---|-------------------------|-------------------------------|--|
| <b>Enforcement residue definition for products of plant origin: 1,4-dimethylnaphthalene (1,4-DMN)</b>  |   |                         |                               |  |
| No amendments required   |   |                         |                               |  |
| <b>Enforcement residue definition for products of animal origin: Sum of 1,4-dimethylnaphthalene and M23 (free and conjugated), expressed as 1,4-dimethylnaphthalene (except honey with MRL code 1040000 for which the residue definition for plants applies)</b> |   |                         |                               |  |
| 1011000  | Swine   |                         |                               |  |
| 1011010  | Muscle – Swine                                      | 0.01*                   | 0.03*                         | Data from ruminant feeding study on dairy cattle extrapolated to swine.<br><br>A risk to consumers is unlikely.        |
| 1011020  | Fat – swine   | 0.01*                   | 0.03*                         |  |
| 1011030  | Liver – swine                                       | 0.01*                   | 0.3                           |  |
| 1011040  | Kidney – swine                                      | 0.01*                   | 0.15                          |  |
| 1011050  | Edible offals (other than liver and kidney) – swine | 0.01*                   | 0.3                           |  |
| 1011990  | Other – swine                                       | 0.01*                   | 0.03*                         |  |
| 1012000  | Bovine  |                         |                               |  |
| 1012010  | Muscle – bovine                                     | 0.01*                   | 0.03*                         | The MRL is sufficiently supported by data derived from ruminant feeding study.<br><br>A risk to consumers is unlikely. |
| 1012020  | Fat – bovine  | 0.01*                   | 0.04                          |  |
| 1012030  | Liver – bovine                                      | 0.01*                   | 0.5                           |  |
| 1012040  | Kidney – bovine                                     | 0.01*                   | 0.4                           |  |

| Product code | Product  | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments  |
|--------------|--|-------------------------|-------------------------------|---|
| 1012050      | Edible offals (other than liver and kidney) – bovine | 0.01*                   | 0.5                           |   |
| 1012990      | Other – bovine                                       | 0.01*                   | 0.03*                         |   |
| 1013000      | Sheep  |                         |                               |   |
| 1013010      | Muscle – sheep                                       | 0.01*                   | 0.03*                         | Data from ruminant feeding study on dairy cattle extrapolated to sheep.<br><br>A risk to consumers is unlikely.           |
| 1013020      | Fat – sheep  | 0.01*                   | 0.04                          |   |
| 1013030      | Liver – sheep  | 0.01*                   | 0.5                           |   |
| 1013040      | Kidney – sheep                                       | 0.01*                   | 0.5                           |   |
| 1013050      | Edible offals (other than liver and kidney) – sheep  | 0.01*                   | 0.5                           |   |
| 1013990      | Other – sheep  | 0.01*                   | 0.03*                         |   |
| 1014000      | Goat   |                         |                               |   |
| 1014010      | Muscle - goat  | 0.01*                   | 0.03*                         | MRLs are based on the lowest MRL for each respective matrix from bovine or sheep.<br><br>A risk to consumers is unlikely. |
| 1014020      | Fat – goat   | 0.01*                   | 0.04                          |   |
| 1014030      | Liver – goat   | 0.01*                   | 0.5                           |   |
| 1014040      | Kidney – goat  | 0.01*                   | 0.4                           |   |
| 1014050      | Edible offals (other than liver and kidney) – goat   | 0.01*                   | 0.5                           |   |
| 1014990      | Other – goat   | 0.01*                   | 0.03*                         |   |

| <b>Product code</b> | <b>Product</b>  | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>   |
|---------------------|---|--------------------------------|--------------------------------------|---|
| 1015000             | Equine  |                                |                                      |   |
| 1015010             | Muscle – equine                                       | 0.01*                          | 0.03*                                | MRLs are based on the lowest MRL for each respective matrix from bovine or sheep.<br><br>A risk to consumers is unlikely. |
| 1015020             | Fat – equine  | 0.01*                          | 0.04                                 |   |
| 1015030             | Liver – equine  | 0.01*                          | 0.5                                  |   |
| 1015040             | Kidney – equine                                       | 0.01*                          | 0.4                                  |   |
| 1015050             | Edible offals (other than liver and kidney) – equine  | 0.01*                          | 0.5                                  |   |
| 1015990             | Others – equine                                       | 0.01*                          | 0.03*                                |   |
| 1016000             | Poultry   |                                |                                      |   |
| 1016010             | Muscle – poultry                                      | 0.01*                          | 0.05                                 | MRLs derived from poultry feeding study on laying hens.<br><br>A risk to consumers is unlikely.                           |
| 1016020             | Fat – poultry   | 0.01*                          | 0.15                                 |   |
| 1016030             | Liver – poultry                                       | 0.01*                          | 0.15                                 |   |
| 1016040             | Kidney – poultry                                      | 0.01*                          | 0.03*                                |   |
| 1016050             | Edible offals (other than liver and kidney) – poultry | 0.01*                          | 0.15                                 |   |
| 1016990             | Other – poultry                                       | 0.01*                          | 0.03*                                |   |
| 1017000             | Other farmed terrestrial animals                      |                                |                                      |   |
| 1017010             | Muscle – other terrestrial animals                    | 0.01*                          | 0.03*                                | MRLs are based on the lowest MRL for each respective matrix from bovine or sheep.   |

