
COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

April 27, 2009

Mark W. Townsend, Chief
HPV Chemicals Branch
Environmental Protection Agency
Office of Pollution Prevention
and Toxics
1201 Constitution Avenue, NW
Washington, DC 20004

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EPA
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Re: Response to EPA Comments on the CPMA Test Plan for 6-amino-4-chloro-m-toluenesulfonic acid ("2B acid") (CAS NO. 88-51-7) and 2-amino-5-chloro-p-toluenesulfonic acid ("C amine") (CAS NO. 88-53-9)

Dear Mr. Townsend:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to your letter of March 10, 2008 in which you review the Environmental Protection Agency's ("EPA") comments on the CPMA test plan and robust summaries for 6-amino-4-chloro-m-toluenesulfonic acid ("2B acid") (Chemical Abstracts Service ("CAS") NO. 88-51-7 and 2-amino-5-chloro-p-toluenesulfonic acid ("C amine") CAS NO. 88-53-9. The test plan was submitted to the EPA as part of the voluntary High Production Volume ("HPV") testing program.

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico, and the United States. CPMA represents small, medium, and large color pigments manufacturers throughout Canada, Mexico and the United States, accounting for 95% of the production of color pigments in North America. Color

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pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, colored cement products, textiles, cosmetics, and artists' colors. Color pigment manufacturers located in other countries with sales in Canada, Mexico, and the United States and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association.

The HPV program is based on the Toxic Substances Control Act ("TSCA") Chemical Inventory update for substances in commerce in 1990. HPV substances subject to the voluntary program are defined as substances with one million pounds or more in commerce. We have reviewed the TSCA Inventory Update data available from the Environmental Protection Agency ("EPA") for the year 2006. 2b acid and C amine are no longer produced in quantities at, or above, 1 million pounds in the United States. Therefore, 2b acid and C amine are no longer High Production Volume ("HPV") priority compounds. Due to long term trends in the downstream pigment, ink and printing industries, including imports of finished pigments, ink and printed products, it is highly unlikely that manufacture and use of 2b acid and C amine will increase in the foreseeable future.

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Also, as discussed in more detail below, 2b acid and C-amine are closed system intermediates with no consumer or downstream commercial exposure. These intermediates are suitable analogs of 4b acid sharing common production processes, structure, characteristics and function.

2b Acid and C Amine are Strictly Chemical Intermediates

EPA comments indicate that more information is needed for EPA to consider 2b acid and C amine closed system intermediate chemicals. 2b acid and C amine are used only as intermediate coupling agents in the manufacture of monoazo red pigments. Monoazo red pigments are used in printing inks, paints and some plastics. 2b acid and C amine are currently used by no more than seven facilities in the United States for the production of monoazo pigments. Monoazo pigments are produced in water based reactions. The precipitated pigments that result from these reactions have measured water solubilities at or below 1 part per million. The diazotization reactions that produce monoazo pigments are considered quantitative. There is little or no unreacted intermediate waste remaining in wastewater or the final pigment used to color other products.

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Quantities Now In Commerce

2b acid is manufactured in the United States and imported into the United States. Based on the most current inventory update data generated by EPA for the year 2006, the total quantity imported or manufactured for use in the United States is less than one million pounds. C amine is only imported into the United States. Less than 500,000 pounds of C amine are imported into the United States.

There is no current manufacture of C amine in the United States. The total number of workers with potential exposure to 2b Acid and C amine is no more than approximately 25 in all facilities where these intermediates are made or used in the United States. These intermediates are shipped in sealed containers before being consumed completely in the water based reaction processes that produce monoazo pigments.

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Reaction Scheme

2b acid, 4b acid and C amine are completely consumed to produce monoazo red pigments. The following reaction schemes are provided as examples:

1.	2b acid --> 3-Hydroxy-2-naphthoic acid C.I. Pigment Red 48
2.	C amine --> 3-Hydroxy-2-naphthoic acid C.I. Pigment Red 52
3.	6-Amino-m-toluenesulfonic acid (4b acid) --> 3-Hydroxy-2-naphthoic acid C.I. Pigment Red 57

It is not possible for 2b acid or C amine to survive these coupling reactions and remain intact in the final pigments. Any traces of un-reacted intermediate present in the reaction process used to produce monoazo red pigments would be contained in the water used as the reaction media. These intermediates are soluble substances in comparison to the final monoazo pigment products and are removed by washing the final insoluble pigments.

