



May 7, 2019

Dr. John Budroe
Chief, Air Toxicology and Risk Assessment Section
Air and Site Assessment and Climate Indicators Branch
Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, California 94612

Re: Comments of the Color Pigments Manufacturers Association, Inc. on the Draft Hot Spots Program Technical Support Document for Cancer Potency Factors, Appendix B, Cancer Inhalation Unit Risk Factors for Cobalt and Cobalt Compounds

Dear Dr. Budroe:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") regarding the above-captioned matter (the "Draft Document").¹

The CPMA is an industry trade association representing small, medium and large color pigments manufacturing companies. In addition, the Association represents intermediate suppliers, companies selling pigment dispersions and preparations, and distributor companies in North America. The Association provides advocacy programs in support of the color pigments industry on matters pertaining to the environment, health, safety issues and trade. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

CPMA strongly supports the comments of the Cobalt Institute on the Draft Document. As proposed, the Draft Document uses multiple layers of excessively conservative assumptions which would grossly overestimate the risks for many Cobalt compounds and products, including complex inorganic color pigments containing Cobalt. As discussed by the Cobalt Institute, the Draft Document sets unrealistically conservative parameters for mutagenicity, solubility and independence of tumors, which, when taken together, generate a disproportionate outcome which is not relevant to any reasonable estimation of risk.

¹ Technical Support Document for Cancer Potency Factors. Appendix B, Cobalt and Cobalt Compounds Cancer Inhalation Unit Risk Factors, Public Comment Draft, March, 2019.
<https://oehha.ca.gov/media/downloads/cnr/cobaltiurdraft030819.pdf>

Assessments such as the Draft Document can have unanticipated negative impacts on the environment and the economy. Overly conservative regulation can act to force inappropriate substitutions which unintentionally bring more hazardous and unevaluated chemistries to the market.

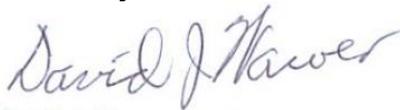
In particular, CPMA agrees with and specifically supports the Cobalt Institute comments on the unsubstantiated Draft Document conclusion that Cobalt and Cobalt compounds are genotoxic, based on studies using non-OECD guidelines such as the comet assay. CPMA agrees with the Cobalt Institute that Cobalt is not mutagenic and has not been shown to exhibit in vivo genotoxicity in OECD guideline studies. The mode of action which has linked certain Cobalt exposures with cancer in animals is through inflammation of the exposed tissues. The assumption that Cobalt is genotoxic vastly overstates the risk posed by Cobalt.

The Draft Document adopts the position that the "Cobalt ion following inhalation is considered to be the primary factor for cancer risk (NTP, 2016)". The Draft Document applies inhalation factors to all water soluble compounds, with a solubility greater than 100 mg/L, and to all water insoluble compounds, with water insolubility less than 100 mg/L.

CPMA believes that it is inappropriate for OEHHA to categorize all compounds with solubilities lower than 100 mg/L as essentially the same for inhalation risk assessment. This one-size-fits-all approach to regulation overstates the risk for many compounds and products, such as complex inorganic color pigments which do not yield significant amounts of bioavailable Cobalt.²

Thank you for your consideration of these comments. Please contact me at 571-348-5106 or davidwawer@cpma.com if you have any additional questions.

Sincerely,



David Wawer
Executive Director

² For example, see the study by D. Steinhoff and U. Mohr, entitled "On the Question of a Carcinogenic Action of Cobalt Containing Compounds", "Exp. Pathol.", Vol. 41, 169-174, 1991, which compared Cobalt Oxide and the pigment identified as Cobalt Aluminum Chrome Spinel in an intratracheal instillation study in rats.