

Summary of Public Comments received on Certain Monoazo Pigments and CAS RN 2814-77-9 Screening Assessment Documents

Comments on the draft screening assessment for Certain Monoazo Pigments and risk management scope document for 2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-, Pigment Red 4 - to be addressed as part of the Aromatic Azo and Benzidine-based Substance Grouping were provided by the Color Pigments Manufacturers Association Inc. (CPMA), and the Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA).

A summary of comments and responses is included below organized by topic:

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TOPIC	COMMENT	RESPONSE
Methodology	The use of Pigment Orange 5 (PO5) and Solvent Red 23 (D&C Red 17) as read-across is supported - as these substances match solubility and structural characteristics of monoazo pigments. They also reflect dermal absorption potential of substances in the β -naphthol pigments subset.	Noted
	Use of summary information from REACH dossiers as a source of information for risk analysis is supported.	Noted
	The 10% weight fraction of PR4 in lipsticks cited in the draft screening assessment for monoazo pigments may be overly-conservative and an artefact of the upper end of the reporting range (<i>i.e.</i> 3–10%) used in the Cosmetic Notification System (CNS). According to good manufacturing practices, the high tinting strength of organic pigments does not support use of 10% concentration of PR4 in lipstick, and informal polling those purchasing this substance for use in lipstick products, suggests a lower concentration range of PR4 in lipstick products.	In the case of PR4, the final SAR has refined the exposure scenario to account for notifications to Health Canada indicating that lipsticks containing PR4 at the higher concentrations used for the exposure estimate in the draft assessment (up to 10%) are no longer on the market in Canada. Current information in Canada supports that PR4 is found in lipsticks at concentrations not greater than 3.0% and this was used for the refined lipstick exposure in the final SAR. Furthermore, the read-across cancer effect levels used for the risk estimate for PR4 lipstick use have also been adjusted. Together, these two refinements resulted in risk estimates for the use of PR4 in lipstick that indicates a low concern at current levels.
	In place of the default 10% concentration used for lipstick in the draft screening assessment, regulatory limit of 3% concentration for PR4 in cosmetic products is proposed for this assessment. This would be in keeping with products in other jurisdictions (<i>e.g.</i> lipsticks in the US and cosmetics in Europe) while still providing an “adequate margin of safety.”	

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Data Gaps	Additional information is requested about the "new information" that resulted in an apparent change in the human health conclusion for PR4 (compared to a previous 2009 conclusion on the same substance under the Challenge initiative). It is also noted that the critical data on PR4 that was presented in the current monoazo draft screening assessment appears to have been available at the time of the previous assessment.	The 2009 assessment of PR4 under the Challenge initiative primarily focused on ecological considerations, while the evaluation of PR4 presented in the current screening assessment involved an expanded scope that included a more detailed human health component. As such, while the specific health effects data for PR4 and/or data on read-across substances (PR3 and PO5) were available at the time of the previous 2009 assessment, this data was considered to be "new information" in the context of the updated scope of the health assessment for PR4 and related monoazo pigments. In addition, information on uses in products such as cosmetics and natural health products were updated since the earlier Challenge assessments on these substances.
Uses and Releases	Registered colour pigment manufacturers do not knowingly sell pigments or pigment formulations of any kind to the unregulated tattoo or permanent cosmetic markets. This policy covers products for tattoos, and it applies to formulators of inks for tattoos or individual tattoo providers that formulate their own inks in Canada. To the knowledge of the industry, pigments for non-permanent cosmetic applications that are regulated. These cosmetic product manufacturers are not known to supply products to unregulated tattoo vendors.	The Government of Canada acknowledges the statement concerning azo pigments in tattoo products. The final screening assessment report will reflect a clarification that members of a specified association do not supply these substances for use by the tattoo industry.
	The characterization of potential exposure from tattoos could generate unwarranted concerns about toxicity in unregulated products.	<p>The draft SAR considered multiple sources of potential exposure to monoazo pigments, including use in tattoo inks. Among the monoazo pigments considered in this screening assessment, PR4, pigment red 112 (PR112) and pigment yellow (PY3) were identified as being used in tattoo products in Canada.</p> <p>Dyes and pigments used for tattoos or permanent make-up are considered cosmetics products and must meet the requirements of the <i>Food and Drugs Act</i> and the <i>Cosmetics Regulations</i>. This includes notifying Health Canada of the product, providing appropriate packaging and labelling, and ensuring that the products are safe to use.</p> <p>While the information presented in the draft SAR supports a low concern for these substances at current levels of exposure for the oral and dermal routes, the potential long-term exposure from the use of these substances via intradermally injected tattoo inks remains an uncertainty.</p>
	The characterization of potential exposures from monoazo pigments in	The draft SAR considered multiple sources of potential exposure to the monoazo

