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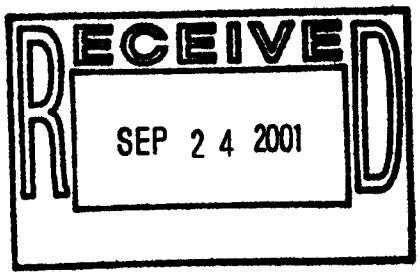

Via E-Mail

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
79 Alexander Drive
Building 4401, Room 3118
P.O. Box 12233
Research Triangle Park, NC 27709

Re: National Toxicology Program: Call for Public Comment on 16 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Eleventh Edition: 66 Fed. Reg. 38430 (July 24, 2001)

Dear Dr. Jameson:

The Metal Catalysts Panel (Panel) of the American Chemistry Council submits these comments in response to the National Toxicology Program's (NTP) call for comments on the proposal to list cobalt sulfate heptahydrate (CAS No. 10026-24-1) in the Eleventh Edition of the *Report on Carcinogens* (*RoC*). 66 Fed. Reg. 38430 (July 24, 2001). The members of the Panel are manufacturers and commercial processors of metal catalysts and their metal suppliers.[1]

The nomination for listing in the *RoC* is based on the results of an NTP rat bioassay with cobalt sulfate heptahydrate and an NTP bioassay on mice with cobalt sulfate heptahydrate.[2]

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1 The Panel members are: Akzo Nobel Chemicals, Inc.; Climax Molybdenum; CRI International, Inc.; Haldor Topsoe, Inc.; OM Group, Inc.; Sud-Chemie, Inc.; UOP LLC; and W.R. Grace & Co.

2 NTP, *NTP Technical Report on the Toxicology and Carcinogenesis Studies of Cobalt Sulfate Heptahydrate (CAS No. 10026-24-1) in F344/N Rats and B6C3F Mice (Inhalation Studies)* (Aug. 1998), Technical Report No. 471. *See also* 66 Fed. Reg. at 38431.

I. NTP SHOULD ISSUE A *FEDERAL REGISTER* NOTICE CLARIFYING THAT ONLY COBALT SULFATE HEPTAHYDRATE, AND NOT COBALT SULFATE, IS UNDER CONSIDERATION FOR POSSIBLE LISTING IN THE *RoC*

The July 24, 2001, *Federal Register* notice lists "cobalt sulfate" as the nominated chemical under consideration for possible listing. This mistake should be corrected, as other evidence shows that the notice apparently was intended to identify only cobalt sulfateheptahydrate as the nominated chemical. For example, the CAS number provided for "cobalt sulfate" -- 10026-24-1 -- is the CAS number for cobalt sulfate heptahydrate. Cobalt sulfate is a distinct chemical entity and has a distinct CAS number -- 10124-43-3 -- a number which is not listed in the notice. Further, the NTP bioassay that is cited as the basis for the nomination (TR 471, 1998) involved the inhalation of cobalt sulfate heptahydrate, identified in the study by CAS number 10026-24-1.

Because of the significant possibility of misunderstanding among the public and scientific community, the Panel urges NTP to issue a *Federal Register* notice clarifying that only cobalt sulfate heptahydrate, not cobalt sulfate, is the nominated chemical. The Panel further notes that if NTP in fact intended to nominate cobalt sulfate*per se*, the *Federal Register* notice provides insufficient notice of that fact. NTP's listing procedures require that the notice of nomination identify the specific chemical under consideration for listing[3]. For these reasons, NTP should issue a new notice that clarifies its intent and that extends the comment period.

II. COBALT SULFATE HEPTAHYDRATE DOES NOT MEET THE NTP STANDARD FOR LISTING AS "REASONABLY ANTICIPATED TO BE A HUMAN CARCINOGEN"

Section 301(b)(4) of the Public Health Service Act, as amended, mandates the Secretary of the Department of Health and Human Services to list only substances that both meet the toxicity listing criteria and to which a significant number of persons residing in the United States are exposed. As discussed in more detail in the Cobalt Development Institute's (CDI) comments, which the Panel supports and incorporates by reference here, industry production and use data gathered to date by CDI are insufficient for NTP to determine whether a significant number of persons residing in the United States are exposed.

The Panel believes, based on CDI's preliminary data, that the number of people reported to be exposed to cobalt sulfateheptahydrate appears to be very small. Thus, there appears to be no basis for NTP to conclude that sufficient numbers of people are exposed to meet the listing criteria. At the least, the Panel urges NTP to consider the information CDI is submitting in assessing whether the listing criteria have been satisfied with reference to cobalt sulfate heptahydrate.

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[3] NTP, Report on Carcinogens: Listing and Delisting Procedures, available at http://ntp-server.niehs.nih.gov/NewHomeRoc/ListDelistProc.html.

III. NTP SHOULD RECOGNIZE THAT THERE IS NO EVIDENCE OF AN ASSOCIATION BETWEEN DERMAL AND ORAL EXPOSURE TO COBALT SULFATE HEPTAHYDRATE IN HUMANS OR ANIMALS

As discussed in more detail in CDI's comments, inhalation exposure to cobalt compounds in an occupational setting is the most likely exposure route for humans. The only occupational study on the exposure of workers to water-soluble cobalt compounds is Muir, *et al.* (1987) and its follow-up study, Moulin, *et al.* (1993), which found no increased risk in the same cohort. The results of these studies do not provide a sufficient basis for the assessment of the risk of lung cancer in occupational settings.

CDI is now developing a risk assessment program to gather relevant data to assess the potential risk to humans from exposure to cobalt compounds. The Panel urges NTP to defer further consideration of the listing of cobalt sulfate heptahydrate until CDI's risk assessment is completed to ensure adequate information is available to assess the potential risk to humans from cobalt compounds. At the least, should NTP proceed with consideration of the listing of cobalt sulfate heptahydrate, it should expressly acknowledge that there is no evidence of an association between dermal and oral exposures to cobalt sulfateheptahydrate and cancer either in humans or in animals. This should be made clear in any notices of listing and in the *RoC* itself.

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Please direct any questions that you might have concerning these comments to Ms. Elizabeth Festa Watson, Manager of the Metal Catalysts Panel, at (703) 741-5629.

Sincerely yours,

Courtney M. Price

Courtney M. Price
Vice President, CHEMSTAR