

Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

**dinotefuran (ISO); (RS)-1-methyl-2-nitro-3-
(tetrahydro-3-furylmethyl)guanidine**

EC Number: -
CAS Number: 165252-70-0

CLH-O-0000007342-79-01/F

Adopted
14 September 2023

RAC
COMMITTEE FOR RISK
ASSESSMENT

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON DINOTEFURAN (ISO); (RS)-1-METHYL-2-NITRO-3-(TETRAHYDRO-3-FURYL METHYL)GUANIDINE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA’s website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: dinotefuran (ISO); (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine

EC number: -

CAS number: 165252-70-0

Dossier submitter: Belgium

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
31.01.2023	Germany		MemberState	1
Comment received				
<p>Section A.4.1.1.3.2: The water/sediment degradation test Calwich Abbey Lake (2020a) that was performed outdoors under natural sunlight should not be considered for the calculation of the geometric mean DT50 in the total system in Table 4.7. This study should be considered as additional information and would otherwise, if included, provide an underestimate of the pure microbial degradation. In particular, since photodegradation in water contribute to the breakdown of Dinotefuran. Thank you.</p> <p>Section A.4.1.1.3.6.1: It is not entirely clear how the difference regarding DT50 in the 2001e soil degradation study for Stolpe, Germany, comes about. In Table A-114 a DT50 of 13.9 d is given and in Table 4.9 a DT50 of 224 d is stated. This is also true for the original study report and not only for the re-evaluation by 2020b/2020c. The normalisation to 12°C also seems to be incorrect for the Stolpe, Germany, sample, since 10°C was apparently assumed as study temperature. However, the study was conducted at 20°C and thus the normalised DT50 at 12°C should be significantly higher with 424.8 d if 224 d is correct. The geomean would, therefore, also change. Please clarify this. Thank you.</p>				
Dossier Submitter’s Response				
<p>#1) BE: Thank you for your comment. We fully agree and the results was not used to derive a Geom DT 50 for CLH purpose. Instead the worst case value is considered relevant for Classification (However the geom was subsequently used for Biocide ENV Risk Assessment). See also our response to comments #5 and #6 from the applicant below.</p>				

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#2) BE: Thank you for your comment. We have re-checked our data and calculation sheet and indeed this is a mistake. For the Stolpe Sample in the 2001e study, the incubation temperature is 20°C and the original DT50 in the report is 13.9d. According to our calculation sheet the normalised DT50 at 12° C is 26.4d. The resulting Geom is 32.4 d as correctly stated in the CLH report. The value of 224d comes from the 2003a study for the MNG metabolite at 10°C. The mistake comes from the fact that in the entry Gartenacker, Switzerland (2003b) the value of the MNG metabolite was inserted in the table in the same time as the Dinotefuran values. Therefore the DT50 values presented in the table 4.9 were incorrectly reproduced. Please find below the corresponding entry for the Stolpe sample in the table 4.9 after correction.

Aerobic conditions						
Soil	Incubation temperature (°C)	Compound	DT₅₀ (d) (Fedrizzi, 2020b)	Normalised DT₅₀ (d) (Fedrizzi, 2020b)	DT₅₀ (d) (original study)	Normalised DT₅₀ (d) (original study)
Gartenacker, Switzerland Völkl (2003b)	20	Dinotefuran	9.79	18.6	10.2	19.3
Gartenacker, Switzerland Völkl (2003b)	10	Dinotefuran	20.3	17.3	21.1	18.0
Ringenwald, Germany Mamouni (2001e)	20	Dinotefuran	15.3	29.0	16.4	31.1
Stolpe, Germany Mamouni (2001e)	20	Dinotefuran	11.4	21.6	13.9	26.4
Zwingenber, Germany Mamouni (2001e)	20	Dinotefuran	13,3	25,2	15,5	29,4
Karolinenhof Germany Mamouni (2001e)	20	Dinotefuran	10,8	20,5	10,7	20,3
Otzberg, Germany Mamouni (2001e)	20	Dinotefuran	9,5	18	9,4	17,8
Borstel, Germany Mamouni (2001e)	20	Dinotefuran	21,5	40,8	23	43,6
Velten, Germany Mamouni (2001e)	20	Dinotefuran	65,3	124	65,5	124,2
Walluf, Germany Mamouni (2001e)	20	Dinotefuran	26,1	49,5	26,1	49,5
Rossdorf, Germany Mamouni (2001e)	20	Dinotefuran	22,3	42,3	22,3	42,3
Phoeben, Germany Mamouni (2001e)	20	Dinotefuran	21	39,8	20,8	39,4
Mechthildshausen, Germany Mamouni (2001e)	20	Dinotefuran	16,6	31,5	16,7	31,7
GEOMETRIC MEAN				31.0		32.4

