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Ciba Specialty Chemicals Corporation
USA

Regulatory Services

Ciba

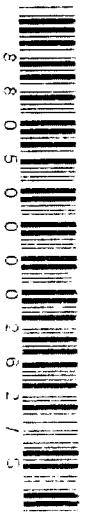
June 9, 2005

8EHQ-0605-16056

Federal Express
Confidential

US Environmental Protection Agency
OPPT Document Control Office Mail Code 7407M
Attention: Section 8(e) Submission
EPA East Building, Room 6428
1201 Constitution Avenue NW
Washington, DC 20460-0001

Company Sanitized



Subject: TSCA 8 (e) Notice – Cyclohexene-carboxylic acid, [(di-propenylamino) carbonyl]- sodium salt, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, ammonium salts

Dear Section 8(e) Coordinator:

This letter contains Confidential Business Information (CBI). CBI is bracketed { }.

In accordance with EPA's March 16, 1978 Policy Statement on Section 8(e) reporting under the Toxic Substances Control Act (TSCA), the EPA's June, 1991 TSCA Section 8(e) Reporting Guide, and EPA'S TSCA Section 8(e) Policy Statement and Guidance dated June 3, 2003 (68 Fed. Reg. 33129), Ciba Specialty Chemicals Corporation wishes to bring to the attention of the Environmental Protection Agency the results observed in a 14 day range finder conducted for above named material. {

}. In a 14 day dose range finding oral toxicity (gavage) study in the Wistar Rat [animals (3/dose) exposed to 100, 300 or 1000 mg/kg/d of compound] unexpected effects were produced on the liver in both sexes. There was no mortality nor any clinical signs or gross pathology to indicate any treatment related effects were evident and the food consumption and body weight gain were similar to controls. Furthermore, no compound related changes were noted during the hematology portion of the study. However, in the males treated with 300 and 1000 mg/kg/d, the absolute and/or relative liver weights were elevated and in the females dosed at 1000mg/kg/d, the liver -to -brain weight ratio was higher than in the controls. Histopathological findings included minimal to slight inflammatory cell foci (lympho-histiocytic) with single cell necrosis and hepatocellular hypertrophy (centrilobular) in all

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test groups and fatty liver changes in some of the highest dosed animals. Based on the results of this study, a NOEL (No Observable Effect Level) could not be determined. One female rat did develop a malignant lymphoma of the liver and spleen however due to the time course of the experiment (14 days) and the occasional occurrence of lymphomas as a background lesion at this young life stage of the test animals (~ 9 weeks old), the pathologist deemed this finding as not treatment related.

Ciba is presently retesting this product in a second 14-day range finding study, to establish a NOEL, and to better understand the cause and/or mechanism of the observed findings by additional investigations:

- An additional dose group will be treated with 30mg/kg/d
- Liver-specific clinical biochemistry will be performed
- Liver microsomal lauric acid 11- and 12-hydroxylase will be determined, as a marker for hepatic peroxisome proliferation.

Please note that this material is currently under PMN review. { }

A sanitized copy of this letter is enclosed. The CBI Substantiation document for this product was previously submitted with TSCA Section 8(e) document control number 8EHQ-05-16024 as indicated by current TSCA 8(e) requirements. Please call the undersigned at 336 801-2352, if you have any questions concerning this submission.

Respectfully,

Bonita G. Reynolds

Bonita G. Reynolds
Sr. Regulatory Specialist

cc: Lorraine Passe, US EPA