

1-18-83

Shaughnessy #: 038901

Due Date: _____

Init: _____

To: Richard Mountfort
Product Manager # 23
Registration Division (TS-767)

From: Joseph C. Reinert, Ph.D., Chief
Review Section # 4
Environmental Fate Branch
Hazard Evaluation Division (TS-769c)

PROPRIETARY

Attached please find the EFB review of...

Reg./File No.: 1F1105 & 2H5016

Chemical: Endothall

Type Product: Algicide/Herbicide

Product Name: Hydrothall 191

Company Name: Pennwalt

Submission Purpose: Dietary Exposure - Drinking Water

ZBB Code: 3(c)(7)

ACTION CODE: 234, 254

Date In: 1/6 /83

EFB # 128, 129

Date Completed: 1/18/83

TAIS (level II) Days

67

4

Deferrals To:

 Ecological Effects Branch

 Residue Chemistry Branch

 X Toxicology Branch

We have reviewed the endothall dietary exposure assessments carried out by the registrant, Pennwalt, and offer the following comments:

- 1) We agree that, for purposes of this assessment, 3 ppm is a reasonable value to use for the initial water concentration immediately following application. We also have gone over all the registrant's calculations which appear mathematically correct. However, we note in Example 2 that it appears the crop dietary contribution was inadvertently omitted from the final answer.
- 2) We differ with the following assumptions used by the registrant:
 - a. EPA routinely uses a value of 2 l/day water consumed by a 60 kg individual (1). Pennwalt used a 1.2 l/day value.
 - b. Based on our information on published and proposed endothall tolerances (2), we calculate a total value of 0.12 mg/day for dietary consumption of all crops. The registrant used a value of 0.15 mg/day (no derivation presented).
 - c. Based on our review of studies submitted by Pennwalt (3), the most common value for the persistence of endothall in natural bodies of water is a half-life of about 12 days. The registrant used a 2.98 day half-life, taken from uncited data.
- 3) Our calculations go as follows:

Example No. 1

$$\frac{2 \text{ l/day} \cdot 3 \text{ ppm}}{60 \text{ kg}} + \frac{0.12 \text{ mg/day}}{60 \text{ kg}} = 0.10 \text{ mg/kg/day}$$

Example No. 2

$$\frac{26 \text{ treatments} \cdot 3 \text{ ppm} \cdot 2 \text{ l/day}}{60 \text{ kg} \cdot 365 \text{ days/yr}} \int_0^{365} e^{-kt} dt + \frac{0.12}{60} =$$

$$\left[k = \frac{\ln 2}{T_{1/2}} = 0.0575 \text{ days}^{-1} \right]$$

$$0.12 + 0.002 = 0.12 \text{ mg/kg/day}$$

Example No. 3

$$\frac{2 \text{ l/day} \cdot 3 \text{ ppm}}{60 \text{ kg}} \left[\int_0^{365} e^{-kt} dt + \int_0^{273.75} e^{-kt} dt + \int_0^{182.5} e^{-kt} dt + \int_0^{91.25} e^{-kt} dt \right]$$

$$+ \frac{0.12}{60} =$$

$$\frac{6}{60} \cdot \frac{4}{365} \cdot \left(\frac{e^{-kt}}{-k} \right) \Bigg|_0^{91.25} + \frac{0.12}{60} =$$

$$\frac{0.4}{365} \cdot \frac{-1}{-0.0575} + \frac{0.12}{60} = 0.019 + 0.002 =$$

$$0.021 \text{ mg/kg/day}$$

4) Comparison of Exposure Results (mg/kg/day)*

		<u>Pennwalt</u>	<u>EFB</u>
Example	1	0.063	0.10
	2	0.021**	0.12
	3	0.0053***	0.021

*Note that all concentrations are expressed as endothall acid equivalents, so an appropriate adjustment must be made if the exposure results are compared with toxicology studies carried out on the basis of concentration expressed as weight of an endothall salt per unit volume.

**It appears that in Example 2 on page 4 of the registrant's document the crop dietary contribution was inadvertently left out of the total dietary burden:

$$\frac{-93.6}{-0.2322} + F (\text{crop contribution}) =$$

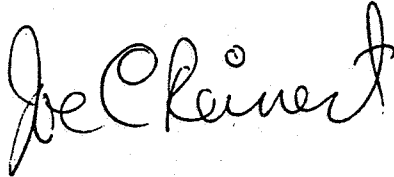
$$\frac{60}{0.0184} + 0.0025 = 0.021 \text{ mg/kg/day}$$

***It seems inconsistent, for comparison purposes, to leave out the crop contribution in only one of the examples. We have therefore added it (0.0025) to the water contribution (0.0028).

