Initial Risk-Based Prioritization of High Production Volume Chemicals

Sponsored Chemical
C.I. Disperse Blue 79:1 (CAS No. 3618-72-2)
(9th CI Name: Acetamide, N-[5-[bis]2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-)

Supporting Chemical
C.I. Disperse Blue 79 (CAS No. 12239-34-8)
(9th CI Name: Acetamide, N-[5-[bis]2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. The information used by EPA includes data submitted under the HPV Challenge Program[1] and the 2006 Inventory Update Reporting (IUR)[2], and data publicly available through other selected sources[3]. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed. These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding these chemicals in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

Hazard and Fate Summary:

- Human Health: Available data indicate that the potential health hazard of this chemical is low based on acute and repeated-dose toxicity. The chemical did not show reproductive or developmental effects. While the sponsored chemical is mutagenic in *in vitro* genetic toxicity tests and negative in *in vivo* genetic toxicity tests, the supporting chemical is negative in both types of tests.
- Environment: Acute aquatic toxicity is not expected at the chemical's solubility limit (0.0052 mg/L). Available data from an early life stage chronic toxicity test indicates that the potential hazard of this chemical to aquatic organisms is low.
- Persistence and Bioaccumulation:
  - Available data indicate that this chemical has moderate persistence.
  - Available data indicate that this chemical has low bioaccumulation potential.

[1] US EPA, HPV Challenge Program information: http://epa.gov/hpv/.
[2] US EPA, IUR information: http://www.epa.gov/oppt/iur/index.htm.
[3] US EPA, Information on additional public databases used: http://www.epa.gov/hpvis/pubdtsum.htm.
[4] US EPA, U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.
[5] US EPA, ChAMP information: http://www.epa.gov/champ/.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources were used in developing this initial prioritization.
- Production Volume: This chemical was a moderate production volume (MPV) chemical in 2005, with an aggregated production and/or import volume in the U.S. in the range of 10,000 to 500,000 pounds. It was a high production volume (HPV) chemical in earlier reporting years.
- Uses: This chemical and related products are used almost exclusively for dyeing or printing polyester fibers.
- General Population and Environment: Based on moderate persistence and potential water releases from known uses, EPA identifies a medium potential that the general population and the environment might be exposed.
- Workers: Worker exposures by inhalation and dermal routes are possible for this chemical. The chemical is manufactured/imported in powder and liquid forms. Experience has shown that use and handling of powders, including many dyes, in workplaces often results in significant worker inhalation exposures to particulates. Dermal exposures are also possible to both the liquid and powder forms. This chemical has a negligible vapor pressure. EPA identifies a high relative ranking for potential worker exposure.
- Consumers: No uses in products intended to be used by consumers were reported in the IUR, nor were any found in other data sources. Although this chemical is used in fabric dyes, EPA's experience indicates that the dye process "fixes" the dye in the fiber, such that the chemical is not available for exposure simply through physical contact with the fabric Accordingly, EPA identifies a low potential that consumers might be exposed.
- Children: No uses in products intended to be used by children were reported in the IUR, nor were any found in other data sources. Based on the same rationale as the consumer exposure scenario, EPA identifies a low potential that children might be exposed.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN.* EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. The potential hazard of this chemical to aquatic organism is low. The low hazard of this chemical to aquatic organisms suggests a low concern for potential risk to aquatic organisms from environmental releases.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN.* EPA identifies a medium potential that the general population might be exposed from environmental releases. The potential human health hazard is low. The available information suggests a low concern for potential risks to the general population.
- Potential Risk to Workers: *LOW CONCERN.* Based on the IUR data in combination with the Agency's professional judgment, EPA identifies a high relative ranking for potential worker exposure. This relative ranking is based mainly on potential inhalation and dermal exposures to particulates. The potential human health hazard is low. The available information suggests a low concern for potential risks to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN.* Based on the IUR data, EPA identifies a low potential that consumers might be exposed through the use of

products containing this chemical. The potential human health hazard is low. Therefore, the available information suggests a low concern for potential risks to consumers.

- Potential Risk to Children: *LOW CONCERN.* EPA identifies a low potential for exposure to children. The potential human health hazard is low. Therefore, the available information suggests a low concern for potential risks to children.

Regulatory and Related Information Summary:

- This sponsored chemical is listed on the TSCA Inventory. It is not otherwise regulated under TSCA.
- EPA and Canada have reached different conclusions about the bioaccumulation potential of the sponsored chemical and the bioaccumulation potential and ecotoxicity of the supporting chemical. (See Appendix A). Overall, EPA considers the information it used for the sponsored chemical to be more reliable than that available for the supporting chemical, because it includes measured data for log K_{ow}, water solubility, and aquatic toxicity. Accordingly, EPA considers the bioaccumulation potential and the aquatic toxicity hazard of the sponsored chemical to be low and using read-across, the bioaccumulation potential and aquatic hazard of its supporting chemical to be low. EPA has shared this information with Canadian officials.

