

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

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Last data extracted on 28.10.2019

Substance name: N-(2-nitrophenyl)phosphoric triamide

CAS number: 874819-71-3

EC number: 477-690-9

Dossier submitter: Austria

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	1
Comment received				
Based on available data, we agree with the classification Repr. 1B, H360FD.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	2
Comment received				
Based on available data, we agree with the classification STOT RE 2, H373 (kidney).				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2019	Sweden		MemberState	3
Comment received				
p. 31-34; Toxicity to algae: The Swedish CA agrees with the proposed environmental classification; Aquatic chronic 3, H412. This is partly based on the algae ErC50 of 51.4 mg/L (nominal concentration). Based on the presented information, the initial exposure concentrations in the algae study were not maintained throughout the testing period. However, at the two highest nominal test concentrations (50 and 100 mg/L) the measured concentrations were close to 80% (79.8 and 81.3 %, respectively) of the nominal concentration at the end of the test. Therefore, it was argued that nominal concentrations could be used for calculating ErC50. The Swedish CA agrees with this and further concludes that if measured concentrations were used instead in the ErC50-calculation, the conclusion would have been the same.				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	United Kingdom		MemberState	4
Comment received				
The algal growth inhibition study dated 2005 was conducted according to OECD Test				

Guideline 201 (1984). We note that the updated Test Guideline 201 (2006 and 2011) includes additional validity criteria to assess study controls. It would be useful for the DS to consider if these criteria were met to demonstrate the reliability of the controls. This is relevant because the study forms the basis of the classification proposal.

The DS considers that a valid NOErC could not be determined because the NOErC at the nominal concentration of 6.25 mg/L was below the limit of detection of 0.503 mg/L. We note that a geometric mean measured concentration of 1.227 mg/L for this treatment is included in the CLP report (Table 26). While the reliability of this endpoint is unclear we note that it is >1mg/L indicating no chronic classification is required. We also note that the online registration (ECHA, 2019) includes an nominal ErC10 of 22 mg/L Based on data in Tables 25 and 26 of the CLH report, it appears a reliable ErC10 could be derived which is likely to be >1 mg/L. On this basis, we think the DS should present a 72-hour ErC10 based on a geometric mean measured dose-response curve.

Given this last point, we consider it would be useful to also present the ErC50 based on geometric mean measured concentrations although we recognise the endpoint is likely to remain >1 mg/L and not impact the classification proposal.

ECHA (2019) <https://echa.europa.eu/registration-dossier/-/registered-dossier/5898> accessed 2019-10-10.

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Belgium		MemberState	5
Comment received				
<p>Aquatic toxicity to algae: A statistical significant effect was observed for biomass and growth rate at a nominal conc of 6.25 mg/L. However analytical results of the lowest test concentration (6.25 and 3.13 mg/L) after 72h were below the detection limit (0.503 mg/L). Following the CLP guidance I.4.1 where concentrations at the end of the test are below the analytical detection limit, such concentrations shall be considered to be half that detection limit, thus NOEC= 0.252 mg/L.</p> <p>Based on the above and the fact that the substance is not rapidly degradable, a classification with Aquatic Chronic 2, H411 seems more appropriate.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	6
Comment received				
<p>P29: In table 26 in column "Results", there are typographical errors. For the fish acute toxicity test, LC50 of 100 mg/L is mentioned whereas a NOEC is set at >= 100 mg/L in the test description (p31). For the acute immobilisation test, the summary table describes an EC50 of 100 mg/L whereas a NOEC is also set at >= 100 mg/L in the test description (p31).</p> <p>P32: Regarding the static algae growth inhibition test, it is indicated that it was not possible to determine an exact NOEC. All the same, a NOEC might have been set at 12.5 mg/L.</p>				

Based on available data, we agree with the proposed classification Aquatic Chronic 3, H412.