

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-11-18490	8812000033	11/29/11

COMMENTS:

DOES NOT CONTAIN CBI

TSCA HEALTH & SAFETY STUDY COVER SHEET

339 774

TSCA CBI STATUS:

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2011 NOV 29 AM 6:02

1.0 SUBMISSION TYPE <input type="checkbox"/> 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 <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		
2.1 SUMMARY/ ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI) <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID 7006-2150-0001-9158-6636 11-0024	2.3 FOR EPA USE ONLY
3.0 CHEMICAL / TEST SUBSTANCE IDENTITY <input type="checkbox"/> Contains CBI Reported Chemical Name (specify nomenclature if other than CAS name): CAS # 2231-57-4 Carbonothioic dihydrazide <input checked="" type="checkbox"/> Single Ingredient <input type="checkbox"/> Commercial / Tech Grade <input type="checkbox"/> Mixture		
4.0 REPORT / STUDY INFORMATION <input checked="" type="checkbox"/> Study is GLP Study Title: In Vitro Mammalian Chromosomal Aberration Test in Human Lymphocytes Study No: DMN0022 Source of Data / Study Sponsor (if different than submitter) Bayer CropScience LP <input type="checkbox"/> Continuation sheet attached		
5.0 STUDY / TSCATS INDEXING TERMS (CHECK ONE) HEALTH EFFECTS (HE): <input checked="" type="checkbox"/> ENVIRONMENTAL EFFECTS (EE): <input type="checkbox"/> ENVIRONMENTAL FATE (EF): <input type="checkbox"/>		
6.0 SUBMITTER INFORMATION Ann M. Blacker, PhD Director, Regulatory Toxicology Bayer CropScience - PO Box 12014, RTP, NC 27709 Phone: 919-549-2973 <input type="checkbox"/> Continuation sheet attached		
7.0 ADDITIONAL / OPTIONAL STUDY COMMENTS <input type="checkbox"/> Contains CBI This compound Is used as a chemical intermediate in the manufacture of a pesticide product. <input type="checkbox"/> Continuation sheet attached		

Submitter Signature: _____

Ann M. Blacker

Date: Nov 22, 2011



CONTAINS NO CBI

8.0 CONTINUATION SHEET

Submitter Tracking Number / Internal ID

7006-2150-0001-9158-6636
11.0024

Continuation of 2.1

Reporting was based on the following results:

Human lymphocytes, in whole blood culture, were stimulated to divide by addition of phytohaemagglutinin, and exposed to the test substance both in the absence and presence of S9 mix derived from rat livers. Solvent and positive control cultures were also included. Two hours before the end of the incubation period, cell division was arrested using Colcemid®, the cells harvested and slides prepared, so that metaphase cells could be examined for chromosomal damage.

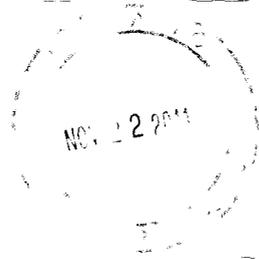
In the absence of S9 mix, the test material caused statistically significant increases in the proportion of metaphase figures containing chromosomal aberrations at concentrations of 137.57 µg/mL ($p < 0.01$: including and excluding gaps) and 382.14 µg/mL ($p < 0.001$: including and excluding gaps), when compared with the solvent control.

In the presence of S9 mix, the test material caused no statistically significant increases in the proportion of metaphase figures containing chromosomal aberrations, at any concentration, when compared with the solvent control.

As a clear statistically significant response was observed in the absence of S9 mix only, with mean values which exceeded the laboratory historical control range, no further testing was conducted.



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