

TABLE III-1.—DYES AND PIGMENTS CONSTITUENTS OF CONCERN—Continued

Chemical compound	Synonyms	CAS
Zinc .....	.....	7440-66-6

Our primary data sources (described in section II.H of this notice and in the public docket for today's rule) used to develop the CoC lists include:

- Sampling and analytical data collected by EPA (as summarized in Table 1 of the *Magruder* consent order) and split sample analytical data compiled and provided by CPMA. These data characterized wastes generated from dyes and/or pigments production.

- Non-CBI RCRA § 3007 survey data characterizing wastes from dyes and/or pigments production.

- A list of 22 aromatic amines associated with azo dyes regulated by the European Union.

- Intermediates associated with dye and pigment products reported to be manufactured in the U.S. in the "Colour Index," Third Edition.

- Public comments on the prior 1994 and 1999 proposed listing determinations for dyes and pigment wastes.

- TRI releases reported by known manufacturers of dyes and/or pigments impacted by this proposal.

We found data linking each of the 35 CoCs listed above to dyes and/or pigments manufacture from at least two (and generally from at least four) of these data sources, and often found additional corroborating data from other more general encyclopedia and chemical dictionaries. In addition, we found toxicity benchmark data for each of these CoCs, allowing us to conduct risk assessment modeling of these compounds. As an example, we identified 4-chloroaniline as a CoC because (1) it was detected in our and CPMA's analytical data; (2) it was confirmed as present in dyes and/or pigments wastes in public comments; (3) it was reported to be released by known dyes and/or pigments manufacturers in the TRI; (4) it is regulated by the European Union as an aromatic amine linked to azo dyes; and (5) we identified toxicity benchmarks that allowed us to conduct risk assessment modeling of this compound.

## 2. What Was EPA's Approach to Conducting Human Health Risk Assessment?

The risk analysis for the dyes and/or pigments production wastes estimates the mass loadings of individual constituents that can be present in each

waste and still provide a specified level of protection to human health and the environment. The risk assessment evaluates waste management scenarios that may occur nationwide. We selected a national analysis that captures variability in meteorological and hydrogeological conditions for this listing determination because facilities that manage the wastes of interest are found in many areas of the country.

For this listing determination, we defined the target level of protection for human health to be an incremental lifetime cancer risk of no greater than one in 100,000 ( $10^{-5}$ ) for carcinogenic chemicals and a hazard quotient of 1.0 for noncarcinogenic chemicals. The hazard quotient is the ratio of an individual's chronic daily dose of a constituent to the reference dose for that constituent, where the reference dose is an estimate of the daily dose that is likely to be without appreciable risk of deleterious effects over a lifetime.

To determine the allowable mass loadings for constituents of concern, we used a probabilistic analysis to calculate the exposure to nearby residents from disposal of those constituents in the types of waste management units used by the dyes and pigments industries. We then set the allowable loading level such that the exposure to each constituent would not exceed the target level of protection for 90 percent of the nearby residents (adults and children). Thus, the allowable mass loadings meet a target cancer risk level of  $10^{-5}$  or hazard quotient of one for 90 percent of the receptor scenarios we evaluated. We calculated estimates of exposure in the upper end of the distribution (*i.e.*, at or above the 90th percentile), while avoiding estimates that are beyond the true distribution. EPA guidance for risk characterizations states that "the 'high end' of the risk distribution (generally the area of concern for risk managers) is conceptually above the 90th percentile of the actual (either measured or estimated) distribution. This conceptual range is not meant to precisely define the limits of this descriptor, but should be used by the assessor as a target range for characterizing 'high-end risk.'" <sup>25</sup> Therefore, a high-end estimate that falls within the range (at or above the 90th

percentile but still realistically on the distribution) is a reasonable input to a decision.

We believe that the 90th percentile levels from our probabilistic analysis are appropriate to set the levels for this mass loadings-based listing. The dyes and/or pigments production waste that remains nonhazardous at the proposed levels would pose risks below that indicated by the benchmark risk level at the 90th percentile. We also used the 90th percentile risk levels in two prior proposed concentration-based listings. See the proposed rules for wastes from paint manufacturing (66 FR 10060, February 13, 2001) and two dyes and/or pigments wastes (64 FR 40192, July 23, 1999).<sup>26</sup>

A probabilistic analysis calculates distributions of results (in this case a protective mass loading for each constituent) by allowing some of the parameters used in the analysis to have more than one value. The model is run numerous times (for this analysis we generally ran the model 10,000 times), each time with different values selected from the distributions of input parameters. A parameter is any one of a number of inputs or variables (such as distance between the waste management unit and the receptor) required for the fate and transport and exposure models and equations that EPA uses to assess risk. In the probabilistic analysis, we vary sensitive parameters for which distributions of data are available.

Parameters varied for this analysis include waste management unit size, parameters related to the location of the waste management unit such as climate and hydrogeologic data, location of the receptor, and exposure factors (*e.g.*, drinking water ingestion rates). In some cases, to maintain the inherent correlation between parameters, we treat multiple parameters as a single parameter for the purpose of conducting the analysis. We do this to prevent inadvertently combining parameters in our analysis in ways that are unrealistic. For example, we treat environmental setting (location) parameters such as climate, depth to groundwater, and

<sup>25</sup> "Guidance on Risk Characterization for Risk Managers and Risk Assessors," by then Deputy Administrator F. Henry Habicht, 1992.

<sup>26</sup> For traditional listing decisions, we have considered a range of probabilistic results at or above the 90th percentile, *e.g.*, see the proposed listings for wastes from the production of chlorinated aliphatics (64 FR 46476, August 25, 1999) and inorganic chemicals (65 FR 55684 September 14, 2000).