There is no further exposure to 2b acid or C amine in downstream commercial uses of finished monoazo pigments or consumer applications and products. Monoazo pigments are encapsulated in the resins which make up inks, paints or plastics.

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Therefore, even if an unreacted intermediate were to remain in a pigment as a result of the production process, the finished pigment, and any unreacted intermediate contained therein, is encapsulated in ink, paint or plastic. As a result, further exposure to the unreacted intermediate is unlikely to downstream users and consumers.

There Are No Other Known Uses of These Intermediates

The OECD SIDS Initial Assessment Report ("SIAR") for 4b acid and our research and discussions with importers, manufacturers and users of 2b acid and C amine indicate that 2b acid and C amine are used only as intermediate reactants in the manufacture of monoazo pigments.

Structural Analogs 4b Acid, 2b Acid and C Amine

CPMA cited the considerable data available for 4b acid as a surrogate analog for 2b acid and C amine. The processes used to manufacture 4b acid and 2b acid are almost identical. 2b acid is produced by sulfonating chloroparatoluidine and 4b acid is produced by sulfonating paratoluidine. The only significant structural difference between 4b acid and the related intermediates 2b acid and C amine is the presence of a single chlorine atom. The single

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chlorine atom is located at the fourth position for 2b acid and fifth position for C amine. 4b acid, the unchlorinated analog of 2b acid and C amine, is a much stronger acid compound, being approximately 2 orders of magnitude more soluble than 2b acid or C amine. Therefore, since 4b acid is much more soluble and reactive than 2b acid or C amine, the use of 4b acid is an extremely conservative surrogate for 2b acid and C amine. In any short to intermediate term study of acute or subchronic toxicity, there is no reason to believe that 2b acid or C amine would exhibit a characteristic different from, or in addition to, that exhibited by the more reactive 4b acid.

Additional Animal Studies

Regarding EPA's request for additional animal studies for 2b acid and C amine, the additional information provided above should be more than sufficient to categorize these compounds appropriately as closed system intermediates. We disagree strongly with the assumption that additional studies will provide useful information commensurate with the cost.

We have also enclosed a copy of the OECD SIAR report and dossier for 4b acid. These reports contain complete robust summaries with additional details for the studies relied on by CPMA

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in our test plan for 2b acid and C amine. (We are continuing to look at these intermediates and analog surrogates.)

2b acid and C amine are also imported, manufactured and used by pigment manufacturers in Europe in large quantities. As a result, these intermediates will be the subject of review and testing, as necessary, under the European Union Registration Evaluation and Authorization of Chemicals ("REACH") regulation. The review, and any additional testing, will cover the data points requested by EPA. This larger group of international producers and users will be required to participate in the REACH program in order to continue to sell and use 2b acid and C amine in Europe. Therefore, since the remaining data points will be addressed by a larger group of manufacturers and users in the REACH program, CPMA members should not be burdened with the obligation to independently fund these studies twice. We will monitor progress of this substance in the REACH program and summarize the data for EPA when any necessary studies are complete.

In any event, since the intermediates 2b acid and C amine are no longer sold in commerce in quantities that would qualify as HPV substances under the original HPV program based on the 1990 TSCA Inventory update, these intermediates are no longer HPV chemicals in commerce and there is no further need for additional studies of

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these intermediates in support of the HPV program. Additionally, these intermediates have limited use and very limited exposure in no more than seven facilities in the United States.

CPMA makes no commitment with respect to the intermediates represented by this letter and the enclosed data or any guideline or requirement established pursuant to the voluntary HPV program or otherwise. Furthermore, CPMA reserves the right to defer the review of this chemical if it or an analog has been the subject of another undertaking in any EPA program or other similar international programs.

CPMA further reserves the right to withdraw this Test Plan should the HPV program, when and if finalized, prove to be different from that understood, from time to time, by CPMA. Since all of the pigments and intermediates represented by CPMA have been used in international commerce for many years, there is extensive data available from a variety of published and unpublished sources.

In conclusion, even though these intermediates are no longer HPV substances with production or import in excess of one million pounds per year, sufficient information has been identified and incorporated in the enclosed to allow for completion of the EPA

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voluntary HPV program for these insoluble intermediates without further redundant and unnecessary testing.

Thank you for your attention. Please call if there are any questions or comments.

Sincerely,

J. Lawrence Robinson
President