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	cosmetics does not accurately reflect the majority of their use in Canada (<i>i.e.</i> commercial and industrial use). Exposure from cosmetic products is already regulated and monitored by Health Canada.	<p>pigments instead of conducting a separate assessment for distinct uses. Based on information available to Health Canada, some of the monoazo pigments were identified as being used in cosmetic products in Canada.</p> <p>Under Canadian law, industry is prohibited from selling any cosmetic that contains a substance that may cause injury under normal conditions of use, and all cosmetics sold to consumers must meet the requirements of the <i>Food and Drugs Act</i>, the current <i>Cosmetic Regulations</i> and all other applicable legislation.</p> <p>However, the final screening assessment conclusion did not consider the exposure to these monoazo pigments (including PR4) from cosmetic use to be a concern for the general population in Canada at current levels of exposure.</p>
Proposed Risk Management	Addition of PR4 to the Cosmetic Ingredient Hotlist with a restriction to limit the concentration of PR4 to 3% in lipsticks and other cosmetic applications is supported. This is considered to be in line with restrictions in the US and Europe, and we feel it is a reasonable risk management approach for this substance, as it does not require the conclusion that PR4 meets the criteria for "toxic" under the <i>Canadian Environmental Protection Act, 1999</i> (CEPA) as it would fall under other regulations (either section 16 of the <i>Food and Drugs Act</i> or a provision of the <i>Cosmetic Regulations</i>).	<p>As indicated below, the exposure estimate for use of PR4 in lipsticks has been updated in the final screening assessment of monoazo pigments. Based on recent information received from companies through notifications submitted to Health Canada under the Cosmetic Regulations, the exposure estimate for use of PR4 in lipsticks was updated in the final screening assessment of monoazo pigments. Companies also confirmed that levels of PR4 in lipsticks that is now available on the Canadian market no longer exceed 3.0%. Furthermore, refined estimates of risk using this information indicate the use of PR4 in lipstick is a low concern at current levels of exposure.</p> <p>Options for monitoring changes in uses of PR4 and other substances that have effects of concern are being investigated. Stakeholders will have the opportunity to provide feedback on a consultation document, describing potential options for information gathering or preventive actions, to be published once assessments for all of the Aromatic Azo and Benzidine-based Substance Grouping are completed.</p>
Conclusion	<p>Conclusions about the environmental releases, ecological toxicity and physical-chemical properties (<i>i.e.</i> solubility, cross-sectional diameter, and distinction between pigments and dyes) of monoazo pigments are supported and endorsed in the draft screening assessment</p> <p>Health assessment conclusions in the draft screening assessment that indicate that the majority of monoazo pigments (excluding PR4) do not present a significant exposure hazard or are not toxic to human health in anticipated exposures are supported.</p>	<p>Noted</p> <p>For many of monoazo pigments, the available health effects data indicate a low potential for toxicity and a correspondingly low risk to human health. However, other monoazo pigments such as PR3, PR4 and PO5 from the β-naphthol pigment subset have effects of concern based on potential carcinogenicity. While current</p>

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	<p>The draft health conclusion for PR4 is not supported.</p>	<p>levels of exposure were considered to be low for these substances, exposures above current levels are recognized as a potential concern.</p> <p>The final screening assessment for PR4 concludes that the substance no longer meets the criteria under section 64(c) of CEPA. This change was based primarily on refinements to the oral exposure estimate for use of PR4 in lipstick, resulting in margins of exposure that are now considered adequate. However, while current exposures to PR4 from use in lipstick do not indicate a risk to human health, there may be a concern if changes in the use of PR4 result in increased exposures above current levels.</p> <p>The other exposure source identified in the draft screening assessment as a potential concern was oral exposure to PR4 from use as a colourant in natural health products (NHPs). In the final assessment, the exposure to PR4 from use in oral natural health products does not indicate a high concern for risk to human health, however the health effects of PR4 including potential carcinogenicity are still recognized. Further information regarding actual concentration or quantity of PR4 in NHPs; number of Canadians consuming natural health products containing this substance; how closely directions are followed for using these products; and exposures from other sources would help to reduce uncertainty in exposure characterization for this subpopulation. Under the mandate of the Natural and Non-prescription Health Products Directorate of Health Canada, options are being considered to address the uncertainties in the risk characterization and ensure potential risks to human health are appropriately mitigated.</p> <p>Options for monitoring changes in the use of PR4 and other monoazo pigments that have effects of concern are being investigated. Stakeholders will have the opportunity to provide feedback on a consultation document, describing potential options for information gathering or preventive actions, to be published once assessments for all of the Aromatic Azo and Benzidine-based Substance Grouping are completed.</p>