

## CODING FORMS FOR SRC INDEXING

<b>Microfiche No.</b>	OTS0559997		
<b>New Doc ID</b>	88010000065S	<b>Old Doc ID</b>	8EHQ-0101-14853S
<b>Date Produced</b>	01/23/01	<b>Date Received</b>	01/30/01
		<b>TSCA Section</b>	3E
<b>Submitting Organization</b>	FMC CORP		
<b>Contractor</b>	FMC TOXICOLOGY LAB		
<b>Document Title</b>	INITIAL SUBMISSION: TSCA HLTH & SFTY STUDY CVR SHT REPORTING CHRONIC RAT FEEDING STUDY WITH [], BENZIMIDAZOYL HETEROCYCLE, DATED 1/23/2001 (SANITIZED)		
<b>Chemical Category</b>	BENZIMIDAZOYL HETEROCYCLE (CONFIDENTIAL)		

A 03

8EHQ-01-14853

TSCA HEALTH & SAFETY STUDY COVER SHEET - revised 6/25/95

RECEIVED  
OPPT/CBIC

TSCA CBI STATUS:

"PUBLIC DISPLAY COPY"

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> <i>Contains CBI</i> <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ <input checked="" type="checkbox"/> Initial Submission <input 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: # _____ <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> 01-140	<b>2.3 FOR EPA USE ONLY</b>						
<b>3.0 CHEMICAL/TEST SUBSTANCE IDENTITY</b> <i>Contains CBI</i> <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS# _____ Purity <u>N.A.</u> % <input checked="" type="checkbox"/> Single Ingredient <input checked="" type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture Trade Name: _____ Common Name: <u>benzimidazolyl heterocycle</u> <table border="1"> <thead> <tr> <th>CAS Number</th> <th>NAME</th> <th>% WEIGHT</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> Other chemical(s) present in tested mixture _____ <input type="checkbox"/> continuation sheet attached			CAS Number	NAME	% WEIGHT			
CAS Number	NAME	% WEIGHT						
<b>4.0 REPORT/STUDY TITLE</b> <i>Contains CBI</i> Chronic Rat Feeding Study <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: <u>STOX</u> SUBJECT: _____ ROUTE OF EXPOSURE (HE only): <u>ORAL</u> VEHICLE OF EXPOSURE (HE only): <u>FOOD</u> ORGANISM (HE, EE only): <u>RATS</u> Other: _____ Other: _____ Other: _____								
<b>6.0 REPORT/STUDY INFORMATION</b> <i>Contains CBI</i> <input checked="" type="checkbox"/> Study is GLP Laboratory: <u>FMC Toxicology Laboratory</u> Report/Study Date: <u>on-going</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> <i>Contains CBI</i> Submitter: <u>Linda M. Clark</u> Title: <u>Product Reg. Affairs</u> Phone: <u>(215) 299-6133</u> Company Name: <u>FMC Corporation</u> Company Address: <u>1735 Market Street</u> <u>Philadelphia, PA 19103</u> Submitter Address (if different): _____ Technical Contact: <u>Jane McCarty</u> Phone: <u>(609) 951-3662</u> <input type="checkbox"/> continuation sheet attached								
<b>8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS</b> <i>Contains CBI</i> <input type="checkbox"/> continuation sheet attached								

COMPANY SANITIZED

8EHQ-01-14853  
880100000655

2001 FEB 21 10:19 AM

RECEIVED  
OPPT/CBIC

Submitter Signature: Linda M. Clark

Date: 1/23/01

9.0 CONTINUATION SHEET

"Public Display Copy"

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

01-140

CONTINUED FROM COVER SHEET SECTION # 2.1

Contains CBI

This study is being submitted under TSCA 8(e) due to death and significant clinical signs at the dose level of 300 ppm.

Groups of seventy rats per sex are receiving in the diet for two years in a combined toxicity/carcinogenicity study. This chemical is and is The study was started on October 26, 2000. The dose levels selected were 0, 20, 60 and 300 ppm in the diet. These dose levels were selected based on the findings in a 90-day study, with rats, in which groups of ten per sex per group received 0, 20, 60, 200 or 600 ppm. Because there was high mortality in the 600 ppm group, and some toxicity in the 200 ppm group, the top dose selected for the chronic study was 300 ppm.

On December 28, our toxicologist was contacted by the study director due to concern about the health of six males in the study. These animals had clinical signs including reduced activity, pale eyes and/or extremities, rolling gait, subdued behavior, hunched posture and weight loss. One of the males was found dead on December 28. The study director recommended lowering the dose level and 200 ppm was decided upon. The new diets were prepared and offered to the high dose males on December 29, 2000. The five other males that had been affected were given untreated diet to see if their condition would improve. Two of these animals were sacrificed on December 29 and 30 because of the severity of the signs. On January 8, the remaining three animals that had been on untreated diet were judged to be in good enough health to return to the 200 ppm diet.