

**Committee for Risk Assessment**  
**RAC**

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

**1-amino-4-hydroxy-2-phenoxyanthraquinone**

**EC Number: 241-442-6**  
**CAS Number: 17418-58-5**

CLH-O-0000007415-74-01/F

**Adopted**  
**14 March 2024**

**RAC**  
COMMITTEE FOR RISK  
ASSESSMENT

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE

### 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: 1-amino-4-hydroxy-2-phenoxyanthraquinone**

**EC number: 241-442-6**

**CAS number: 17418-58-5**

**Dossier submitter: Sweden**

#### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19.07.2023	Italy	Manteco SpA	Company-Manufacturer	1
Comment received				
<p>Manteco has been a leading textile company for premium quality fabrics and circularity since 1943. The company is fully committed to circular fashion. It is a Member of the Ellen MacArthur Foundation's Network and a Partner of the Monitor for Circular Fashion by SDA Bocconi and has developed numerous projects in order to achieve it: a zero-waste system to recover all the scraps coming from production phases, a sustainable design philosophy to create recyclable fabrics, or Project43 and Project53 to take back and recycle the offcuts produced during garment making or unsold knits. In addition, Manteco was the first textile company to ever apply a science-based LCA (Life Cycle Assessment) study on its luxury recycled wools, which was also approved by the scientific community, published as a scientific article on MDPI resources, and certified through the EPD international scheme.</p> <p>Manteco welcomes the opportunity to submit comments on the proposal for the harmonised classification of Disperse Red 60 as a skin sensitiser 1A in CLP. While we do not intend to challenge the harmonised classification per se, we want to express our concerns with regard to the future inclusion of this dye in the REACH restriction proposal on skin sensitiser in textile and leather articles. More specifically, we would like to draw your attention to the implications that this could pose for mechanical textile recycling.</p> <p>The abovementioned REACH restriction proposal covers all substances with a harmonised classification as skin sensitiser in CLP at present and in the future through the so-called dynamic link, including Disperse Red 60.</p> <p>We understand that Disperse Red 60 has been on the market for approximately 60 years</p>				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

<p>and is widely used to print and dye polyester in several shades. As a result, we expect that Disperse Red 60 will be easily found in post-consumer textile waste that will be subject to mechanical recycling operations. This will not only be limited to polyester waste but will cover other fibres, such as wool or cotton, which are increasingly blended with polyester to achieve optimised performance.</p> <p>The future ban of Disperse Red 60 is, therefore, expected to severely affect mechanical textile recycling.</p> <p>In light of this, we support the request for a specific risk assessment and analysis of the socio-economic implications of banning Disperse Red 60 before its inclusion in the scope of the REACH restriction proposal on skin sensitisers in textile and leather articles.</p>
<b>Dossier Submitter's Response</b>
Thank you for the comment. Restriction in REACH is not within the scope of the consultation on harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone.
<b>RAC's response</b>
RAC has taken note of your comment.

Date	Country	Organisation	Type of Organisation	Comment number
06.07.2023	India		Individual	2
<b>Comment received</b>				
Not required				
<b>Dossier Submitter's Response</b>				
Noted.				
<b>RAC's response</b>				
RAC has taken note of your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
05.07.2023	Germany		MemberState	3
<b>Comment received</b>				
<p>SID: Structural formula: The structural formula is not included in this dossier. We are not sure if it results from a malfunction of our software. If not, it should be added.</p> <p>Physchem: Boiling point: it might be more informative to indicate that the "substance decomposes before boiling (starting at 310 °C)" instead of state "waiving".</p>				
<b>Dossier Submitter's Response</b>				
Thank you for the comment. The structural formula is included in the CLH-report. We agree to include "substance decomposes before boiling (starting at 310 °C)" instead of "waiving".				
<b>RAC's response</b>				
RAC has taken note of your comment.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

