

TSCA HEALTH & SAFETY STUDY COVER SHEET

"PUBLIC DISPLAY COPY"

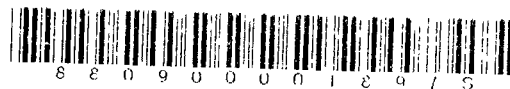
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1.0 SUBMISSION TYPE <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify <input checked="" type="checkbox"/> Initial Submission <input 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 7006-2150-0001-9158-6476 09-0039	2.3 FOR EPA USE ONLY
3.0 CHEMICAL / TEST SUBSTANCE IDENTITY <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS number and chemical name are claimed as CBI. <input checked="" type="checkbox"/> Single Ingredient <input type="checkbox"/> Commercial / Tech Grade <input type="checkbox"/> Mixture Common Name: carboxamide		
4.0 REPORT / STUDY INFORMATION <input checked="" type="checkbox"/> Study is GLP Study Title: Complementary chronic toxicity and carcinogenicity study in the male Wistar rat by dietary administration Study No.: SA05250 Source of Data / Study Sponsor: 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 J. Michael Wey Head – Health, Safety, Environment Expertise Center Bayer CropScience - PO Box 12014, RTP, NC 27709 Phone: 304-767-6680 Technical Contact: 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"/> Continuation sheet attached		

Submitter Signature: *J. Michael Wey*

Date: March 31, 2009



Company Sanitized

318346

8.0 CONTINUATION SHEET

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Submitter Tracking Number / Internal ID

7006-2150-0001-9158-6476
09-0039

Continuation of 2.1

Reporting was based on the following results:

Groups of 70 male rats were exposed to test material via dietary admixture at 0, 50, 300 and 2000 ppm. After 54 weeks, the surviving 10 males from each group allocated to the chronic (12-month) phase were necropsied at the first scheduled interim sacrifice. The remaining 60 animals/sex/group, allocated to the carcinogenicity (24-month) phase of the study, continued treatment until final sacrifice of the study after at least 104 weeks of treatment, when surviving animals were necropsied.

Liver and thyroid were identified as target organs in the mid- and high dose groups. Microscopic changes consisted of the following:

At 2000 ppm:

- Liver - minimal to moderate centrilobular to panlobular hypertrophy, minimal brown pigments, slightly higher incidence and severity of eosinophilic foci and a concomitant higher incidence and severity of cystic degeneration
- Thyroid - higher incidences of focal/multifocal follicular cell hyperplasia and diffuse follicular cell hypertrophy along with a higher incidence and/or severity of colloid alteration and a higher incidence of brown pigments in follicular cells

300 ppm

- Liver - minimal centrilobular to panlobular hypertrophy
- Thyroid - higher incidence and severity of colloid alteration