

## COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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**Last data extracted on 15.11.2023**

**Substance name: N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine**

**CAS number: 793-24-8**

**EC number: 212-344-0**

**Dossier submitter: Austria**

### ENVIRONMENTAL HAZARDS – Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
14.11.2023	Germany	EU PPD Consortium	Company-Manufacturer	1

Comment received

Currenta on behalf of the EU PPD Consortium<sup>1</sup> has submitted comments on the draft CLH report as prepared by the Environment Agency Austria on behalf of the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology. We would like to inform that the published acute toxicity study of 6PPD-Quinone (Lo et al., 2023) has been considered in our original comments dated 2023-08-29 (see Section 2, p. 3).

The 24 h LC50 of 0.041 µg/L derived in Lo et al., 2023, is comparable to the 24 h LC50 of 0.079 µg/L (Tian et al., 2022) used as key value in the CLH report. We would like to reiterate that both toxicity values are obtained from tests with *Oncorhynchus kisutch* (coho salmon). In comparison to other fish and aquatic species, *O. kisutch* is not only significantly more sensitive than other fish and aquatic species but it is also highly sensitive compared to other closely related species in the Salmonidae family.

The differential sensitivity of *O. kisutch* in comparison to other aquatic species is unlikely explained by experimental factors but could be reasonably driven by inherent susceptibility and specific mechanisms of action displayed in *O. kisutch* (Hiki et al., 2021). Therefore, *O. kisutch* does not appear to be representative for the acute mortality of 6PPD quinone to aquatic species and may not be used as the main species for classification due to over-estimation of effects and unrealistic hazard assessment.

Importantly, regarding the relevance of the study by Lo et al., the EU PPD Consortium wants to point out once more that the CLP regulation is supposed to focus on the hazard towards the EU specifically which means that any M-factor for aquatic acute toxicity should consider EU relevant and representative species and the possibility to realistically assess the hazard of 6PPD and its transformation products via SSD.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Currenta 6PPD CLH Report comment 2023-11-14.pdf

Date	Country	Organisation	Type of Organisation	Comment number
10.11.2023	Germany		MemberState	2

Comment received

In our opinion the published acute toxicity study of 6PPD-Quinone (Lo et al., 2023) is valid

and reliable. As the toxicity value for one of the tested species (*Oncorhynchus kisutch*) is lower but in the same order of magnitude as those reported in the CLH report, it strengthens the classification proposal. This is the case even for this shorter exposure duration (24h) compared to the regular one (96h).

#### PUBLIC ATTACHMENTS

1. Currenta 6PPD CLH Report comment 2023-11-14.pdf [Please refer to comment No. 1]