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PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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

Subject: Public Comments on the HPV Challenge Program Test Plan for the Aluminum Alkoxides Category by The Soap and Detergent Association (SDA).

The following comments on the HPV Challenge Program test plan for the Aluminum Alkoxides Category by SDA 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.

We commend SDA for its use of existing data on the hydrolysis products of the aluminum alkoxides, noting the "Generally Recognized as Safe" (GRAS) status of alumina, and for its consideration of the weight-of-evidence for these chemicals, possessing generally low toxicity and exposure risk, to characterize health and environmental risks while reducing the number of animals used for testing. This approach is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information.

The aluminum alkoxides category consists of two chemical substances: 2-propanol, aluminum salt (CAS No. 555-31-7) and an aluminum salts mixture, C2-30, aluminum salts (CAS No. 68937-64-4), consisting of 15 individual salts. Greater than 90% of the aluminum salt mixture consists of C6 to C16 alkoxides with the average chain length around C10. Each component of the aluminum salts mixture is comprised of an inorganic component and a linear alcohol component.

2-propanol, aluminum salt is used as an intermediate in the production of 2-propanol and pharmaceuticals. It is also used in aluminum soaps, paints, cosmetics, and pesticides. The aluminum salt mixture is a site-limited intermediate used in alcohol manufacturing. Engineering controls including local exhaust ventilation control worker exposure and releases to the environment. SDA notes that the lack of significant exposure may obviate the need to fill apparent data gaps with mammalian testing, especially in light of animal welfare concerns.

Aluminum alkoxides hydrolyze rapidly to their constituent alcohols and alumina. While SDA notes that no rates of hydrolysis for aluminum alkoxides are available, data for silicone alkoxide show rapid hydrolysis in aqueous systems. Further, based on reaction dynamics, aluminum alkoxide would be expected to undergo even faster hydrolysis than

silicone alkoxide under both environmental and physiological conditions. Because of this rapid hydrolysis, data for the alcohols and alumina are representative of the aluminum alkoxides. A similar approach was endorsed by the 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.

Aliphatic alcohols have low mammalian toxicity; aquatic toxicity varies depending on the carbon chain length. Alumina or aluminum oxide is present at a relatively low percentage in these chemicals. Alumina is naturally occurring, ubiquitous in the environment and generally non-toxic. It is listed by the US Food and Drug Administration (FDA) as being cleared for limited food contact use. Further, the trihydrated form, aluminum hydroxide, is listed as GRAS. Therefore, alumina would be expected to be considered GRAS as well, and toxicity to mammals from the alumina component of the aluminum alkoxides category is not a significant concern.

SDA notes that the aquatic toxicity of aliphatic alcohols has been extensively studied. Acute fish toxicity data are available for most of the corresponding carbon chain length alcohols that make up the alkoxide mixture. The data indicate very low toxicity for the alcohols with carbon chain lengths below C8 and then a clear pattern of increasing toxicity with increasing chain length until approximately C14, beyond which no toxicity is observed. The 2-propanol portion of aluminum alkoxide has low aquatic toxicity. The mixture in which >90% of the compounds are C6 to C16 would be expected to have an aquatic toxicity relative to the varying toxicities of the mixture components. The aquatic toxicity of alumina has been studied using Daphnia magna, fathead minnows and rainbow trout, and all results indicate very low toxicity.

The mammalian toxicity of aliphatic alcohols has also been extensively studied. Acute oral toxicity data are available for nearly all of the corresponding alcohols. Repeated dose, reproductive and developmental toxicity data are available for the corresponding C2 - C18 alcohols. These data clearly demonstrate very low toxicity to various mammalian species across a wide range of carbon chain lengths. This carbon range accounts for 2-propanol and approximately 98% of the material in the mixture. Although few data are available for the corresponding C24-30 alcohols, based on a clear inverse relationship that exists between chain length and toxicity, substances with chain lengths exceeding the upper range tested can be expected to possess toxicological properties similar to those tested.

In its test plan for the aluminum alkoxides category, SDA cites existing data on the hydrolysis products of the aluminum alkoxides, noting the GRAS status of alumina, and considers the overall weight-of-evidence for these chemicals, possessing generally low toxicity and exposure risk, to characterize health and environmental risks while reducing the number of animals used for testing. We commend this thoughtful approach to toxicology, which is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information.

Thank you for your attention to these comments. I may be reached at (757) 622-7382, ext. 8001, or via e-mail at josephm@peta.org.

Sincerely,

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Research & Investigations