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ARIZONA CHEM CO			
Contractor			
PHARMAKON LABS, *			
Document Title			
SUPPORT: LETTER FROM ATTYS FOR ARIZONA CHEM CO TO USEPA SUBMITTING STUDIES PURSUANT TO TSCA COMPLIANCE AUDIT AGREEMENT, WITH ATTACHMENTS (17 STUDY REPORTS) AND DATED 11/02/1999			
Chemical Category			
AQUEOUS ROSIN ESTER DISPERSION (CONFIDENTIAL), TALL-OIL *, *			

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OFFICE OF TOXIC SUBSTANCES
INDEXING FORM FOR GLOBAL INDEXING

REV. 12/78

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Memorandum

To: Ed Gross
From: Larry Culleen
Date: February 20, 2001
Re: November 2, 1999 Submittals

Attached is a complete set of the November 2, 1999 TSCA § 8(e) submittal for your files. Please call me if you have any questions at 202/942-5477.

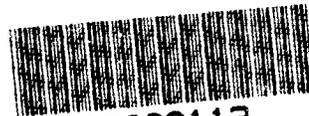


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NEW YORK
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November 2, 1999

Hand Delivery

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[Mail Code 7407]
Attention: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

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Re: TSCA § 8(e) Submittal

Dear Sir/Madam:

Enclosed are 17 studies submitted pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). These studies are being submitted pursuant to the TSCA Compliance Audit Agreement between EPA and the Arizona Chemical Company (Arizona). Arizona Chemical Company has its headquarters at 5220 Belfort Road, Suite 200, Jacksonville, Florida 32256-6012.

Following is a summary of the relevant results of each study, including the chemical identity of the substance tested, the adverse effects being reported, and a discussion of exposure and other considerations.

1. Acute Oral Toxicity of Aqueous Rosin Ester Dispersion

An acute oral toxicity study in rats was conducted on a commercial Arizona product that can be described generically as an aqueous rosin ester dispersion.¹ The specific composition of this substance is

¹ Because the trade name and specific identity of the test material are TSCA Confidential Business Information, both confidential and non-confidential versions of this letter and the study are being submitted.

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The test was conducted by Pharmakon Laboratories (Study #PH402-AZ-003-89). One animal died in the study. The LD₅₀ was determined to be greater than 5,000 mg/kg body weight. However, the test laboratory reported observations of "abnormal gait, abnormal stance, piloerection and dyspnea" in some test animals. This study is being submitted pursuant to Section 8(e) based upon EPA guidance that an abnormal stance and abnormal gait observed in test animals potentially are behavioral effects that might be indicative of neurotoxicological effects of a test substance. Two LD₅₀ studies on the major component of this product also have been conducted. The results of these tests showed no animal deaths at the highest dose (5,000 mg/kg in one study and 2,000 mg/g in the other study). No neurobehavioral effects were noted in either study.

2. Sensitization Study of Tall-Oil Fatty Acids

A skin sensitization study in guinea pigs was conducted on a commercial Arizona product, tall oil fatty acids (CASRN 61790-12-3). The test was conducted by Huntingdon Laboratories (Study #HRC920168D/BGV 5/SS). Ten out of twenty animals in the study were reported to have shown signs of sensitization based upon erythema observed at the challenge site. No animal deaths occurred during the study. The test animals exhibited only moderate skin sensitization. However, the study is being submitted pursuant to Section 8(e) based upon EPA guidance that skin sensitization studies might be reportable if there is evidence of strong sensitization and there is either actual or significant potential for exposure to the test substance. Arizona has found no other studies indicating that tall oil fatty acid is a skin sensitizer, and Arizona is aware of two studies in which tall oil fatty acid was determined not to be a skin sensitizer in tests performed using human volunteers. In addition, Arizona has no record of indications of skin sensitization in workers who handle material at its facilities.

3. Fifteen Ecotoxicity Studies on Tall-Oil Fatty Acids, Tall Oil Pitch, Alpha Pinene, Delta-3-Carene, and Tall Oil

EPA has provided guidance to industry regarding the reportability of acute ecotoxicity studies under TSCA Section 8(e). Based upon this guidance, test materials with LC₅₀ or EC₅₀ values of less than 1 mg/L are considered by the Agency to be of "high" concern; test materials with LC₅₀ or EC₅₀ values between 1 and 100 mg/L are considered to be of "moderate" concern; and test materials with LC₅₀ or EC₅₀ values of greater than 100 mg/L are considered to be of "low" concern. EPA guidance further states that acute ecotoxicity studies indicating a high concern should be submitted under Section 8(e) if there also is evidence that the test material has bioaccumulated to a pronounced degree or that it is or could be (based on use patterns) widespread in

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environmental media. Agency guidance states that test results showing moderate concerns should be reported if usage patterns and/or monitoring data for the test material suggest that the material is present in environmental media at or near concentrations where the effects in question could reasonably be expected to be manifested. According to EPA, results of acute ecotoxicity studies indicating a low concern need not be submitted.

