UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Timothy A. Gardner
Registration Division (TS-767)

THRU: William Butler, Section Head #3
Toxicology Branch
Hazard Evaluation Division (TS-769) for WB 4/29/83

SUBJECT: PP#2F2707/2H5355; Larvadex (Cyromazine) in eggs, meat, poultry, fat and meat byproducts of poultry. CASWELL #167B

Petitioner: Ciba-Geigy
Greensboro, North Carolina

Action Requested:

Permanent tolerance for residues of cyromazine and its principle metabolite, melamine (1,3,5-triazine-2,4,6-triamine) in eggs, meat, fat and meat byproducts of poultry at 0.4 ppm.

Recommendation and Conclusions:

Based upon the existing toxicity data base, the requested permanent tolerances can be supported.

Data to Set Tolerances:

Study No. 382-081, a two year feeding and oncogenicity study in the rat can be used as a basis for the ADI. The NOEL of 30 ppm (1.5 mg/kg) in this study and a safety factor of 100 yields an ADI of 0.015 mg/kg/day and an MPI of 0.90 mg/day (60 kg).

A previous TOX approved action, 9G2230, produced a TMRC of 0.0334 mg/day (1.5 kg) which occupied 3.71% of the ADI and contained some of the same RAC's as requested in the current action.

The present action increases the percentage of the ADI occupied from 3.71% to 5.61% and the TMRC from 0.0334 mg/day (1.5 kg) to 0.0505 mg/day (1.5 kg). The printout is attached.

Data Gaps:

There are no data gaps for Larvadex at this time.

RPAR State:

N/A

Formulations:

I. Larvadex

Cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) - 95%

Inert Ingredients

[redacted]

The proposed use is 900 lbs of Larvadex premix in poultry feed for direct consumption by 20 million chickens over a two-year period.

II. Larvadex Premix

Cyromazine Technical, 95% a.i. - 0.32%

Inert Ingredients

[redacted]

Summary of Data Reviewed Previously:

Oral LD_{50} rat - 3387 mg/kg
Oral LD_{50} mouse - 2029 mg/kg
Oral LD_{50} rabbit - 1467 mg/kg
Acute dermal LD_{50} rat >3100 mg/kg
Sensitization, guinea pig - non-sensitizing
Ames - negative
90 day rat feeding NOEL 30 ppm
Teratology rat - NOEL teratology >600 mg/kg
NOEL-fetotoxicity 300 mg/kg, LEL = 600 mg/kg