

TSCA HEALTH & SAFETY STUDY COVER SHEET

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<b>1.0 SUBMISSION TYPE</b> <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> <b>8(e)</b> <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ XX- Initial Submission    - Follow-up Submission    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> 7004 2510 0002 4033 8438 05-2-03	<b>2.3 FOR EPA USE ONLY</b>   BEHQ-0405-160195				
<b>3.0 CHEMICAL/TEST SUBSTANCE IDENTITY</b> Reported Chemical Name (specify nomenclature if other than CAS name): _____ CAS# _____ Purity ____% <input checked="" type="checkbox"/> Single Ingredient <input type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture    Trade Name _____    Common Name: Pyrasulfotole <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:30%;"></td> <td style="width:30%; text-align: center;"><u>CAS Number</u></td> <td style="width:30%; text-align: center;"><u>NAME</u></td> <td style="width:10%; text-align: center;"><u>%WEIGHT</u></td> </tr> </table> Other chemical(s) present in tested mixture _____ <input type="checkbox"/> continuation sheet attached				<u>CAS Number</u>	<u>NAME</u>	<u>%WEIGHT</u>
	<u>CAS Number</u>	<u>NAME</u>	<u>%WEIGHT</u>			
<b>4.0 REPORT/STUDY TITLE</b> One-Generation Reproduction Study in Wistar Rats (Pilot study for a Two-Generation Reproduction Study with Administration in the Diet)  <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>RTOX</u> SUBJECT ORGANISM (HE, EE only): <u>RATS</u> ROUTE OF EXPOSURE (HE only): _____    VEHICLE OF EXPOSURE (HE only): _____ Other: _____    Other: _____						
<b>6.0 REPORT/STUDY INFORMATION</b> <input type="checkbox"/> Study is GLP Laboratory <u>Bayer HealthCare AG, PH-PD Toxicology International</u> Report/Study Date: <u>3/2/05</u> Source of Data/Study Sponsor (if different than submitter) <u>Bayer CropScience</u> Number of pages <u>-</u> <input type="checkbox"/> continuation sheet attached						
<b>7.0 SUBMITTER INFORMATION</b> Janet M. Mostowy, Ph.D. VP, Product Safety & Regulatory Affairs    Phone: 412-777-3490 Bayer Material Science Corporation - 100 Bayer Road, Pittsburgh, PA. 15205  Submitter Address (if different): _____ Technical Contact: <input type="checkbox"/> Same as above    Phone: ( ) _____ <input type="checkbox"/> continuation sheet attached						
<b>8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS</b> This compound is _____  <input type="checkbox"/> continuation sheet attached						

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Submitter Signature: \_\_\_\_\_ Date: 3/21/05



**9.0 CONTINUATION SHEET**  
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Submitter Tracking Number/Internal ID

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**Continuation of 2.1**

Reporting was based on the following results:

The purpose of this one-generation study was to evaluate possible effects of **AE 0317309** on the parental generation and the entire reproduction process in Wistar rats. This study was intended as a pilot study for a subsequent two-generation study. **AE 0317309** was administered to groups of 10 male and 10 female rats at concentrations of 0 (control), 100, 600 or 3600 ppm in their diet. Survival, appearance and behavior of F<sub>1</sub> rats were not affected up to 3600 ppm. The male F<sub>1</sub> rat body weight depression was evident from 600 ppm onwards. In F<sub>1</sub> females the body weight gain was decreased at some time points of gestation and lactation at 3600 ppm. At 3600 ppm F<sub>1</sub> rats exhibited an increase in food intake per kg body weight. At necropsy parental rats showed no macroscopic treatment-related findings up to 3600 ppm. There was a non-dose related increased absolute and relative weights of the testes and epididymides in all treatment groups are not considered to reflect a toxic effect. From 600 ppm onwards increased relative liver and kidney weights were calculated in males. The indices of insemination, fertility, gestation, rearing and life births as well as mating performance, duration of pregnancy, birth weights, number of pups born, percentages of males born and prenatal loss were not affected at levels of up to 3600 ppm. At 3600 ppm the number of implantation sites and the mean litter size were reduced. The pup weights were retarded from post-natal day 21 onwards.

There were no treatment related changes in viability or lactation indices at any dose level. Clinical observation of F<sub>1</sub> pups revealed no remarkable changes up to 3600 ppm. At 3600 ppm pups exhibited a slight incidence of renal pelvic dilation (6/94 vs 0/97 in controls). There was a tendency for reduced absolute and relative spleen weights in male and female F<sub>1</sub> pups from 600 ppm onwards. Thus, the no-effect level (NOEL) for the parental animals and pup body weights from post-natal day 21 onwards was 100 ppm. The NOEL for reproduction parameters was 600 ppm.