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CODING FORMS FOR SRC INDEXING

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Date Produced	Date Received	TSCA Section
12/22/99	12/27/99	8E
Submitting Organization		
FMC CORP		
Contractor		
Document Title		
INITIAL SUBMISSION: TSCA HLTH & SFTY STUDY CVR SHT W/CONTINUATION. SHT RE RESULTS OF RAT PILOT TERATOLOGY STUDY WITH CMC [], BENZIMIDAZOLYL HETEROCYCLE, DATED 122299 (SANITIZED)		
Chemical Category		
BENZIMIDAZOLYL HETEROCYCLE (CONFIDENTIAL)		

INITIAL SUB-MISSION

TSCA HEALTH & SAFETY STUDY COVER SHEET - revised 6/25/96

8EHQ-1299-14621,S

TSCA CBI STATUS: **"PUBLIC DISPLAY COPY"**

CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

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1.0 SUBMISSION TYPE ' Contains CBI

' 8(d) X 8(e) ' FYI ' 4 ' OTHER: Specify _____

X Initial Submission ' Follow-up Submission ' Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: Docket Number, if any: #

' continuation sheet attached

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID	2.3 FOR EPA USE ONLY
X YES ' NO	99-135	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ' Contains CBI

Reported Chemical Name (specify nomenclature if other than CAS name):

CAS# _____

Company Sanitized

Purity N.A. %

' Single Ingredient

' Commercial/Tech Grade

' Mixture

Trade Name: _____ *Common Name:* benzimidazolyl heterocycle

	CAS Number	NAME	% WEIGHT
Other chemical(s) present in tested mixture			

' continuation sheet attached

4.0 REPORT/STUDY TITLE ' Contains CBI

Rat Pilot Teratology with CMC

MR 30385

' continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): ____ ENVIRONMENTAL FATE (EF): ____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: TERA SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): GAVG VEHICLE OF EXPOSURE (HE only) CMC

Other: ____ *Other:* ____ *Other:* ____ *Other:* ____

6.0 REPORT/STUDY INFORMATION ' Contains CBI X Study is GLP

Laboratory FMC Toxicology Laboratory Report/Study Date on-going

Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _____

' continuation sheet attached

7.0 SUBMITTER INFORMATION ' Contains CBI

Submitter: Linda M. Clark Title: Manager, Product Reg. Affairs Phone: (215) 299-6133

Company Name: FMC Corporation Company Address: 1735 Market Street

Philadelphia, PA 19103 Submitter Address (if different): _____

Technical Contact: Jane McCarty Phone: (609) 951-3662

' continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS ' Contains CBI

' continuation sheet attached

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Submitter Signature: Linda M Clark Date: 12/22/99

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9.0 CONTINUATION SHEET

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99-135

CONTINUED FROM COVER SHEET SECTION # 2.1

Contains CBI

This study is being submitted due to the decreased fetal body weights seen at 5 mg/kg and greater and the increased early resorptions at 10 mg/kg and greater in the absence of maternal toxicity.

Groups of eight mated female rats were administered suspended in 1% carboxymethylcellulose (CMC) on days 6 – 19 of gestation. is an experimental still in the R&D pre-commercialization phase. The dose levels were 0, 1.0, 3.0, 5.0, 10 and 30 mg/kg/day. Clinical observations were recorded daily; body weights and food consumption were recorded at three-day intervals. Prior to c-section, blood was collected for hematology determinations. A c-section was performed on each dam. Fetuses were weighed, sexed and examined for external alterations.

Maternal effects included vocalization in 4/8 rats at 30 mg/kg, increases in total white blood cell counts, segmented neutrophils, lymphocytes and nucleated red blood cells. Decreases in maternal body weights were attributed to early resorptions. Effects on the fetus included decreased litter size and increased complete resorptions at 30 mg/kg/day. At 10 mg/kg/day and greater, there was an increased incidence of early resorptions. At 5 mg/kg/day and greater there was a decrease in fetal body weights. The maternal NOEL is 10 mg/kg/day and the fetal NOEL is 3 mg/kg/day. Also, one fetus at 5 mg/kg/day had a protruding tongue and micrognathia (small jaw). This is an unusual finding which was also seen in one fetus in a study submitted earlier to EPA (8EHQ-98-14138). In the previous study with a similar design, was administered in corn oil to groups of ten rats at doses of 0, 1, 3, 10, 30 and 100 mg/kg. The maternal and fetal NOELs were 3 mg/kg/day based on decreased food consumption and MCHC in the dams and decreased fetal body weights at 10 mg/kg/day.

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CERTIFICATE OF AUTHENTICITY

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