Date	Country	Organisation	Type of Organisation	Comment number
21.07.2023	Germany	DyStar Colours Distribution GmbH	Company-Manufacturer	4
Comment received				
<p>DyStar Colours Distribution GmbH supports the contribution of the EUCTL and ETAD regarding the indirect effects on Disperse Red 60 (Disperse Red 60; CAS 17418-58-5) caused by the proposed restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitizing substances. Kindly find more information in attachment.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20230721_DyStar-contribution_Disperse Red 60.pdf</p>				
Dossier Submitter's Response				
Thank you for the comment. Restriction in REACH is not within the scope of the consultation on harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone.				
RAC's response				
RAC has taken note of your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
21.07.2023	Switzerland	ETAD	Industry or trade association	5
Comment received				
<p>Our association supports the H317 classification of Disperse Red 60 but finds important to alert about the possible quite severe consequences of this classification due to the restriction proposal on skin sensitizers. Details are provided in the attached documents.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment ETAD_CLH_Comments on Disperse Red 60_July 2023.zip</p>				
Dossier Submitter's Response				
Thank you for the comment and the support for harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone as a skin sensitizer. Restriction in REACH is not within the scope of the consultation.				
RAC's response				
RAC has taken note of your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
20.07.2023	Germany	Verband TEGEWA e.V.	Industry or trade association	6
Comment received				
<p>Verband TEGEWA e. V. is an association representing chemical companies based in Germany, Switzerland and Netherlands manufacturing and marketing inter alia chemicals for leather and textile production and treatment.</p> <p>TEGEWA supports the contribution of the EUCTL regarding the indirect effects on Disperse Red 60 (DP Red 60; CAS 17418-58-5) caused by the proposed restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitizing substances (<a href="https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136">https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136</a>). If DP Red 60 is classified as H317 as proposed, which</p>				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

TEGEWA does not question, DP Red 60 will automatically fall within the scope of the proposed restriction without a risk assessment and a socio-economic evaluation having been carried out specifically for this disperse dye and without interested parties having the opportunity to submit information on these two aspects before the substance is included in the scope of the restriction. In our view, this is due to the very broad scope of the proposed restriction, which, as proposed in the original restriction proposal purely on the basis of hazard, includes all substances currently included in Annex VI of the CLP Regulation with classification H317 and, via a so-called dynamic link, all substances with classification H317 that will be included in Annex VI in the future.

TEGEWA believes that this approach is not appropriate as it does not reflect the use of DP Red 60 in polyester dyeing and printing, which has been taking place for decades in large quantities and without any negative impact on consumers (see supplementary information submitted via the EUCTL contribution).

As the proposal to restrict skin sensitizing substances for textiles and leather does not allow to submit information on specific substances or to request a derogation for these substances, as this is not foreseen in the proposal, and due to the pure hazard grouping approach and automatism, to include any harmonized classified substance with H317, TEGEWA currently sees no other option than to raise its concern and request a derogation for DP Red 60 from the proposed restrictions on skin sensitizing substances through this CLH intention process. We hope that ECHA and ECHA's RAC and especially SEAC Committees will consider our TEGEWA input and bring this case to the still ongoing process regarding the proposal to restrict skin sensitizers.

**Dossier Submitter's Response**

Thank you for the comment. Restriction in REACH is not within the scope of the consultation on harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone.

**RAC's response**

RAC has taken note of your comment.

Date	Country	Organisation	Type of Organisation	Comment number
20.07.2023	Belgium	European Chemistry for Textile and Leather AISBL (EUCTL)	Industry or trade association	7

**Comment received**

The Association European Chemicals for Textile and Leather AISBL (EUCTL) represents more than 70% of textile and leather chemical manufacturers in Europe.

EUCTL is fully aware that the intention of CLH to classify Disperse Red 60 (DP Red 60; CAS 17418-58-5) as Skin Sens. 1A (H317) and to include it in Annex VI of Regulation (EC) No. 1272/2008 (=CLP Regulation) will have an immediate and huge impact on the availability of this disperse dye on the EU market as well as on the use of this dye for polyester dyeing and sublimation printing worldwide in view of the proposed REACH restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances already proposed in April 2019 (<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136>).

As the restriction proposal process is still ongoing and the outcome is still unclear, we have to assume that the originally proposed scope of the restriction, i.e. a.) all substances already currently included in CLP Annex VI with a classification as H317 and b.) via a so-called "dynamic link" all substances with a classification as H317 included in CLP Annex VI in the future, will apply when the restriction is implemented according to the original proposal. Therefore, DP Red 60 will either be directly subject to this proposed restriction because DP Red 60 is already included in CLP Annex VI when the proposed restriction is published and

