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From: Allen Irish [airish@paint.org]
Sent: Friday, March 31, 2006 2:11 PM
To: NIOSH Docket Office
Cc: Skip Edwards
Subject: Public Comments for Docket #100 from Web site: TiO2
Importance: High
Attachments: NPCA Comments on NIOSH Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide.doc

Dear Sir or Madam:

Please accept these comments of the National Paint and Coatings Association concerning the NIOSH CURRENT INTELLIGENCE BULLETIN: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide, November 22, 2005. Docket Number NIOSH-033.

Please contact me by email or at 202-462-6272 should you have any questions or if these comments do not come through directly. Thank you.

Allen Irish, NPCA

4/3/2006



March 31, 2006

NIOSH Docket Office
ATTN: Diane Miller
Robert A. Taft Laboratories
4676 Columbia Parkway, M/S C-34
Cincinnati, Ohio 45226
513/533-8450

RE: NIOSH CURRENT INTELLIGENCE BULLETIN: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide, November 22, 2005. Docket Number NIOSH-033

Dear Sir or Madam:

The National Paint and Coatings Association (NPCA) is pleased to submit these comments on the National Institute for Occupational Safety and Health's (NIOSH) Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide (NIOSH Docket #33).¹ NPCA is a voluntary, nonprofit trade association representing some 400 manufacturers of paints, coatings, adhesives, sealants, and caulks, as well as raw materials suppliers to the industry and product distributors. As the preeminent organization representing the coatings industry in the United States, NPCA's primary role is to serve as ally and advocate on legislative, regulatory and judicial issues at the federal, state, and local levels.

NPCA concurs with comments submitted by the Titanium Dioxide Panel of the American Chemistry Council (ACC) and the Titanium Dioxide Manufacturers Association and Physical Sunscreen Manufacturers Association of the European Chemical Industry Council (hereinafter referred to collectively as ACC) on the Draft CIB submitted and adds its support to those comments. However, while we support those comments submitted by ACC, there are a number of additional points of emphasis we wish to add to those comments.

NIOSH has stated that the goals of the draft CIB are three-fold: (1) to describe the relevant animal, human, and in vitro studies on the health effects of Titanium Dioxide (TiO₂); (2) to provide a quantitative risk assessment based on dose-response information from the rat and human lung dosimetry modeling; and (3) to describe the rationale NIOSH used in the

¹ See 70 Fed. Reg. 77399 (December 30, 2005).



development of the draft recommended exposure limits (REL).² In preparing these comments, NPCA has been guided by the five questions that NIOSH posed for the Peer Reviewers:

1. Is the hazard identification and discussion of health effects for TiO₂ a full and reasonable reflection of the human and animal studies in the scientific literature?
2. Are the risk assessment and dosimetric modeling methods used in this document appropriate and relevant?
3. Are the sampling and analysis methods adequate to characterize worker exposure to fine and ultrafine TiO₂?
4. Is the use of particle surface area as a dose metric appropriate for estimating worker risks from inhalation of TiO₂?
5. Are there additional relevant studies or methods that NIOSH should consider in developing its RELs for TiO₂?³

Hazard Identification and Discussion of Health Effects for TiO₂

The most significant flaw in this document is its failure to produce adequate support for characterizing any observed health effects as peculiarly resulting from exposure to fine and/or ultrafine TiO₂ particulates, rather than to small particulates in general. As a result, we are unconvinced that there is sufficient evidence to ascribe any detrimental health effects to exposure specific to TiO₂ particulates. Although NIOSH has classified TiO₂ as a potential occupational carcinogen in 1988, based on observations that TiO₂ caused lung tumors in rats in a long-term, high-dose bioassay, the International Agency for Research on Cancer (IARC) currently classifies TiO₂ only in Group 3 (“limited evidence of animal carcinogenicity and inadequate evidence for human carcinogenicity”). Given the ambiguous state of the scientific evidence pertaining to the carcinogenicity of TiO₂, it is incumbent upon NIOSH to provide more specific information that would tie any observed health effects to TiO₂ specifically, rather than merely to fine or ultrafine particulates, which is, of course, an entirely different matter. Given the failure to meet this fundamental requirement, it is our view that this study has failed to meet the basic prerequisite for scientific and legal validity, and that in its current state, NIOSH cannot validly rely upon it as a basis for a recommended exposure limit of any kind.

Additionally, even assuming for the sake of argument that any observed health effects can be ascribed to TiO₂, the NIOSH CIB insufficiently characterizes the issue of particle size distribution (fine versus ultrafine). Accordingly, it is incumbent upon NIOSH to provide

² See NIOSH, “Draft Document for Scientific Peer Review: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide,” available at <http://www.cdc.gov/niosh/review/peer/tio2/#a>.