Arizona has in its possession ecotoxicity studies on tall oil fatty acids, tall oil pitch, alpha pinene, delta-3-carene, and tall oil. The results of the studies are summarized below. Arizona does not have any information to support a conclusion that these substances are widespread in environmental media or that they are present in environmental media at or near concentrations where the effects in question could reasonably be expected to be manifested. Further, Arizona has questions regarding the interpretation of these data because of the manner in which the test materials were introduced into the test medium. Nevertheless, Arizona is submitting these data pursuant to Section 8(e) out of an abundance of caution, because four of these substances are commercial products currently manufactured by Arizona and because one (delta-3-carene) is not manufactured by Arizona but is a terpene that is likely to be a component in turpentine-derived products that are manufactured by Arizona.

Of the five ecotoxicity studies that were conducted on the commercial Arizona product, tall oil fatty acids (CASRN 61790-12-3), only one study included results which EPA classifies within the range of high concerns, and the remainder indicated moderate concern. Three algal growth inhibition studies showed EC₅₀ values from 0.79 to 9 mg/L (test report #s STZ 12/5/98, 308061/472 and 308201/649). One immobilization test with *Daphnia Magna* showed a 48-hour EC₅₀ value of 55.7 mg/L (test report #308069/472). One acute toxicity test on zebrafish showed a 96-hour LC₅₀ value of 10-20 mg/L (test report #308065/472).

Two ecotoxicity studies that were conducted on the commercial Arizona product, tall oil pitch (CASRN 8016-81-7), indicated low concern. An algal growth inhibition study showed an EC₅₀ value of greater than 1000 mg/L (test report #308061/473). An immobilization test with *Daphnia Magna* showed a 48-hour EC₅₀ value of greater than 2000mg/L (test report #308069/473). Nominal concentrations of test substance were used to determine the EC₅₀ values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; therefore, it also is likely that EC₅₀ values for the soluble portion of the test substance are less than 10 mg/L.

Three ecotoxicity studies were conducted on a commercial Arizona product, alpha pinene (CASRN 80-56-8; the substance also might be described by CASRN 65996-65-9

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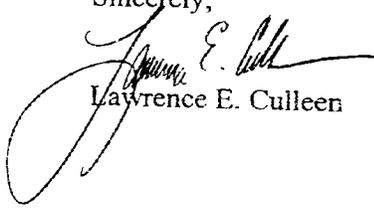
for "terpenes and terpenoids, turpentine oil, alpha pinene fraction"). These studies indicated moderate to low concern. An algal growth inhibition study showed an EC₅₀ value of 278 mg/L (test report #308061/487). An immobilization test with *Daphnia Magna* showed a 48-hour EC₅₀ value of 6.74 mg/L (test report #308069/487). An acute toxicity test on zebrafish showed a 96-hour LC₅₀ value of 10-20 mg/L (test report #308065/487). Nominal concentrations of the test substance were used to determine the EC₅₀ and LC₅₀ values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC₅₀ and LC₅₀ values for the soluble portion of the test substance are less than 10 mg/L.

Three ecotoxicity studies were conducted on delta-3-carene (CASRN 13466-78-9; the substance might also be described by CASRN 91770-80-8 for "terpenes and terpenoids, turpentine oil, 3-carene fraction"). These studies indicated moderate to low concern. This substance is not manufactured by Arizona in the U.S.; however, it is likely to be a naturally occurring component in turpentine-derived products that are manufactured by Arizona. An algal growth inhibition study showed an EC₅₀ value of 100-200 mg/L (test report #308061/488). An immobilization test with *Daphnia Magna* showed a 48-hour EC₅₀ value of 18.3 mg/L (test report #308069/488). A test on acute toxicity to zebrafish showed a 96-hour LC₅₀ value of 5-10 mg/L (test report #308065/488). Nominal concentrations of test substance were used to determine the EC₅₀ and LC₅₀ values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; therefore, it also is likely that EC₅₀ and LC₅₀ values for the soluble portion of the test substance are less than 10 mg/L.

Two ecotoxicity studies that were conducted on the commercial Arizona product, tall oil (CASRN 8002-26-4), indicated moderate concern. An algal growth inhibition study showed an EC₅₀ value of 15 mg/L (test report #STZ 14/98). An immobilization test with *Daphnia Magna* showed a 48-hour EC₅₀ value of 30 mg/L (test report #STZ 14/98).

Please contact me (at 202/942-5477) with any comments or questions that you have concerning these matters. Thank you.

Sincerely,


Lawrence E. Culleen

Enclosures

cc: Tony Ellis, EPA
Diane Staab, Arizona