

Chemical Name: Diphenyl Cresyl phosphate
Trade Name(s): Kronitex CDP
CAS No: 26444-49-5
Lab Study ID No: CIBA-GLIGY 10 Oct. 1985 AIR # 408692

FINAL REPORT ACTION ITEM CHECK-OFF LIST

- ☐ Reviewed for possible:
 - ☐ FIFRA 6 (a) (2) and/or
 - ☐ TSCA Section 8 (e) reporting
- ☐ Copy of FIFRA 6 (a) (2) and/or TSCA Section 8 (e) letter to the following Agency(ies), if applicable:
 - ☐ EPA-FIFRA
 - ☐ EPA-TSCA
 - ☐ California [FIFRA 6 (a) (2)s]
 - ☐ Other States [FIFRA 6 (a) (2)s]: _____
 - _____
 - _____
- ☐ Confidentiality Statement page addressed, signed, and dated in FIFRA reports
- ☐ GLP Compliance page signed and dated in FIFRA reports
- ☐ Flagging Statement page addressed, signed and dated in FIFRA reports
- ☐ Copy of report submitted to the Agency(ies) in conjunction and/or support of one or more of the following:
 - ☐ TSCA Consent Order/Agreement
 - ☐ FIFRA Registration or Re-registration
 - ☐ California Registration
 - ☐ EU Notification
 - ☐ Japanese MITI Notification
 - ☐ Japanese MAFF Notification
 - ☐ Canadian (DSL) Notification
 - ☐ FIFRA 6 (a) (2) Submission
 - ☐ TSCA 8 (e) Submission
 - ☐ TSCA 8 (d) Data-Call-In
 - ☐ PMN Submission
 - ☐ Other: _____
- ☒ All information regarding the chemical and the study report entered into the IUCLID Toxicity Data Base
- ☒ Study Report reviewed for MSDS information *Already on MSDS*
- ☒ Copy of Cover & Summary report pages to Business Unit MSDS information center (domestic and international)
- ☐ Active Study file merged with final report in Regulatory Affairs file room

on MSDS

SL 66

CIBA-GEIGY Pharmaceuticals
STAMFORD LODGE UK
PHARMA TOXICOLOGY

045/85/SL
CONFIDENTIAL

Cresyl Diphenyl Phosphate (Batch 17)

Delayed Neurotoxicity in
Domestic Hens (ED50)

10th October 1985

ED 50

CC1=CC=CC=C1OP(=O)(OC2=CC=CC=C2)OC3=CC=CC=C3

ED₅₀ between 200mg/Kg and 300 mg/Kg

Signed:

Vec'd 3.12.84
no amount

Cresyl Diphenyl Phosphate
(Batch 17)

Test Substance : Cresyl Diphenyl Phosphate (Batch 17)

Description of Study : ED50 Neurotoxicity Study in
Hens

Study Sponsor : CIBA-GEIGY P & A Co.
Industrial Chemicals Division
Tenax Road
Trafford Park
Manchester M17 1WI

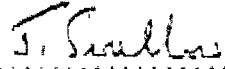
Testing Facility : CIBA-GEIGY Pharmaceuticals
Stamford Lodge
Wilmslow
Cheshire UK
Pharma Toxicology


Experimental No. : 85C002


Starting Date : 05.02.85

Finishing Date
(Date of last autopsy) : 18.09.85

Location of Raw Data : As for testing facility

Study Director :  17.10.85
J.J. Swallow, BVMS, MVM, MRCVS.

Responsible for conduct
of animal studies :  01.10.85
K.O'Brien, AIAT.

Head of Toxicology :  17.10.85
W.A. Bradley, BVSc, MRCVS.
CIBA-GEIGY
Pharmaceuticals Division
Stamford Lodge
Wilmslow
Cheshire UK

85C002

Cresyl Diphenyl Phosphate
(Batch 17)

ASSESSMENT

The median effective dose (ED50) for delayed neurotoxicity of Cresyl Diphenyl Phosphate (Batch 17) in young hens was 921 mg/kg body weight with 95% confidence limits of 1333 mg/kg and 636 mg/kg.

85C002
Cresyl Diphenyl Phosphate
(Batch 17)

EXPERIMENTAL PROCEDURE

Hens

White Leghorn hens with a mean body weight of 1.74kg were used. All birds had been maintained on the premises for at least 3 months and were approximately 1 year old.

All were clinically healthy at the start of the test.

Husbandry

Two birds (one from each series) were placed in one pen not less than 48 hours prior to the start of the test.

All birds were allowed access to a commercial diet (FARMGATE LAYERS PELLETS) and water on an ad lib basis.

Compound

A pale yellow liquid labelled:

Cresyl Diphenyl Phosphate Batch 17
A.R. No 408692

Administration of Compound

The hens were divided into 2 series of 6 birds each (an odd numbered and an even numbered series). Two hens, one from each series, were dosed initially and then depending on the clinical symptoms seen a further 2 hens were dosed 21 days later with either an increased dosage (no clinical symptoms in preceding hen in series) or a reduced dosage (clinical symptoms in preceding hen in series). This was repeated until 6 hens had been dosed in each series.

The compound was administered, as supplied, orally, by gavage, as a single dose at the appropriate rate.

85C002
Cresyl Diphenyl Phosphate
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Observations

Clinical signs were recorded at least once daily, for a period of 21 days. Necropsies were carried out on any hen that showed severe signs during the observation period and at the end of this period.

ED50 Calculation

The 'Up and Down' Method with Small Samples as described by Brownlee K.A., Dodges J.L. and Rosenblatt M (1953) J.Amer. Stat. Assoc. 48., was used.

85C002
Cresyl Diphenyl Phosphate
(Batch 17)

Hen Number	Dose mg/kg	Day Number	Signs	
<u>Series 1:</u>				
1002	800	21	No signs	Hen Killed
1004	1250	19	Slight ataxia	
		21	Slight ataxia	Hen Killed
1006	800	21	No signs	Hen Killed
1008	1250	11	Slight ataxia	
		15	Moderate ataxia	
		21	Moderate ataxia	Hen Killed
1010	800	21	No signs	Hen Killed
1012	1250	15	Slight ataxia	
		21	Slight ataxia	Hen Killed
<u>Series 2:</u>				
2002	800	21	No signs	Hen Killed
2004	1250	17	Slight ataxia	
		21	Slight ataxia	Hen Killed
2006	800	19	Slight ataxia	
		21	Slight ataxia	Hen Killed
2008	500	21	No signs	Hen Killed
2010	800	21	No signs	Hen Killed
2012	1250	11	Slight ataxia	
		17	Moderate ataxia	
		21	Moderate ataxia	Hen Killed