

US EPA ARCHIVE DOCUMENT

Memorandum

Date: 28 June 1982

Subject: EPA Reg. No. 10308-1 NEOPYNAMIN TECHNICAL GRADE  
Caswell #844

From: B. T. Backus  
IRB/TSS

To: Mr. Franklin Gee  
Product Manager 17

Registrant: Sumitomo Chemical Co., Ltd.  
c/o Dr. Eugene J. Gerberg  
1330 Dillon Heights Ave.  
Baltimore, MD 21228

Active Ingredient:

Neopynamin.....	90%
Inerts.....	10%

Background:

The registrant has submitted several subchronic dietary studies on this product, including a 104-week study involving male rats; a 104-week study on both male and female rats; and a 26-week study involving male and female beagles.

Comments and Recommendations:

1. In two 104-week dietary administration studies (EPA Acc. 247280) male rats receiving this material in their diet (up to 5,000 ppm) showed an increased incidence of testicular interstitial cell adenoma. Incidence was correlated with dosage level. Further, there was a pronounced tendency for involvement of both testes at higher dosage levels.
2. Female rats in the 104-week study showed a reduced incidence of mammary fibroadenoma, particularly at the highest dosage (5,000 ppm) level. This is noteworthy since female beagles receiving a similar dosage level in the 26-week study (Hazleton Project No. 343-127; dated 17 July 1981) showed a lack of estrus activity.
3. While no testicular changes were noted in the male beagles in the 26-week study, these subjects were exposed for a considerably shorter time than were the rats in the 104-week studies. Exposure was even less in terms of relative life expectancies.

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4. These studies should be referred to HED for review, comment, and appropriate recommendations.

5. IRB/TSS has no labeling recommendations for this product at this time.

Byron T Backus 06/28/82

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