| <b>Product code</b> | <b>Product</b>  | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>  |
|---------------------|---|--------------------------------|--------------------------------------|--|
| 1017020             | Fat – other terrestrial animals   | 0.01*                          | 0.04                                 |  |
| 1017030             | Liver – other terrestrial animals                                       | 0.01*                          | 0.5                                  |  |
| 1017040             | Kidney – other terrestrial animals                                      | 0.01*                          | 0.4                                  |  |
| 1017050             | Edible offals (other than liver and kidney) – other terrestrial animals | 0.01*                          | 0.5                                  |  |
| 1017990             | Other – Other terrestrial animals                                       | 0.01*                          | 0.03*                                |  |
| 1020000             | Milk  |                                |                                      |  |
| 1020010             | Cattle – milk   | 0.01*                          | 0.03                                 | MRLs are derived from ruminant feeding study for cattle and sheep.<br><br>For goat, horse, other MRL based on the lowest MRL established for bovine or sheep |
| 1020020             | Sheep – milk  | 0.01*                          | 0.04                                 |  |
| 1020030             | Goat – milk   | 0.01*                          | 0.03                                 |  |
| 1020040             | Horse – milk  | 0.01*                          | 0.03                                 |  |
| 1020990             | Others – milk and cream   | 0.01*                          | 0.03                                 |  |
| 1030000             | Birds eggs  | 0.01*                          | 0.03*                                | MRLs derived from poultry feeding study on laying hens.  |
| 1050000             | Amphibians and reptiles   | 0.01*                          | 0.03*                                | Based on LOQ validated for muscle  |

| Product code | Product                             | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                          |
|--------------|-------------------------------------|-------------------------|-------------------------------|-----------------------------------|
| 1060000      | Terrestrial invertebrate animals    | 0.01*                   | 0.03*                         | Based on LOQ validated for muscle |
| 1070000      | Wild terrestrial vertebrate animals | 0.01*                   | 0.03*                         | Based on LOQ validated for muscle |

\* Indicates that the MRL is set at the limit of quantification/determination

### Date of entry into force

The MRLs shall enter into force and appear in the [GB MRL Statutory Register](#) on 3 August 2022.

**The GB MRL Statutory Register should be consulted to verify the MRLs set and the legal provisions established.**

### Supplementary information

The competent authority identified that there was some missing information on the analytical methods for enforcement and monitoring of residues in products of animal origin. The full data requirement is outlined in the MRL decision document GB MRL 2022/011. These data must be provided to the competent authority by **31 August 2023**.

All other MRLs remain unchanged in the Register.

## The active substance and formulated product

### Active substance

|                              |                                   |
|------------------------------|-----------------------------------|
| <b>ISO common name</b>       | 1,4-dimethylnaphthalene (1,4-DMN) |
| <b>Chemical name (IUPAC)</b> | 1,4-dimethylnaphthalene           |

### Formulated product

|                                  |                             |
|----------------------------------|-----------------------------|
| <b>Product name</b>              | 1,4-Sight                   |
| <b>Formulation type and code</b> | Hot fogging concentrate, HN |
| <b>Active substance content</b>  | 980 g/kg                    |
| <b>Function</b>                  | Dormancy enhancement        |
| <b>Effective against</b>         | -                           |
| <b>Field of use</b>              | Post-harvest treatment/ GB  |
| <b>Application method</b>        | Hot fog                     |

Full details of the Good Agricultural Practices (GAPs) are outlined in Appendix 1.

# Appendix 1 – GAP supported by the assessment

PPP: 1,4-Sight  
 Active substance: 1,4-DMN  
 Applicant: Dormfresh Ltd

| Crop and/or situation (a) | GB or Country For Import Tolerance | Product name | F or G Or I (b) | Pests or Group of pests controlled (l) | Preparation |                | Application   |                                     |                    |                                    | Application rate per treatment |                      |                         | PHI (days) (m) | Remarks                      |
|---------------------------|------------------------------------|--------------|-----------------|--|-------------|----------------|---|-------------------------------------|--------------------|------------------------------------|--------------------------------|----------------------|-------------------------|----------------|------------------------------|
|                           |                                    |              |                 |  | Type (d-f)  | Conc. a.s. (i) | method kind (f-h)   | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | g a.s./hL min-max (l)          | Water (L/ha) min-max | g a.s./ha min-max (l)   |                |                              |
| potato / post-harvest use | GB                                 | 1,4-Sight    | I               | Dormancy Enhancement                   | HN          | 933 g/L        | Apply with suitable fogging equipment and use internal ventilation. Store must remain closed for 24-48 hours after treatment. | BBCH 99 Sept-Aug                    | 1 – 6              | 4-6 weeks                          | N.A.                           | N.A.                 | max. 20 g a.s./ 1000 kg | 30             | Not for use on seed potatoes |

Decision on amending the MRLs for 1,4-DMN in products of animal origin

|   |   |
|---|---|
| <p>(a) For crops, the GB 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) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</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. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</p> <p>(j) Growth stage range from first to 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 applications 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> |
|---|---|





