

Summary of Public Comments Received on Five Diarylide Yellow Pigments (CAS 5102-83-0, 5567-15-7, 6358-85-6, 78952-70-2, and 90268-24-9) Draft Screening Assessment Report

Comments on the draft Screening Assessment Report for five diarylide pigments to be addressed as part of the Aromatic Azo and Benzidine-based Substance Grouping.

A summary of comments from the Color Pigment Manufacturers Association (CPMA) and responses is included below, organized by topic:

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TOPIC	COMMENT	RESPONSE
Uses and Releases	To our knowledge, diarylide pigments are not used in food and drug applications in Canada, nor are they normally used in cosmetic applications regulated by Health Canada. As such, the characterization of potential exposures from cosmetics does not accurately reflect the majority use of diarylide pigments in Canada (<i>i.e.</i> commercial and industrial use). The assessment should consider the potential exposures from cosmetics and other products regulated under Health Canada in a separate analysis.	<p>The draft Screening Assessment Report (SAR) considered multiple sources of potential exposure to diarylide pigments; rather than conduct a separate assessment for distinct uses. Based on information available to Health Canada, none of the five diarylide pigments are being directly used in foods or drugs in Canada, however PY12 and PY83 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>The conclusion of the SAR did not consider the current use of diarylide pigments in cosmetic products to be a concern for the general population in Canada.</p>
	CPMA members do not knowingly sell pigments or pigment formulations of any kind to the unregulated tattoo or permanent cosmetic markets. This policy includes products for tattoos, formulators of inks for tattoos or individual tattoo providers which formulate their own inks in Canada. CPMA members do provide pigments for non-permanent cosmetic applications which are regulated by local, national and international	The Government of Canada acknowledges the statement of the CPMA vis-à-vis azo pigments in tattoo products; the final Screening Assessment report will reflect this clarification from the CPMA that, in Canada, its members do not supply these substances for use by the tattoo industry .

TOPIC	COMMENT	RESPONSE
	<p>entities. To our knowledge, these cosmetic product manufacturers do not, in turn, supply products to unregulated tattoo vendors.</p>	
	<p>We feel that the characterization of potential exposure from tattoos could generate unwarranted concerns about toxicity in unregulated products that our members neither support nor provide.</p>	<p>The draft Screening Assessment report (SAR) considered multiple sources of potential exposure to diarylide pigments, including use in tattoo inks. Among the five diarylide yellow pigments, PY12 and PY83 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 very low hazard potential of diarylide pigments from the oral and dermal exposure routes, the potential long-term exposure from the use of these substances via intradermally injected tattoo inks remains an uncertainty.</p>
<p>Risk Assessment Conclusion</p>	<p>We support the use of scientific data for substances submitted in the REACH dossiers. Since they are subject to verification and review by government authorities, the summaries of these data in the dossiers are considered reliable and should be used as an alternative to mandatory section 71 surveys under the <i>Canadian Environmental Protection Act, 1999</i>.</p>	<p>The use of existing data—including that found in secondary sources—is an important source of information for the assessment report. Its use is determined according to several factors, including the level of detail provided, whether the original data is published elsewhere, and the transparency in the source/author of the data. In this regard, the use of data summaries from REACH dossiers is evaluated on a case-by-case basis.</p>
<p>Overarching Comments</p>	<p>We support the conclusion presented in the draft Screening Assessment report. It is well-written and accurate, and we feel that it provides a thorough and complete review of the properties, toxicity and ecotoxicity of the substances.</p>	<p>The Government of Canada thanks the commentor for their response.</p>