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TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS:

CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (*Contains CBI*).
Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

8EHQ-0699-14476

1.0 SUBMISSION TYPE *Contains CBI*

8(d) **XX 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)	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID P917-006-903 99-2-34	2.3 FOR EPA USE ONLY
X- YES <input type="checkbox"/> NO		

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY *Contains CBI*

CAS# 148477-71-8 *Reported Chemical Name (specify nomenclature if other than CAS name):*
3-(2,4-Dichlorophenyl)-2-oxo-1-oxaspiro (4.5)-3-en-4-yl ester 2,2-dimethyl-butanoic acid

Purity %

X- Single Ingredient

Commercial/Tech Grade

Mixture *Trade Name:* BAJ 2740 *Common Name:* _____

<i>CAS Number</i>	<i>NAME</i>	<i>% WEIGHT</i>
Other chemical(s) present in tested mixture		

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4.0 REPORT/STUDY TITLE *Contains CBI*

Subacute Dog Study (4 weeks) Study No. T6060776

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5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

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

STUDY TYPE: _____	SUBJECT ORGANISM (HE, EE only): <u>DOGS</u>	ROUTE OF EXPOSURE (HE only): <u>Oral</u>	VEHICLE OF EXPOSURE (HE only): <u>FOOD</u>
<i>Other:</i> Subacute	<i>Other:</i> _____	<i>Other:</i> _____	<i>Other:</i> _____

6.0 REPORT/STUDY INFORMATION *Contains CBI* Study is GLP

Laboratory Bayer AG Toxicology Lab, Wuppertal, Germany Report/Study Date N/A

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

continuation sheet attached

7.0 SUBMITTER INFORMATION *Contains CBI*

Submitter: Donald W. Lamb Title: VP, Product Safety & Regulatory Affairs Phone: 412-777-7431

Company Name: Bayer Corporation Company Address: 100 Bayer Road, Pittsburgh, PA. 15205

Technical Contact: Same as above Submitter Address (if different): _____ Phone: () _____

continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS *Contains CBI*

This compound is an experimental insecticide

Note: This is all the information we have at this time. The completed report will be submitted when we receive.

continuation sheet attached

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DRPT CRIC
99 JUN 23 AM 9:10

RECEIVED
DRPT CRIC
5 JUN 25 PM 12:1

Submitter Signature: Donald W. Lamb Date: 6/16/99

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Contains No CBI

9.0 CONTINUATION SHEET

TSCA CBI STATUS:

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Submitter Tracking Number/Internal ID

P917 006 903
99-2-34

Continuation of 2.1

As reproductive findings are a trigger for reporting preliminary toxicity findings, the following data is being reported.

Abstract:

In a subacute dog study (feeding) conducted with BAJ 2740 (dose levels: 0, 400, 2,000, and 10,000 ppm), the testes from males dosed at 2,000 ppm and above revealed bilateral minimal vacuolation of the Leydig cells (0/0/2/2). In one high-dose animal, this finding was combined with a hypertrophy/activation of the Leydig cells. Furthermore, the germinal epithelium of both testes and the prostate of this animal were considered to be slightly immature. The epididymides showed a massive oligo-/aspermia and slight spermatic debris.

In both this study and a 13-week subchronic dog study (reported separately), the leydig cell alterations were considered to most probably be the result of impaired testosterone synthesis or metabolism. Degeneration of the germinal epithelium, oligo-/aspermia of the epididymides, and immaturity of the prostates were regarded as secondary to the Leydig cell vacuolation and its possible testosterone imbalances.

STATUS OF PROJECT: BAJ 2740

Project Management Toxicology

Results of an orientating subacute feeding study in dogs (T 6060776) (4 weeks)

Dose (ppm)	BW/FC	Clin. signs	Clinical chemistry/hematology	Organ weights	Histology
400	-	-	ECOD (↑) (m)	-	-
2000	-	-	ALT (↑) (m/f) CYT/ODE/NDE ↑ (m/f) ECOD ↑ (m/f)	Liver (rel): ↑	Adrenal cortex: cytoplasm. vacuolation Jejunum: vacuolation of superficial mucosal epithel. cells Testes: vacuolation of Leydig cells
10000	-	-	AST/ALT/AP/GLDH ↑ (m/f), CYT/ODE/NDE ↑ (m/f) ECOD/ALD ↑ (m/f) GLU-T ↑ (m) Chol/triglyc. ↓ (m/f), T4 ↓ (m/f)	Liver (rel): ↑	Adrenal cortex: cytoplasm. vacuolation Jejunum: vacuolation of superficial mucosal epithel. cells Liver: periportal single cell necroses (m/f) Testes: vacuolation of Leydig cells, 1 animal: hypertrophy/activation of Leydig cells, testes and prostate slightly immature

n = 2/dose/sex

Dose proposal for subchronic study:

0 - 200 - 630 - 2000 ppm