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Stephen Johnson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101 -A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

Subject: Public Comments on the HPV Challenge Program Test Plan for 9-Octadecenoic Acid (Z)-Cobalt Salt (cobalt oleate; CAS #14666-94-5) by ExxonMobil Chemical Company.

The following comments on the HPV Challenge Program test plan for cobalt oleate by ExxonMobil Chemical Company (EMCC) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Cobalt oleate is a metal carboxylate salt used as a catalyst in the production of oxo alcohols. EMCC notes that although the form of the cobalt changes in the reaction process, it is recovered and recycled on-site in a sustainable manner to produce more cobalt oleate, and neither cobalt oleate nor any of the cobalt reaction co-products are manufactured for sale or leave the production site. Thus, although this substance is not a closed-system intermediate per se, it is a site-limited intermediate, and potential exposures are very limited.

EMCC proposes no additional testing for cobalt oleate. Instead, it proposes to use read-across data for its dissociation products, oleic acid and ionic cobalt, as well as for cobalt stearate and fatty acids, tall oil, cobalt salt. These two compounds have been submitted in an HPV test plan prepared by the Synthetic Organic Chemical Manufacturers Association (SOCMA) Metal Carboxylates Coalition. EMCC notes that both are similar in structure to cobalt oleate. EMCC's thoughtful use of existing data for dissociation products and analogs saves animals' lives by avoiding duplicative tests. However, we must reiterate our objections to the testing proposed in the SOCMA test plan for cobalt stearate and fatty acids, tall oil, cobalt salt.

In the SOCMA test plan, it was observed that metal carboxylates readily dissociate into free metal and free acid. The proportion of dissociated salt is dependent on the pH, and the dissociation constant (pKa) is the pH at which 50% dissociation occurs. EMCC does not list a pKa value for cobalt oleate, but SOCMA reports pKa values for cobalt stearate and for fatty acids, tall oil to be 7.5 and 5.82, respectively. These values indicate that complete dissociation will occur at the physiologically relevant pH of the mammalian stomach (pH 1.2). Therefore, it is expected that when administered orally the toxicity of cobalt oleate will be due to the independent action of its dissociation products. As a

result, mammalian toxicity data for oleic acid and ionic cobalt, or its simple metal salts, can serve as surrogate data for that of cobalt oleate. EMCC notes that work described in the SOCMA test plan[1] shows that cobalt chloride is similar to, or more bioavailable than, the corresponding cobalt carboxylate salt, making cobalt chloride a conservative surrogate in estimating the toxicity of ionic cobalt.

EMCC proposes to use data for cobalt oleate's dissociation products as well as for cobalt stearate to characterize cobalt oleate's potential acute toxicity. Interestingly, the oral rat LD_{50} value reported by EMCC for cobalt stearate, 9820 mg/kg, appears to be taken from a study performed for The Shepherd Chemical Company, one of the sponsors of the SOCMA test plan. It was unclear whether a new LD_{50} test for cobalt stearate was proposed in the SOCMA test plan since, although one was listed in the test plan summary and table, it was not discussed in the proposed test plan section. Also, no mention was made of The Shepherd Chemical Company study in the SOCMA test plan, although it was summarized. We urge EPA to verify that no new LD_{50} test will be conducted for cobalt stearate by SOCMA for the HPV Program. Further, SOCMA clearly proposed a new LD_{50} for fatty acids, tall oil, cobalt salts, the other category member in this test plan. The existing data summarized by SOCMA and cited here by EMCC should satisfy this endpoint by read-across. It is inconceivable that this exceptionally agonizing test could have been proposed for one or both category members in the SOCMA test plan when reducing testing by read-across is the rationale for establishing categories of related chemicals to begin with.

EMCC also proposes to use data for cobalt oleate's dissociation products as well as for cobalt stearate to characterize cobalt oleate's potential repeated-dose, developmental and reproductive toxicity. The SOCMA test plan summarizes repeated-dose toxicity data for cobalt chloride, stearic acid and tall oil fatty acid, as well as developmental and reproductive toxicity data for tall oil fatty acid and cobalt chloride. Although this existing data for dissociation products, along with category read-across, satisfy the data requirements for cobalt stearate and fatty acids, tall oil, cobalt salt without the need for new testing, SOCMA proposed to conduct a repeated-dose test with repro/developmental screen, OECD 422, for cobalt stearate. EPA has not yet commented on the SOCMA test plan. We urge EPA to reject this proposed test which will result in the deaths of approximately 675 animals. A similar approach, using existing data on dissociation products, was endorsed by EPA and all stakeholders in 2004 for E. I. du Pont de Nemours & Company's test plan for triisopropylborate, a compound which breaks down to isopropanol and boric acid in water (see http://www.epa.gov/oppt/chemrtk/triprobt/c14841tc.htm) and this approach has also been used in a number of other test plans in which compounds dissociate at low pH.

EMCC proposes to use data for cobalt oleate's dissociation products, as well as for tall oil fatty acid and for cobalt stearate to characterize cobalt oleate's aquatic toxicity. Interestingly, the 96 h *Pimephales promelas* (fathead minnow) LL_{50} reported by EMCC for tall oil fatty acid, greater than 1000 mg/L, was cited in the SOCMA test plan and is originally from a Pine Chemicals Association HPV test plan for tall oil fatty acids and related substances. 1000 mg/L was the highest loading rate tested, indicating low aquatic

toxicity. As was the case for repeated-dose, developmental and reproductive toxicity discussed above, this existing data for dissociation products, along with category read-across, satisfy the data requirements for cobalt stearate and fatty acids, tall oil, cobalt salt without the need for new testing. Nevertheless, SOCMA proposed to conduct a fish acute toxicity test, OECD 203, for cobalt stearate. Again, we urge EPA to reject this proposed test which will result in the deaths of approximately 120 animals. In addition, EMCC reports that results obtained from the ECOSAR computer model for cobalt oleate indicate that the compound may not be soluble enough to measure effects. ECOSAR results for oleic acid indicated that effects are unlikely to be seen at saturation. EMCC's use of a quantitative structure-activity relationship to model cobalt oleate toxicity also saves animals' lives by avoiding unnecessary tests.

ExxonMobil Chemical Company's use of existing data for cobalt oleate's dissociation products, together with data calculated by ECOSAR is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information, and this approach saves animals' lives by avoiding duplicative and unnecessary tests. Further, cobalt oleate is expected to present a low health risk and exposure is limited. However, we must take this opportunity to reiterate our objections to the testing proposed in the SOCMA test plan for cobalt stearate and fatty acids, tall oil, cobalt salt cited in the current test plan. Existing data for dissociation products, along with category read-across, satisfies the data requirements for these substances without the need for new testing. We urge EPA to reevaluate the SOCMA test plan and to reject the proposed tests which will result in the deaths of approximately 815 animals.

Thank you for your attention to these comments. I may be reached at 610-586-3975, or via e-mail at josephm@peta.org.

Sincerely,

Joseph Manuppello
Research Associate
Research & Investigations

[1] Stopford W., Turner J, Cappellini D, and Brock T. 2003. Bioaccessibility testing of cobalt compounds. J. Environ. Monit. 5(4): 675-680.