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 17.05.2021

Substance name: 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. ; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine
CAS number: 68953-84-4
EC number: 273-227-8
Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
14.05.2021	Belgium	DAPD Consortium	Company-Manufacturer	1
Comment received				
Please refer to the non-confidential attachment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment DAPD Consortium - Comments on public consultation for CLH proposal - FINAL - 14.5.21 - 96198617_1.pdf				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
14.05.2021	Belgium	DAPD Consortium	Company-Manufacturer	2
Comment received				
Please refer to the non-confidential attachment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment DAPD Consortium - Comments on public consultation for CLH proposal - FINAL - 14.5.21 - 96198617_1.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
12.05.2021	Sweden		MemberState	3
Comment received				
Fertility The Swedish CA agree that the dystocia observed in the 2-generational study as well as in the 1-generation mechanistic study, resulting in a significantly reduced delivery of viable offspring, is an adverse effect that warrants classification, in line with previous conclusions by RAC. In the 2-generational study this effect showed a dose-dependent increase, being significant at 25 and 100 mg/kg/d, but with possible changes already at 7.5 mg/kg/d. SE consider the degree of maternal toxicity as key for a classification in either category 1B or 2 and the proposal would benefit from a clearer description of this. Was the maternal toxicity (e.g. body weight changes, clinical symptoms, necrosis of liver				

and kidney (including the degree of severity) at 100 mg/kg/d) more pronounced in the dams that did not deliver viable pups? Were there any body-weight changes or clinical symptoms observed at 7.5 and 25 mg/kg/d. If the maternal toxicity can be considered not to be of sufficient magnitude to cause the observed effects Cat 1B is supported. Any data available from repeated dose-studies on the effects of BENPAT on hormonal levels in female rats could provide further mechanistic insights/support as to if the affected cyclicity could play a role in the observed dystocia.

Developmental toxicity
Polycystic kidneys were observed in all generations of the 2-generational study and the 1-generation mechanistic study. The offspring generations (F1 and F2) are clearly more sensitive to this effect as indicated by their significantly higher incidences than the parental generation. However, we do not consider it clear whether this effect should be regarded as a developmental effect or not. If not any structural disturbances of the development of the kidney have occurred, this effect could rather be considered as a systemic toxic effect (relevant for classification). Any additional mechanistic data on the possible development of polycystic kidneys from BENPAT or other similar substances would be helpful.

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
14.05.2021	Belgium	DAPD Consortium	Company-Manufacturer	4
Comment received				
Please refer to the non-confidential attachment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment DAPD Consortium - Comments on public consultation for CLH proposal - FINAL - 14.5.21 - 96198617_1.pdf				

PUBLIC ATTACHMENTS
1. DAPD Consortium - Comments on public consultation for CLH proposal - FINAL - 14.5.21 - 96198617_1.pdf [Please refer to comment No. 1, 2, 4]