Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and labelling at EU level of

2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol; (Disperse Blue 106)

EC Number: 271-183-4
CAS Number: 68516-81-4

CLH-O-0000007071-84-01/F

Adopted
18 March 2022

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.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol
EC number: 271-183-4
CAS number: 68516-81-4
Dossier submitter: Germany

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2021	Sweden		MemberState	1
Comment received				
The SE CA supports the proposed harmonised classification of Disperse Blue 106 as Skin Sens. 1A; H317, with an SCL of 0.001% based on animal data (key study LLNA with EC3 = 0.012-0.017%). Human evidence further supports classification of Disperse Blue 106 as a potent skin sensitiser.				
Dossier Submitter's Response				
The Dossier Submitter thanks for the comment and appreciates the support of the SE CA.				
RAC's response				
Thank you for comment and clear view supporting classification Skin Sens. 1A; H317, with an SCL of 0.001 % based on animal data.				

Date	Country	Organisation	Type of Organisation	Comment number
17.06.2021	France		MemberState	2
Comment received				
Regarding both the animal and human data, there is no doubt on the sensitising potency of Disperse Blue (DB) 106, and deserve, at least, a classification as skin sens 1. In human, studies on consecutive dermatitis patients show for half of them high frequency of dermal reaction, and for the other half to low/moderate frequency. Studies on selected dermatitis patient, on the contrary, mainly lead to high frequency of dermal reaction occurrence. In experimental animals, the key study, a LLNA, concluded on a very high sensitising				

potency of DB106 with EC3 values of 0.012 and 0.017% in the two experiments. Based on the CLP guidance indicating that "evidence from animal studies is usually much more reliable than evidence from human exposure", FR agrees with the proposal to subcategorise as skin sens. 1A. Finally, regarding the results of the LLNA, an extreme skin sensitising potency of the DB106 was identified. This is not the case for the other in vivo tests where a conclusion is possible, but in every cases, strong or extreme potency cannot be excluded. Therefore, FR agrees to set an SCL of 0.001%.   These conclusions are in line with the RAC conclusions for a structurally similar compound, DB124.
Dossier Submitter's Response
The Dossier submitter thanks the FR CA for the summary. The support of the CLH proposal is appreciated.
RAC's response
Thank you for comment and analysis of data supporting classification Skin Sens. 1A; H317, with an SCL of 0.001 %