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Anh Nguyen

05/05/04 09:13 AM

To: NCIC HPV@EPA

CC:

Subject: Fw: Environmental Defense comments on Methylcyclopentadienyl Manganese Tricarbonyl (CAS# 12108-13-3)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/05/2004 09:13 AM -----



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05/05/2004 08:55 AM

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Subject: Environmental Defense comments on Methylcyclopentadienyl Manganese Tricarbonyl (CAS# 12108-13-3)

(Submitted via Internet 5/3/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and sarah\_McLallen@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methylcyclopentadienyl Manganese Tricarbonyl (CAS# 12108-13-3).

The American Chemistry Council Petroleum Additive Panel's Health, Environmental, and Regulatory Task Group (HERTG) and its participating members, in response to EPA's High Production Volume (HPV) Chemical Challenge, have submitted robust summaries and a test plan describing available data and proposed additional studies for methylcyclopentadienyl manganese tricarbonyl (MMT).

The concise test plan provides brief descriptions of the synthesis, transport and use of MMT as a fuel additive and proposes necessary additional studies and technical discussion. According to this submission MMT is quite toxic to mammals by all routes of administration and considerable care needs to be taken to avoid human contact or release into the environment prior to its incorporation into gasoline. According to the sponsor, at its normal level of use, 10 to 40 ppm, in gasoline, MMT does not significantly increase the toxicity of gasoline: "Gasoline with and without MMT has the same toxicity, i.e., the MMT is such a dilute component of the fuel it presents no health issues beyond that of the gasoline itself." Environmental Defense does not concur with this view. We have long been concerned about the potential neurotoxicity of MMT, given that manganese is a well-known neurotoxicant. Accordingly, we strongly supported EPA's 1993 decision not to approve use of MMT as a gasoline additive because of lack of adequate data on MMT's neurotoxicity. (Unfortunately, the courts later compelled EPA to register MMT for use in gasoline on the remarkable ground that EPA lacked the statutory authority to consider MMT's potential health impacts.) Subsequent studies have only reinforced concerns about the neurotoxicity of MMT.

Although we continue to believe that additional neurotoxicity data on MMT are needed, we acknowledge that neurotoxicity data are not required under the HPV program. With regard to data elements that are required under the HPV program, the test plan briefly describes existing data that appear to meet most of the required elements and proposes additional studies to determine MMT toxicity to fish and algae. It also proposes to use computer modeling to provide estimates of fugacity and to address the subject of hydrolysis through technical discussion.

On review of this test plan we find it generally acceptable, but note the following relatively minor inconsistencies:

1. MMT is said to be "not readily biodegradable" in the test plan, although approximately 40% was degraded in 28 days, as reported in the robust summaries. This quantitative result, in addition to or rather than

the general statement, "not readily biodegraded", should be included in the test plan.

2. Section 6.1.1 of the test plan states that "Reliable aquatic ecotoxicity data for fish and reliable aquatic ecotoxicity data for algae are not available". This statement is in conflict with the following statement from Section 6.1.2 "The available acute aquatic toxicity data in Daphnia and fish are adequate and reliable." (The latter is probably just a typo since we note that additional studies of MMT to fish are proposed in the test plan.)

3. MMT is reported to be non-mutagenic in Salmonella but the test plan neglects to point out that MMT was toxic to bacteria and therefore could not be tested at very high concentrations.

Our review of the robust summaries indicates that most of the studies were not done under GLP. Since most of these studies were conducted prior to GLP and appear to be well-designed and conducted, that may be permissible. However, the acceptability of these studies comes into question when one notes that in almost all studies, even the most recent studies that are said to have been conducted under GLP, the purity of the test compound is not provided. In most cases the purity of the "test substance" is said to be "As Received" or "Not Provided". In our opinion, failure to confirm the purity of the test material, while occasionally permissible, is not acceptable when it is the case for virtually all studies cited. Thus, we would recommend either that additional assurance of the purity of the material tested be provided, or that additional studies be conducted to confirm the toxicity of MMT of known and representative composition.

Thank you for this opportunity to comment.

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