³ *Id.*

additional information on this point. Since, as noted, the exposure data for nano-sized TiO₂ particles reveals that any relevant health effects derive not from TiO₂ specifically, but from fine and ultrafine particulates in general, all affected parties need clarification about whether this document will ultimately come to represent NIOSH's approach for all inert ultrafine particulates not otherwise addressed by specific occupational exposure standards.

Risk Assessment and Dosimetric Modeling Methods

NIOSH recommends exposure limits of 1.5 mg/m³ for fine TiO₂ and 0.1 mg/m³ for ultrafine 70 TiO₂, as time-weighted average concentrations (TWA) for up to 10 hr/day during a 40-hour work week. In many industries, including and perhaps particularly, the coatings industry, the work environment is characterized by a variety of particulates of varying sizes and species. Most, if not all, current exposure data for TiO₂ is in the form of gravimetric total dust, and no specific information is available for TiO₂. Many coatings manufacturing facilities have put quite good dust control measures into place over the years. Thus, it is very difficult, if not impossible, to determine how stringent the proposed exposure limits are and whether it is even feasible to control workplace exposures to TiO₂ to the recommended level.

NIOSH has failed to address the critical issue of how industrial hygienists are expected to measure and appropriately speciate particulates in order to determine what fraction constitutes TiO₂. Unless there is a practicable way in which to make this crucial measurement, it will be virtually impossible to determine whether or not a REL for TiO₂ can be met. In this regard, NIOSH has failed to address or evaluate whether, given current sampling methodologies, meeting the recommended exposure limit is technologically and/or economically feasible. In accordance with NIOSH's charter to develop and establish recommended occupational safety and health standards and devise appropriate exposure monitoring and control strategies, it does contend that its interim sampling recommendations are based on current methodology.⁴ Having made that contention, it is critical that NIOSH address fully the sampling difficulties inherent in conforming to a REL for fine and ultrafine TiO₂ in a mixed-particulate workplace.

Additionally, NPCA concurs with the significant questions raised by the ACC comments concerning the relevance of the animal studies NIOSH relies upon as the basis for its recommendations. As was discussed extensively at the recent public hearing in Cincinnati, many of the animal studies summarized in Section 3 of the draft CIB either have been mischaracterized or misinterpreted by NIOSH, and the weight of the scientific evidence clearly refutes the appropriateness of the use of rats to characterize human lung responses to TiO₂. As the ACC comments observe, there are significant species differences in lung responses to overload concentrations of both pigment-grade and P25 ultrafine TiO₂ particles,⁵ and that rats, as opposed to other species used in such studies, have a unique lung response not observed in other species, such as mice or hamsters, that is likely to be the responsible mechanism for idiosyncratic lung tumor development.

⁴ CIB, p. 5, line 90.

⁵ P25 is a TiO₂ particulate mix comprised of 80 per cent anatase and 20 per cent rutile.

As an industry that is a significant user of TiO₂, we believe the CIB fails to account for the absence of reported health impacts and other epidemiological evidence of risk to our worker population (and many other similar industries) from these particulates. In our manufacturing environments TiO₂ (as well as many other powders and pigments of varying particle distributions) have historically been evaluated and properly managed to comply with exposure limits for respirable or total dust (particulate). When proper ventilation and/or PPE are used, the lack of health impacts appears to indicate that these existing and available protection methods are already successfully serving to protect human health fully.

Sampling and Analysis Methods

Any exposure assessment for TiO₂ done in order to assess risk must be conducted with a method that has been validated per NIOSH criteria, and complies with NIOSH-promulgated guidelines for development and evaluation of air sampling methods.⁶ It is clear that any evaluation of occupational risk performed as part of the CIB must be done in conformance with a method that both meets NIOSH-established criteria and is listed in the NMAM. We view this failure to employ a validated sampling and analytical method as a serious flaw in the development of the CIB. We urge NIOSH to validate and employ an appropriate method for sampling and analyzing “fine and ultra fine particulates” before continuing this effort.

Use of Particle Surface Area as a Dose Metric

We concur with comments submitted by the American Chemistry Council on this issue.

Additional Relevant Studies or Methods

Research protocols are being developed to measure levels of TiO₂ in the workplace and to investigate control technologies. This protocol should include investigations at workplaces with complex particulate exposures (*e.g.*, a plant manufacturing architectural coatings).

NPCA appreciates this opportunity to provide its comments, and urges NIOSH to revise the draft CIB to reflect the concerns we have identified herein.

Sincerely,

Lance “Skip” Edwards, CIH
Director, Health & Safety Affairs

H. Allen Irish, Esq.
Counsel, Government Affairs

*** Sent electronically (niocindocket@cdc.gov) and in hard-copy ***

⁶ A list of such validated methods is contained in the NIOSH Manual of Analytical Methods (NMAM).