Glyphosate / Tox

(14)

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

RELEASABLE

MEMORANDUM

MAR 15 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Robert Taylor (25)
Registration Division (TS-767)

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Glyphosate (Roundup®) tolerance in ~~Coconut~~ CASWELL
PP#2F2680; EPA Reg.#524-308; CASWELL#661A

Recommendations:

1) The requested tolerance can be toxicologically supported.

2) An oncogenic study in a second species and chronic (and subchronic) oral toxicity in a non-rodent species are data gaps.

Review:

1. Action Requested: This petition requests a tolerance for the combined residues of the herbicide glyphosate (N-phosphonomethyl glycine) and its metabolite, aminomethylphosphonic acid, in or on the raw agricultural commodity:

coconut - 0.1 ppm.

A prior toxicologically approved request was for a tolerance for glyphosate and its metabolite in or on copra - 0.1 ppm and food additive tolerances in:

coconut oil - 0.1 ppm
copra meal - 0.1 ppm
desiccated coconut - 0.1 ppm,

which was revised to the present request to comply with the recommendation of the Agency (RCB, HED).

2. The formulation to be used will be Roundup® (MON 2139). Inerts are cleared under 180.1001.

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3. Toxicological Studies:

No new data were submitted. Studies supporting this action are listed in the previous review on this subject (memo dated 9-3-82 from Teeters to Taylor); since then the two IBT subchronic oral toxicity studies (#B-1020, rat and #B-1021, dog) and the reproduction study (IBT#B-566, rat) mentioned in the referenced memo have been evaluated and declared invalid.

Recently (memo dated 2-10-83 from Dykstra to Taylor), a question has arisen concerning the significance of the incidence of C-cell carcinomas of the thyroid in female rats in the lifetime feeding study in this species with Glyphosate, and the thyroid slides will be reevaluted; the tentative conclusion reached is that Glyphosate was not oncogenic in that study.

Current data gaps include chronic (and subchronic) toxicity in a non-rodent species and an oncogenic study in a second species.

4. Many tolerances have been established under 40 CFR 180.364; several fruits (avocades, bananas, papayas, mangoes, guava, and citrus) have tolerances of 0.2 ppm.

5. Evaluation of the ADI:

Based on a NOEL of 10 mg/kg/day in the reproduction study (Bio/dynamics, 9/18/81) and using a safety factor of 100, the ADI is 0.1 mg/kg/day (10 mg/kg x $\frac{1}{100}$ = 0.1 mg/kg/day).

The MPI for a 60 kg person is 6 mg/day.

6. The published tolerances utilize 5.90% of the ADI. Total published and unpublished, but Tox approved, tolerances utlize 23.73% of the ADI. All tolerances, including the one in this action (contribution 0.00005 mg/day) utilize 23.73% of the ADI and the TMRC is 1.4238 mg/day, based on a 1.5 kg diet.

7. No regulatory actions are pending against the pesticide and no RPAR criteria have been exceeded.

8. Other relevant considerations:

Concentrations of 0.2-0.4 ppm of N-nitro-glyphosate (NNG) are present in the formulated product (memo of 12-2-77 from RCB, PP#7F1971/FAP 7H5168) and there are three IBT studies with NNG which are yet to be evaluated (2-year oral in rat and dog and a rat reproduction). However, considering the extremely small contribution of this action to the TMRC, only 0.0001 mg/day, a related NNG residue is not a serious toxicological concern.

9. Conclusion:

a) This request to establish a permanent tolerance for coconut at 0.1 ppm can be toxicologically supported.

b) Chronic (and subchronic) oral toxicity data in a non-rodent species and an oncogenic study in a second species are data gaps.

Winnie Teeters
Winnie Teeters, Ph.D.
Toxicology Branch/HED (TS-769)

FOC 2/22/83

TS-769:th:TOX/HED:WTeeters:2-17-83:card 1

CFR 180.364 Glyphosate Roundup 1/20/83

File last updated 1/20/83

ACCEPTABLE DAILY INTAKE DATA

NOEL change not recorded per

RAT,Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
10.000	200.00	100	0.1000	6.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Grain Crops(64)	0.100	13.79	0.02069
Avocados(6)	0.200	0.03	0.00009
Citrus Fruits(33)	0.200	3.81	0.01144
Coffee(36)	1.000	0.75	0.01119
Grapes, inc raisins(66)	0.100	0.49	0.00074
Leafy Vegetables(80)	0.200	2.76	0.00828
Nuts(101)	0.200	0.10	0.00031
Pome Fruits(126)	0.200	2.79	0.00837
Root Crop Veg(138)	0.200	11.00	0.03299
Seed&Pod Veg(143)	0.200	3.66	0.01098
Palm Oil(202)	0.100	0.03	0.00005
Pistachio nuts(210)	0.200	0.03	0.00009
Asparagus(5)	0.200	0.14	0.00043
Bananas(7)	0.200	1.42	0.00426
Olives(104)	0.100	0.06	0.00009
Stone Fruits(151)	0.200	1.25	0.00374
Sugar,cane&beet(154)	2.000	3.64	0.10915
Molasses(96)	20.000	0.03	0.00920
Cranberries(44)	0.200	0.03	0.00009
Cottonseed (oil)(41)	15.000	0.15	0.03375
Kidney(203)	0.500	0.03	0.00023
Liver(211)	0.500	0.03	0.00023
Peanuts(115)	0.100	0.36	0.00054
Guava(184)	0.200	0.03	0.00009
Papayas(109)	0.200	0.03	0.00009
Mangoes(88)	0.200	0.03	0.00009
Soybeans (oil)(148)	6.000	0.92	0.08263
Pineapple(123)	0.100	0.30	0.00044
Fish,shellfish(59)	0.250	1.08	0.00406

MPI	TMRC	% ADI
6.0000 mg/day(60kg)	0.3543 mg/day(1.5kg)	5.90

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Unpublished,Tox Approved 9F2163,2329,1E2444,9H5204,2G2686,1H5310

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cucurbits(49)	0.100	2.84	0.00426
Fruiting Vegetables(60)	0.100	2.99	0.00449
Small Fruit,berries(146)	0.100	0.83	0.00124
Hops(73)	0.100	0.03	0.00005
Potable Water(198)	0.500	133.33	1.00000
Soybeans (oil)(148)	4.000	0.92	0.05509
Tea(162)	4.000	0.07	0.00429

MPI	TMRC	% ADI

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6.0000 mg/day(60kg)	1.4237 mg/day(1.5kg)	23.73

Current Action 2F2680

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Coconut(35)	0.100	0.03	0.00005

MPI	TMRC	% ADI
6.0000 mg/day(60kg)	1.4238 mg/day(1.5kg)	23.73