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

<p>enters into force, or will automatically be subject to the restriction via the dynamic link once DP Red 60 is classified as H317 and included in CLP Annex VI after the restriction already entered into force.</p> <p>In both cases, no risk assessment and socio-economic evaluation is carried out in relation to DP Red 60, which we believe needs to be carried out, as ECHA can judge from the information we have provided in the attachment.</p> <p>We are fully aware that this information does not affect the proposed classification and we do not question the proposed classification in line with the REACH restriction dossier. However, the classification will have a major impact on the substance and textiles dyed or printed with the substance, although we do not understand it to pose a risk to consumers. Since there is no substance-specific evaluation in the proposed restriction, we see this CLH process as the only way to address our concerns and objections to the proposed restriction for DP Red 60. Therefore, we are already requesting an exemption for DP Red 60 from the proposed restriction, as we again see no other way to comply with this request. We hope that ECHA will take into account our request and the information submitted and discuss this case with the Member States and the EU Commission when discussing the restriction proposal and its (future) impact and consequences on additional inclusions of substances classified with H317 in CLP Annex VI in future.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment DPred60_CLH-intention_prior-assessment-to-REACH-restriction.zip</p>
<b>Dossier Submitter’s Response</b>
Thank you for the comment and the support for harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone as a skin sensitiser. Restriction in REACH is not within the scope of the consultation.
<b>RAC’s response</b>
RAC has taken note of your comment.

**OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
06.07.2023	India		Individual	8
<b>Comment received</b>				
chronic or acute should be define on the basis of concentration and risk to be minimize with precautionary P228				
<b>Dossier Submitter’s Response</b>				
Thank you for your comment. For skin sensitisation classification according to CLP criteria there is no distinction between chronic and acute effects. Precautionary statements are not part of the harmonised proposal for classification.				
<b>RAC’s response</b>				
RAC has taken note of your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
05.07.2023	Germany		MemberState	9
<b>Comment received</b>				
The DE CA supports the proposed classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone as Skin Sens. 1A (H317).				
In a Skin Sensitisation Guinea Pig Maximisation Test (GPMT) performed according to OECD TG 406, ten of ten animals exhibited positive reactions at 24 h and 48 h after treatment				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

with 1 % intradermal induction of the substance. Therefore, allocation to the Skin Sens. sub-category 1A is justified according to table 3.4.3 of the CLP Regulation for the GPMT namely "≥ 60 % responding at > 0.1 % to ≤ 1 % intradermal induction dose".
The DE CA further agrees not to propose an SCL: A further differentiation between "strong" and "extreme" sensitiser is not possible because the injected intradermal induction dose was greater than 0.1 %.
<b>Dossier Submitter's Response</b>
Thank you for your support.
<b>RAC's response</b>
RAC has taken note of your comment.

Date	Country	Organisation	Type of Organisation	Comment number
21.07.2023	Italy	REACH&Colours Kft	Company-Importer	10
Comment received				
The attached document contains relevant information regarding the application of the dynamic link to CLP of restriction proposal for skin sensitizer substances.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH dossier_Disperse Red 60.rar				
<b>Dossier Submitter's Response</b>				
Thank you for the comment and the support for harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone as a skin sensitiser. Restriction in REACH is not within the scope of the consultation.				
<b>RAC's response</b>				
RAC has taken note of your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
20.07.2023	Germany	Verband TEGEWA e.V.	Industry or trade association	11
Comment received				
No comment				
<b>Dossier Submitter's Response</b>				
Noted.				
<b>RAC's response</b>				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.07.2023	France		MemberState	12
Comment received				
FR agrees with the classification proposal Skin Sens. 1A – H317, as 100% of animals responded to an intradermal induction dose of 1% 1-amino-4-hydroxy-2-phenoxyanthraquinone in a GPMT.				
<b>Dossier Submitter's Response</b>				
Thank you for your support.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-AMINO-4-HYDROXY-2-PHENOXYANTHRAQUINONE**

RAC's response				
RAC has taken note of your comment.				
Date	Country	Organisation	Type of Organisation	Comment number
20.07.2023	Belgium	European Chemistry for Textile and Leather AISBL (EUCTL)	Industry or trade association	13
Comment received				
No comments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment DPred60_CLH-intention_prior-assessment-to-REACH-restriction.zip				
Dossier Submitter's Response				
Thank you for the comment and the support for harmonised classification of 1-amino-4-hydroxy-2-phenoxyanthraquinone as a skin sensitiser. Restriction in REACH is not within the scope of the consultation.				
RAC's response				
RAC has taken note of your comment.				

**PUBLIC ATTACHMENTS**

1. 20230721\_DyStar-contribution\_Disperse Red 60.pdf [Please refer to comment No. 4]
2. CLH dossier\_Disperse Red 60.rar [Please refer to comment No. 10]
3. ETAD\_CLH\_Comments on Disperse Red 60\_July 2023.zip [Please refer to comment No. 5]
4. DPred60\_CLH-intention\_prior-assessment-to-REACH-restriction.zip [Please refer to comment No. 7, 13]