

TSCA HEALTH & SAFETY STUDY COVER SHEET

MR# 299581

RECEIVED  
OPPT CBIC

2006 OCT 23 AM 11:12

**1.0 SUBMISSION TYPE**  Contains CBI  
 8(d)  8(e)  FYI  4  OTHER: Specify  
 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)  YES  NO  
**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID**  
 7000-1670-0003-2815-2503  
 06-0183  
**2.3 FOR EPA USE ONLY**

**3.0 CHEMICAL / TEST SUBSTANCE IDENTITY**  Contains CBI  
 CAS # 66346-01-8 1-(4-Chlorophenyl)-4,4-dimethyl-3-pentanone  
*Reported Chemical Name (specify nomenclature if other than CAS name):*  
 Purity %  
 Single Ingredient  Commercial / Tech Grade  Mixture  
 Trade Name: \_\_\_\_\_ Common Name: alkylketone

**4.0 REPORT / STUDY INFORMATION**  Study is GLP  
 Study Title: Dose Range Finding Combined Repeated Dose Toxicity Study with the  
 Reproduction/Developmental Toxicity Screening Test Study No: 06-P12-GE  
 Source of Data / Study Sponsor (if different than submitter) Bayer CropScience LP  
 Continuation sheet attached

**5.0 STUDY / TSCATS INDEXING TERMS** (CHECK ONE)  
 HEALTH EFFECTS (HE):  ENVIRONMENTAL EFFECTS (EE):  ENVIRONMENTAL FATE (EF):

**6.0 SUBMITTER INFORMATION**  
 George S. Goodridge  
 Assistant General Counsel  
 Bayer CropScience - PO Box 12014, RTP, NC 27709 Phone: 919-549-2418  
 Technical Contact: Ann M. Blacker, PhD  
 Director, Regulatory Toxicology  
 Bayer CropScience - PO Box 12014, RTP, NC 27709 Phone: 919-549-2973  
 Continuation sheet attached.

**7.0 ADDITIONAL / OPTIONAL STUDY COMMENTS**  Contains CBI  
 This compound is an intermediate for production of a pesticide.  
 Continuation sheet attached

Submitter Signature:

*George S. Goodridge*

Date: October 17, 2006



## 9.0 CONTINUATION SHEET

Submitter Tracking Number / Internal ID

7000-1670-0003-2815-2503  
06-0183

### Continuation of 2.1

Reporting was based on the following results:

In a range-finding study, male and female Wistar rats were dosed daily by oral gavage at 0, 100, 500, or 1000 mg/kg/day beginning two weeks prior to mating and continuing until terminal sacrifice. Urogenital staining was observed in both males and females at 500 and 1000 mg/kg/day. Mating, fertility and gestation indices were unaffected by treatment but a slight decrease in mean litter size and in the number of implantations sites was seen at 1000 mg/kg/day. Pup birth weight was not affected at any dose tested but compared to control, a lower total weight gain was observed from lactation day 0 to 4 at 500 mg/kg/day (-12.5%) and 1000 mg/kg/day (-37.5%). At terminal sacrifice, increases in absolute weights were noted for liver, kidney, and testes in parental males at 500 and 1000 mg/kg/day and for liver in parental females at both of these doses.

The results of the range-finding study will be reported in an appendix of the definitive study to be initiated before the end of 2006.