In the text above the table 4.9, the sentence :“ Consequently it is appropriate to use of the value of 190.2 days (Stolpe, Germany, normalised to 12°C) – please refer to section 5 “Assessment of exclusion criteria, substitution criteria and POP”.“ Has been corrected and is now : “Consequently it is appropriate to use of the value of 124.2days (Velten, Germany, normalised to 12°C) – please refer to section 5 “Assessment of exclusion criteria, substitution criteria and POP”.“

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RAC's response
Thank you for your comment. Noted.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
31.01.2023	Germany		MemberState	2
Comment received				
P.176, Chronic toxicity to aquatic invertebrates – Dinotefuran: Please check the NOEC for the chronic toxicity test with D. magna given in the text below Table A-125. In the Assessment Report and in Table A-125, a NOEC of 100 mg/L is given instead of 10.0 mg/L. Thank you.				
Dossier Submitter's Response				
BE: Thank you for your comment. This is a typo : indeed the NOEC was 100 mg/L and not 10.0 mg/L.				
RAC's response				
Thank you for your comment. The typo is noted.				

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2023	United Kingdom	Health and Safety Executive	National Authority	3
Comment received				
Dinotefuran (ISO); (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine; (EC: , CAS 165252-70-0). Based on the available data, we agree that Chironomus are the most acutely and chronically sensitive test species. While the draft OECD TG 219 (Anon., 2003a in the CLH report) study employed a water-sediment test system, we agree that the data described in the CLH report and in the RSS (ECHA, 2023) support a long-term endpoint based on measured aquatic phase concentrations noting that ≤20% losses were observed between initial measured (1-hour) and 27-day measured concentrations. Recognising that the analytical verification did not cover all treatments results in some uncertainty, we note that the surrogate approach using the Reliability 1, acute Chironomus endpoint (48-hour LC50 0.0721 mg/L) also results in Aquatic Chronic 1 with an M-factor of 10. The REACH RSS includes an EC10 endpoint based on nominal concentrations. Given ECx are preferred to NOECs, it is possible to determine an EC10 endpoint based on measured concentrations? ECHA (2023) https://echa.europa.eu/registration-dossier/-/registered-dossier/22640/6/3/?documentUUID=3722e247-06c6-4239-a320-a101eeb46757 . Accessed 26-January-2023				
Dossier Submitter's Response				
BE: Thank you for your comment. We agree that there are some uncertainties as the analytical verifications did not cover all test concentrations. However according to OECD TG 219 when the test substance is stable, its concentrations could be measured at least				

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at the start (1h after spiking the water) and at the end of the test, at the highest concentration and a lower one. Therefore setting the reliability of this study to 1 was relevant.

No EC10 value was calculated in the report of the study provided for CLH (Anon., 2003a) and it was not further calculated as it was not considered mandatory. After carefully comparing this test and those presented in REACH RSS, it appears that it was the same study. Therefore the EC10 value calculated in REACH RSS could also be relevant for the CLH report. However please note that this EC10 value (4.6 µg/L) was based on nominal concentrations, while the NOEC presented in the CLH (2.54 µg/L) was based on a mean measured concentration (see our answer below). Note that as both values are in the same range, it would not change the outcome of the classification.

RAC's response

Thank you for your comment.
 RAC agrees that Chironomus are the most acutely and chronically sensitive test species.
 RAC is of the opinion that the nominal EC₁₀ value of 0.0046 mg/L is relevant for the classification of dinotefuran. In addition, RAC notes that mean measured NOEC and nominal EC₁₀ values are in the same range and are both below the threshold value of 0.1 mg/L for not rapidly degradable substances, therefore RAC concludes that a classification as Aquatic Chronic 1 (H400) with chronic M-factor of 10 (0.001 < NOEC ≤ 0.01 mg/L) is justified.

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2023	France		MemberState	4

Comment received

We agree with the proposal classification Aquatic Acute 1 (H400, M=10) and Aquatic Chronic 1 (H410, M=10). For information in the Table A-139 of the CLH report, the NOEC = 2.54 µg/L is identified as an initial NOEC. However, in the CAR Doc IIA of Dinotefuran (June 2014) Table 4.24, this NOEC is identified as measured. This may be a typing error.

Dossier Submitter's Response

BE: Thank you for your comment. This is a typo : as specified above, the NOEC is calculated as the geometric mean of the lowest percentage of test item present in analysed concentrations at the start and end of the test (72 and 56 % respectively) multiplied by the nominal NOEC. This results in a NOEC value of 2.54 µg/L. Therefore the NOEC is indeed based on measured concentration.

RAC's response

Thank you for your comment. The typo is noted. RAC agrees with DS proposal to classify dinotefuran as Aquatic Acute 1 with M = 10 and Aquatic Chronic 1 with M = 10.