MEMORANDUM

DATE: February 3, 1987 Record no. 186628

SUBJECT: EPA REG NO. 100-ATR, Larvadex® 1% Premix

FROM: Dona Williams
IRB/TSS

TO: Art Castillo
Product Manager-17

Registrant: CIBA GEIGY CORP
Ag. Division
PO BOX 18300
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Active Ingredient:
Cyromazine 1%
Inert Ingredient: 99%
[redacted]

BACKGROUND INFORMATION:
Submission of acute toxicity data to support new product registration. Proposed product is a ready to use premix mixed with poultry feed to control label specified flies that develop in poultry manure..

COMMENTS & RECOMMENDATIONS:

1. Product label is acceptable.

2. All submitted studies are acceptable and based on thier acute toxicities the product was assigned the following categories.

	Study Class.	Tox Cat.	EPA ACC#
ACUTE ORAL LD_{50}	CORE MIN.	IV	265418
ACUTE DERMAL LD_{50}	CORE MIN.	III	"
ACUTE INHALATION	CORE MIN.	III	"
EYE IRRITATION	CORE MIN.	III	"
DERMAL IRRITATION	CORE MIN.	IV	"
DERMAL SENSITIZATION	CORE MIN.	NON-SENSITIZER	

STUDY REVIEWS:
TEST COMPOUND- LARVADEX 1% PREMIX
TESTING LAB - Stillmeadow, Inc., Biological Testing Lab., 9525 Town Park DR., Huston TX 77036.

1. Acute Oral LD_{50} (LIMIT TEST)
Project no. 3949-86, study initiated 1/31/86.
5M & 5F SD rats received a single oral gavage dose of

5050 mg/kg of test material suspended in corn oil, with subsequent 14 day observation period.
Toxic Signs: Constricted pupils, diarrhea and piloerection.
Necropsies: Unremarkable.
ACUTE ORAL LD_{50} > 5050 mg/kg 0% Mortality
Study Classification: Core Minimum
Toxicity Category: IV

2. Acute Dermal LD_{50} (LIMIT TEST)
Project no. 3950-86, study initiated 1/28/86.
5M & 5F NZ White rabbits received a single 24-hr occluded dermal exposure to 2010 mg/kg of test material moistened with saline and applied to intact skin. Animals were observed for a 14 day period.
Toxic Signs: Decreased urination and diarrhea. Two animals died during observation period.
Necropsies: Salivation, nasal discharge and GIT distended with gas and discolored (findings for one expired male test animal).
ACUTE DERMAL LD_{50} > 2010 mg/kg 20% Mortality
Study Classification: Core Minimum
Toxicity Category: III

3. Acute Inhalation
Project no. 3954-86, study initiated 3/06/86.
5M & 5F SD rats received a continuous 4-hr whole-body exposure to a mean gravimetric concentration of 3.59 mg/L of dust aerosol. Animals were observed during and following exposure for 14 days.
Toxic Signs: Piloerection, nasal discharge and salivation.
Necropsies: Unremarkable.
ACUTE INHALATION >3.59 mg/L 0% Mortality
84% particles collected were less than 14.33 microns
MMAD 4.646 microns $\pm$ 2.843 microns
Study Classification: Core Minimum
Toxicity Category: III

4. Eye Irritation
Project no. 3951-86, study initiated 1/27/86.
9 NZ White rabbits received a single ocular application of 0.1 gms of undiluted test material instilled into the right conjunctival sac of each test material. Three of the nine test animals received a one minute wash 30 secs pt. All exposed eyes were examined and scored for 7-days pt.
Toxic Signs: No corneal opacity or irisits was exhibited. Conjunctivae was expressed in (9/9) animals at 24-hrs pt clearing in all by day-7.
Study Classification: Core Minimum
Toxicity Category: III

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5. Dermal Irritation
Project no. 3952-86, study initiated 1/30/86.
6 NZ White rabbits received a single 4-hr occluded dermal exposure to 500 mg of test material moistened with water and applied to intact skin. Animals were scored observed and scored for 72-hrs pt.
Toxic Signs: No dermal irritation was elicted.
PDIS-0.0
Study Classification: Core Minimum
Toxicity Category: IV

6. Dermal Sensitization
Project no. 3953-86, study initiated 1/29/86.
10M Hartley guinea pigs received ten 6-hr occluded dermal induction applications of test material moistened with water and applied to intact skin. A 0.05% solution of DNCB served as the positive control. Animals were challenged 2 wks post induction at original test site and at a virgin site. Animals were scored 24 & 48-hrs after treatment numbers 1, 10 and 36 all other treatments were scored 24-hrs after treatment.
Toxic Signs: No dermal irritation was elicted during induction nor during challenge.
Product Classification: Non-Sensitizer
Study Classification: Core Minimum