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Office of Toxic Substances
US Environmental Protection Agency
401 M Street SW
Washington, DC 20460
Attn: TSCA 8(e) Coordinator

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Witco Corporation
OrganoSilicones Group
Sistersville Plant
3500 South State Route 2
Friendly, WV 26146
(304) 652-8000

July 15, 1998

8EHQ - 0798 - 14227S

Dear Sir or Madam:

OSi Specialties Inc., a subsidiary of Witco Corporation, herewith submits the following information pursuant to TSCA Section 8(e) concerning preliminary audited information from a 28-day repeated dose (gavage) study with rats on an amine catalyst, Niax® Catalyst A-400.

Niax® Catalyst A-400 is a mixture containing a maximum concentration of the following:

% Maximum Concentration*	Chemical Name	CAS #
	Niax® Catalyst A-99 [(bis(2-dimethylaminoethyl)ether]	3033-62-3

Water	7732-18-5
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*Maximum Concentration will not occur in all components at the same time.

The information provided in this letter is based on the instructions regarding reportability of toxicity data stated in the EPA's TSCA Section 8(e) Reporting Guide. This information was received as described herein on July 6, 1998. This information is summarized below.

A study of Niax® Catalyst A-400 (A-400) in Sprague-Dawley rats was conducted in order to evaluate the possible toxic effects of A-400 when administered orally (gavage) to rats for 28 days. The oral route was selected since this is an acceptable and standard method for administering the test article under OECD Guideline 407. Ingestion is not a potential route of exposure for humans, other than through accidental ingestion by workers handling the test article. The preliminary audited information from this study indicates that A-400 produces histopathological changes in multiple organs following oral exposure.

The test article in the vehicle (deionized water) was administered orally by gavage at dosage levels of 100, 300, and 1000 mg/kg/day. All animals in the high dose group showed signs of toxic effects (red discharge of the eye(s), labored respiration and hypothermia) and died prior to the scheduled necropsy. All animals in other dose groups survived to scheduled necropsy without exhibiting test article-related clinical signs, body weight or food consumption effects, effects on hematology or serum chemistry parameters, changes in organ weight data or macroscopic findings. Test article-related macroscopic gastrointestinal findings were also observed in the 1000 mg/kg/day group. Test article-related microscopic changes in the 1000 mg/kg/day group were observed in the liver, lung, kidney, small and large intestine, trachea, spleen, uterus, mesenteric and submandibular lymph nodes and glandular and nonglandular stomach, predominantly as vacuolar change of multiple cell types. Probable test article-related effects in the 1000 mg/kg/day group were observed in the vasculature and smooth muscle of multiple organs. Changes in testis and epididymis in the 1000 mg/kg/day group were possible test article-related, but drawing such conclusions is complicated because the animals were found dead before the end of the study. Test article-related changes in the 300 mg/kg/day group were observed as hepatocellular degeneration of the liver and vacuolar change of multiple cell types of the kidney, stomach, ileum, lung, trachea and mesenteric lymph node and vascular smooth muscle. Microscopic findings in the 300 mg/kg/day group were in general of minimal severity and observed only in a few animals. No test article-related effects were noted in the 100 mg/kg/day group.

A full copy of the audited report will be provided upon request. Please contact the undersigned with questions, if any, at (304) 652-8825.

Sincerely,

Lisa M. DuMars

Lisa M. DuMars

Manager, Product Safety and Regulatory Affairs

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