



# CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

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May 25, 2016

To: Inorganic Pigments Committee

From: David J Wawer, CPMA Executive Director

Subject: NTP Final Monograph for Cobalt and Cobalt Compounds

[The National Toxicology Program](#) (NTP) published its Final Monograph, "[Cobalt and Cobalt Compounds That Release Cobalt Ions In-Vivo](#)", on April 22, 2016. Originally proposed in 2014, the final Monograph concludes that ingested or inhaled Cobalt compounds which release Cobalt ions are "reasonably anticipated to be human carcinogens".

**What's next?** The conclusions of the Monograph will be incorporated into the [NTP Report on Carcinogens](#), a congressionally mandated public health report. As a result, according to the Hazard Communication Standard, 29 CFR §1200, manufacturers will be required to incorporate this carcinogenicity determination in product safety data sheets if relevant to the product. The conclusions presented in the final Monograph are only relevant to soluble and poorly soluble Cobalt compounds, not including insoluble Cobalt compounds.

**What does this mean for your company?** Since many complex inorganic color pigments are considered "insoluble", companies will have to make a determination on the applicability of the Monograph conclusions to their products. For each process and product, the manufacturer or user should determine if the specific Cobalt pigments manufactured or used yield Cobalt ions in-vivo and whether they are, as a result, considered to be poorly soluble forms of Cobalt as described in the Monograph or insoluble forms of Cobalt not covered by the Monograph.

**CPMA comments and stakeholder input:** In collaboration with the IP Consortium, CPMA comments on the proposed Monograph supported the recommendation from the Cobalt Development Institute (CDI) to separate the analysis of highly bioavailable, soluble Cobalt substances, such as Cobalt Sulfate Heptahydrate, from nonbioavailable, poorly soluble compounds, such as Cobalt Oxide. CPMA also supported the IP Consortium position regarding the unique attributes of complex inorganic color pigments. CPMA recommended that the NTP recognize that extremely insoluble substances, such as complex inorganic color pigments containing Cobalt, are not significant sources of bioavailable Cobalt and that the toxicity of Cobalt compounds is a function of Cobalt bioavailability. CPMA argued that insoluble Cobalt compounds, such as complex inorganic color pigments containing Cobalt, which do not present a significant exposure to Cobalt in use, should not be assumed to be bioavailable substances and categorized as soluble and poorly soluble Cobalt compounds.

**Exclusion for insoluble compounds:** The final Monograph does not provide a distinction between soluble and poorly soluble substances such as Cobalt Oxide as recommended by CDI. Poorly soluble Cobalt compounds are listed as reasonably anticipated to be human carcinogens even though the compounds are acknowledged to be poorly soluble. The Monograph identifies a list of specific soluble and poorly soluble compounds. *Complex inorganic color pigments are not specifically identified or addressed in the Monograph.* Complex inorganic color pigments, such as Cobalt Aluminate Blue Spinels, are much less soluble than Cobalt Oxide and generally characterized as insoluble compounds, not poorly soluble compounds. The only specific insoluble compound which is excluded from the Monograph is vitamin B12, because the authors describe vitamin B12 as not yielding Cobalt ions in-vivo.