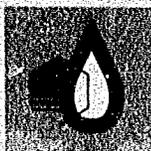


CODING FORMS FOR SRC INDEXING

Microfiche No.	OTS0559230		
New Doc ID	88980000078	Old Doc ID	8EHQ-0198-14109
Date Produced	12/05/97	Date Received	01/16/98
		TSCA Section	8E
Submitting Organization	BAYER CORP; *		
Contractor			
Document Title	INITIAL SUBMISSION: UNAUDITED SUMMARY DATA FROM DOSE RANGE-FINDING TERATOLOGY & DEVELOPMENTAL TOXICITY STUDIES OF FLUORESCENT BRIGHTENER 220 IN RABBITS, W/CVR LTR DT'D 1/16/98		
Chemical Category	C.I. FLUORESCENT BRIGHTENER 220		

ETAD



8EHQ-0198-14109

Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers

U.S. DYE MANUFACTURERS OPERATING COMMITTEE OF ETAD

January 16, 1998

Document Receipt Office
Room G 099
Attn: TSCA 8(e) Submission
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency (7407)
401 M Street, SW
Washington, DC 20460-0001

Contains No CBI

98 JAN 15 PM 1

RECEIVED

RE: TSCA 8(e) Report
C. I. Fluorescent Brightener 220 (CI 40623)
CAS No. 16470-24-9



8EHQ-98-14109

To Whom It May Concern:

ETAD submits, on behalf of the members of its Stilbene Whitening Agents Task Force (SWATF), the enclosed information as a Section 8 (e) report in accordance with procedures under the Toxic Substances Control Act. This submission contains no confidential information.

As part of pilot studies to establish dose levels for teratology and developmental toxicity studies of stilbene whiteners, the SWATF received draft, unaudited summary tables of data. Upon review of these data, the SWATF concluded that maternal toxicity was demonstrated in rabbits for the whitener, C. I. Fluorescent Brightener 220 (CAS No. 16470-24-9), at the highest dose tested, 1,000 mg/kg bw/day. A summary of these data appears in the following paragraphs.

88980000079



At the 1,000 mg/kg/day dose of Brightener 220, 1 rabbit died due to an apparent gavage error, 3 rabbits aborted their litters, 2 rabbits were found dead and 1 rabbit was euthanized *in extremis*. All of the deaths/euthanasia (except the apparent gavage error) and abortions were preceded by prolonged anorexia (multiple days) and were attributed to treatment. The abortions were considered a result of inanition, secondary to anorexia, and were not considered a direct result of treatment. Given the anorexia, the abortions were considered a manifestation of maternal toxicity.

Clinical observations attributed to treatment were limited to the 1,000 mg/kg/day dose of Brightener 220 and included aborted tissue in the fecal pans, prostration, dehydration, decreased activity, loss of righting reflex, decreased defecation, discolored feces, cold to the touch, eyes and skin area pale, and labored breathing.

Decreased food consumption was also attributed to treatment at the 1,000 mg/kg/day dose during days 13-16 and days 16-19. There was no significant effect on

98 JAN 26 AM 8:59

RECEIVED
DRIFT/HCIC

body weight. Body weight change was decreased at 1,000 mg/kg/day during days 13-16 and days 16-19.

An increased incidence of necropsy observations at 1,000 mg/kg/day included lung foci and discoloration, spleen discoloration, liver discoloration and accentuated lobulation, stomach edema and erosions, kidney discoloration and intestinal foci, discoloration and hemorrhage. No effect of treatment was noted on the reproductive or developmental endpoints.

ETAD is an international technical organization formed by the dyes manufacturing industry to address health and environmental issues pertaining to organic colorants. The SWATF is a separately funded task force organized under ETAD address health and environmental issues pertaining specifically to stilbene whiteners. The members of SWATF are Bayer, Ciba Specialty Chemicals, Clariant, and Crompton and Knowles.

Please contact the undersigned directly at 202-721-4154 if there are any questions in connection with this submission.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Tucker Helmes". The signature is written in a cursive style with a large initial "C" and "H".

C. Tucker Helmes, Ph.D.
Executive Director

Enclosure

File: SWA/EPA/TOX/2.2