We note that the different assumptions used by EFB affect the exposure values only modestly.

- 5) We defer to Toxicology Branch for an evaluation of the registrant's Hazard Assessment.

Joe Reinert, EFB



References

1. Kim, V. J. National Interim Primary Drinking Water Regulations. EPA-570/9-76-003. USEPA. 1976.
2. Endothall CFR 180.293, 10/22/81 update (CBI).
3. EFB review of 2/5/76 (CBI).

cc: Bill Burnam
Randy Perfetti

File last updated 10/22/81

ACCEPTABLE DAILY INTAKE DATA

RAT, Older NOEL	S.F.	ADI	NPI
mg/kg ppm		mg/kg/day	mg/day (60kg)
5.000 100.00	100	0.0500	3.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Cottonseed (oil) (41)	0.100	0.15	0.00022
Potatoes (127)	0.100	5.43	0.00814
Rice (137)	0.050	0.55	0.00041

NPI	TMRC	% ADI
0.0000 mg/day (60kg)	0.0008 mg/day (1.5kg)	0.29

Current Action PP 1F1105/2H5016

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Potable Water (198)	3.000	133.33	0.00000
Fish, shellfish (59)	0.100	1.08	0.00162
Avocados (6)	0.100	0.03	0.00005
Citrus Fruits (33)	0.100	3.31	0.00572
Cucurbits (49)	0.100	2.84	0.00426
Leafy vegetables (60)	0.100	2.99	0.00449
Grain, inc raisins (66)	0.100	0.49	0.00074
Grain Crops (64)	0.100	13.79	0.002069
Hops (73)	0.100	0.03	0.00005
Nuts (101)	0.100	0.10	0.00015
Bone Fruits (11)	0.100	0.10	0.00015
Cross veg (138)	0.100	11.00	0.00165
Seed/veg (143)	0.100	11.00	0.00165
1 Fruit, berries (146)	0.100	0.33	0.00050
Stone Fruits (151)	0.100	1.33	0.00200
Sugar, cane/beet (154)	0.100	0.33	0.00050
Leafy vegetables (150)	0.100	0.70	0.00105
Dairy Products (93)	0.020	20.00	0.00040
Meat, inc poultry (89)	0.020	15.00	0.00030
Eggs (54)	0.020	2.77	0.00033

NPI	TMRC	% ADI
3.0000 mg/day (60kg)	6.1155 mg/day (1.5kg)	203.35

File last updated 10/22/81

ACCEPTABLE DAILY INTAKE DATA

RAT, Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
5.000	100.00	100	0.0500	3.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cottonseed (oil) (41)	0.100	0.15	0.00022
Potatoes (127)	0.100	5.43	0.00814
Rice (137)	0.050	0.55	0.00041

MPI	TMRC	% ADI
0.0000 mg/day(60kg)	0.0088 mg/day(1.5kg)	0.29

Current Action PP 1F1105/2H5016

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Potable Water (198)	3.000	133.33	0.00000
Fish, shellfish (59)	0.100	1.08	0.00162
Avocados (6)	0.100	0.03	0.00005
Citrus Fruits (33)	0.100	3.81	0.00572
Cucurbits (49)	0.100	2.84	0.00426
Leafy Vegetables (60)	0.100	2.99	0.00449
Apples, inc raisins (66)	0.100	0.45	0.00074
Grain Crops (64)	0.100	13.79	0.00206
Hops (73)	0.100	0.03	0.00005
Nuts (101)	0.100	0.10	0.00015
Bone Fruits (111)	0.100	0.10	0.00015
Root Crop Veg (138)	0.100	11.55	0.00164
Seed & root veg (143)	0.100	1.00	0.00054
Small fruit, berries (146)	0.100	0.33	0.00124
Stone Fruits (151)	0.100	1.25	0.00167
Sugar, cane & beet (154)	0.100	0.04	0.00054
Leafy vegetables (60)	0.020	0.70	0.00053
Milk & dairy Products (93)	0.020	20.32	0.00053
Meat, inc poultry (89)	0.020	13.05	0.00041
Eggs (54)	0.020	2.77	0.00083

MPI	TMRC	% ADI
3.0000 mg/day(60kg)	6.1155 mg/day(1.5kg)	203.35

0.11552
0.12