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DOES NOT CONTAIN CBI



SOLVAY SPECIALTY POLYMERS

350737

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December 17, 2012

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302



Re: TSCA 8(e) Submission of Findings from a Local Lymph Node Assay in Mice

Dear Sir/Madam:

Solvay Specialty Polymers USA, LLC (Solvay) is making this submission to the U.S. Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e). The submission provides information from a recent Local Lymph Node Assay (LLNA) conducted on 4,4 Biphenol (Biphenol), CAS# 92-88-6.

The potential of Biphenol to cause skin sensitization reactions following topical application to the skin of mice was assessed using the LLNA: BrdU-ELISA method, according to the OECD Guideline No. 442b. In the preliminary phase, a pretest was used to identify a non-toxic and minimally irritant concentration. A positive control group received a-hexylcinnamaldehyde, a known mild sensitizer.

In the main assay, Biphenol was applied to the dorsal surface of both ears of groups of female mice on three consecutive days at concentrations of 25, 10 and 5% w/w, in acetone: olive oil 4:1 (v/v) under a dose volume of 25 µl. On Day 5, a solution of BrdU, at a concentration of 10 mg/mL in physiological saline was administered to each animal by intraperitoneal injection, under a dose volume of 0.5 mL/animal. The testing laboratory advised that a chemical is

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considered a potential skin sensitizer when the stimulation index (SI) for any single treatment dose group is ≥ 1.6 . A dose response relationship was not observed in the test being reported.

Increases in cell proliferation were observed only at the low and high exposures. The calculated SI was 1.98, 1.32, and 2.00 in the low, middle, and high dose groups, respectively. Although the mid-dose increase was less than 2.0, the value that indicates the potential of the test item to induce sensitization, the reporting laboratory criterion is to conclude that a substance is a potential sensitizer if any group show an SI increase greater than or equal to 1.6. In the group treated with the positive control item, a SI of 4.97 was calculated. Because it was greater than 2, the test system was regarded as valid.

The effects reported for the low and high exposures were statistically significant when compared to controls. Therefore, the results obtained in this study indicate that 4,4-biphenol may have the potential to elicit a sensitization response in mice following dermal exposure. A literature search turned up no reports of the allergenic potential for this substance or structurally similar materials.

Nothing in this letter is considered confidential business information. This information is voluntarily submitted as a precautionary measure because it is not clear that the reporting criteria have been met, and not because it is information in which EPA may have an interest.

If you have any questions or require additional information regarding this submission, please do not hesitate to contact me.

Sincerely,



Carrie McMichael
Regulatory Affairs & Product Stewardship Manager
Solvay Specialty Polymers USA, LLC
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