Assumptions and Uncertainties:

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses and prior assessment experience with disperse dyes.
- Although the submitted acute aquatic data were judged inadequate because testing was conducted above the chemical's aqueous water solubility, they do show that effects are not expected at the chemical's solubility limit. Furthermore, chronic test data are preferable in this case and the submitted chronic fish data were judged adequate for assessing aquatic toxicity endpoints.

Rationale Leading To Prioritization Decision:

- Hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address concerns for occupational exposures.
- This chemical has a low hazard profile which is expected to mitigate concerns in other situations where exposure may occur.
- Additional information regarding existing controls on potential worker exposure and the environmental releases could be useful to better characterize potential risks. However, such information would not be likely to change this prioritization decision.

Prioritization Decision:

- LOW PRIORITY - Follow-up action not suggested at this time.

Appendix A: Comparison of EPA and Canada Analyses.

Supporting Documentation:

Screening-Level Risk Characterization: July 2008
Screening-Level Hazard Characterization: July 2008
Screening-Level Exposure Characterization: July 2008

Appendix A: EPA's Analyses of C.I. Disperse Blue 79:1 and C.I. Disperse Blue 79.

- EPA and Canada have reached different conclusions about the bioaccumulation potential of C.I. Disperse Blue 79:1 and the bioaccumulation potential and ecotoxicity of C.I. Disperse Blue 79 (U.S. HPV supporting chemical). As part of its Domestic Substances List categorization, Canada considered C.I. Disperse Blue 79:1 to be persistent and bioaccumulative (PB) but not inherently toxic to non-human organisms (iT_{eco}) and therefore, not categorized "In". Canada categorized C.I. Disperse Blue 79, as $PBiT_{eco}$ and identified it as a high priority chemical under its DSL Challenge (Batch 5).
- While the U.S. and Canada both used modeled data for making a bioaccumulation determination, Canada made their "B" determination primarily on model estimates that appear to rely on log K_{ow} and used an estimated log K_{ow} (5.53) for Disperse Blue 79[6]. In contrast, EPA relied on the BCFWin model within the EPISuite[7] software (which Canada also considered). The BCFWin model for aromatic azo dyes is based on measured bioconcentration (BCF) data for 8 ionic and 7 non-ionic aromatic azo dyes with measured log BCF values. The measured log BCFs for these azo dyes range from 0.48 to 1.86, indicating that this class of chemicals does not to bioconcentrate to a great extent and bioconcentration is influenced by properties other than log K_{ow} (e.g., metabolism). Therefore, EPA believes, based on knowledge of the behavior of this class of compounds from measured data on similar chemicals, that both C.I. Disperse Blue 79:1 and C.I. Disperse Blue 79 have a low potential for bioaccumulation.
- EPA's characterization of aquatic toxicity for both Disperse Blue 79:1 and 79 is based on an empirical chronic toxicity study in which fish were exposed to multiple measured concentrations C.I. Disperse Blue 79:1 up to the water solubility limit. No effects were observed at any concentration, leading to the conclusion that there were "no effects at saturation" and therefore, that the aquatic hazard of C.I. Disperse Blue 79:1 is low. Canada's characterization of aquatic toxicity of C.I. Disperse Blue 79 is based on an estimate from U.S. EPA's ECOSAR program. The concentration estimated by ECOSAR is approximately 100 times greater than the solubility of C.I. Disperse Blue 79 and hence, is flagged with a note to the user that the chemical may not be soluble enough to achieve the predicted toxicity. EPA interprets this type of ECOSAR result as "no effects at saturation". Therefore, using both an analog approach, in which measured data for Disperse Blue 79:1 is 'read-across' to Disperse Blue 79, and ECOSAR estimates, EPA concludes that both Disperse Blue 79:1 and 79 have low aquatic toxicity.
- Overall, EPA considers the information it used for C.I. Disperse Blue 79:1 to be more reliable than that available for Disperse Blue 79, because it includes measured data for log K_{ow}, water solubility and aquatic toxicity. Accordingly, EPA considers the bioaccumulation potential and the aquatic toxicity hazard of C.I. Disperse Blue 79:1 to be low and using read-across, the bioaccumulation potential and aquatic hazard of its supporting chemical, C.I. Disperse Blue 79, to be low. EPA has shared this information with Canadian officials.

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[6] Substance Profile for the Challenge: Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-(Disperse Blue 79) CAS RN 12239-34-8: http://www.ec.gc.ca/substances/ese/eng/challenge/batch5/batch5_12239-34-8_en.pdf.

[7] US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA.