

TSCA HEALTH & SAFETY STUDY COVER SHEET

8EHQ-0100-144895

TSCA CBI STATUS:

CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section ( Contains CBI).  
Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

<b>1.0 SUBMISSION TYPE</b> - Contains CBI <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ - Initial Submission <input checked="" type="checkbox"/> Follow-up Submission <input type="checkbox"/> Final Report Submission Previous EPA Submission Number or Title if update or follow-up: _____ Docket Number, if any: # _____ Preliminary Data from Combined Chronic Toxicity/Carcinogenicity Study in Wistar Rats <input type="checkbox"/> continuation sheet attached		
<b>2.1 SUMMARY/ABSTRACT ATTACHED</b> (may be required for 8(e): optional for §4, 8(d) & FYI)  <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	<b>2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID</b> P917-006-957 99-2-81	<b>2.3 FOR EPA USE ONLY</b> 2000 JAN -3 AM 11:49 RECEIVED DPPT CBI/C
<b>3.0 CHEMICAL/TEST SUBSTANCE IDENTITY</b> - Contains CBI Reported Chemical Name (specify nomenclature if other than CAS name): CAS# _____ Purity _____ % X- Single Ingredient <input type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture Trade Name: _____ Common Name: <b>BYF 2740</b> CAS Number _____ NAME _____ % WEIGHT _____ Other chemical(s) present in tested mixture _____ <input type="checkbox"/> continuation sheet attached		
<p><b>Confidential Information Has Been Sanitized</b></p>		
<b>4.0 REPORT/STUDY TITLE</b> - Contains CBI Additional preliminary data from Study of Chronic Toxicity & Carcinogenicity in Wistar Rats Company Sanitized <input type="checkbox"/> continuation sheet attached		
<b>5.1 STUDY/TSCATS INDEXING TERMS</b> [CHECK ONE] HEALTH EFFECTS (HE): <input checked="" type="checkbox"/> ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____		
<b>5.2 STUDY/TSCATS INDEXING TERMS</b> (see instructions for 4 digit codes) STUDY TYPE: TOX/CARC _____ SUBJECT ORGANISM (HE, EE only): <u>RATS</u> ROUTE OF EXPOSURE (HE only): _____ VEHICLE OF EXPOSURE (HE only): _____ Other: _____ Other: _____ Other: _____ Other: _____		
<b>6.0 REPORT/STUDY INFORMATION</b> <input type="checkbox"/> Contains CBI <input type="checkbox"/> Study is GLP Laboratory <u>Bayer Toxicology Lab, Stilwell, KS</u> Report/Study Date <u>12/17/99</u> Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _____ <input type="checkbox"/> continuation sheet attached		
<b>7.0 SUBMITTER INFORMATION</b> <input type="checkbox"/> Contains CBI Submitter: Donald W. Lamb Title: VP, Product Safety & Regulatory Affairs Phone: 412-777-7431 Company Name: <u>Bayer Corporation</u> Company Address: <u>100 Bayer Road, Pittsburgh, PA. 15205</u> _____ Submitter Address (if different): _____ Technical Contact: <u>Same as above</u> Phone: ( ) _____ <input type="checkbox"/> continuation sheet attached		
<b>8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS</b> - Contains CBI This is all the information we have at this time. Complete report will be submitted if completed and upon our receipt. <input type="checkbox"/> continuation sheet attached		

2000 JAN 29 PM 12:32

RECEIVED  
DPPT CBI/C

Submitter Signature: Donald W Lamb Date: 12/29/99

8EHQ-99-14489  
29000000705

## 9.0 CONTINUATION SHEET

TSCA CBI STATUS:

**CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)**

Clearly mark the confidential information with bracketing and check the box in the appropriate section (*Contains CBI*).  
Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

**Submitter Tracking Number/Internal ID**

P917 006 957 99-2-81
-------------------------

Continuation of 2.1

Preliminary information from this chronic rat study shows a statistically significant increase ( $p < 0.05$ ) in the incidence of adenocarcinomas in the uterine endometrium in the highest dose group. This is being reported as a follow-up to our June 23, 1999 submission.

### Abstract

In this study, groups of Wistar rats (50 animals/dose/sex) were exposed over a two year period to technical-grade material in the diet using nominal concentrations of 0 (control), 50, 100, 350, or 2500 ppm.

Histopathological investigations have shown a statistically significant increase ( $p < 0.05$ ) in the incidence of adenocarcinomas in the uterine endometrium in the highest dose group (4 / 5 / 3 / 2 / 12; control, low, mid, mid-high, and high dose groups, respectively).

Since the histopathological investigation and the evaluation of the remaining parameters being examined in this study are in progress, this information is preliminary.

**Confidential Information Has Been Sanitized**