



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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Registration of the End-Use Product, NEU 1161I RTU [Canola Oil + Pyrethrins (File Symbol 67702-A)] Review of Product Chemistry Data MRID Nos. 440971-01, -02 and -03. Reviews of Waiver Requests for (a) Toxicology and (b) Nontarget Organism, Fate and Expression. DP Barcodes No. D233214, D233215 and D233216.

FROM: Paul L. Zubkoff, Ph.D., Chemist Date: December 24, 1997
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1230-97

TO: Susanne Cerrelli, Registration Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511W)

ACTION REQUESTED:

Walter G. Talarek, on behalf of W. Neudorff GmbH KG, Emmerthal, Germany requests registration of end-use product, NEU 1161I RTU, (EPA File Symbol 67702-A). The product contains 1% Canola Oil (PC Code 011332) and 0.01% Pyrethrum Extract (PC Codes 069001 + 063501) as active ingredients; and 98.9% inert ingredients. The product will be used to control a variety of insects pests present in the dormant season and scale insects, mites and mealybugs on shrubs, evergreens, woody plants, fruit trees and shade trees and many agricultural crops. Other proposed uses include post-harvest treatment of tomatoes and fruits, and the control of fleas and ticks on cats and dogs.

CONCLUSIONS AND RECOMMENDATIONS:

1. The submitted product chemistry data for biochemical pest control agent, NEU 1161 RTU satisfy the requirements for 40 CFR §158.690(a): 151-10 Product Identity; 151-11 Manufacturing Process; 151-12 Discussion of Formation of Unintentional Products; 151-13 Analysis of Samples; 151-15 Certification of Limits; 151-16 Analytical Methods. The Physical and Chemical Properties (151-17) are listed in Table 1.

2. The Registrant requested that toxicity data submitted in support of NEU 1161 I (EPA File Symbol, 67702-L) be used to satisfy the toxicology data requirements (152-10, -11, -12, -13, and -14). The Agency is bridging the toxicity data that was performed with the NEU 1161I formulation because the concentrations of canola oil and naturally occurring pyrethrins in NEU 1161I are far greater than those in NEU 116 I RTU . In addition, all of the inerts in the NEU 1161 I RTU formulation (File symbol 67702-A) have been cleared by the Agency under 40 CFR §180.1001(c), (d), or (e). See Table 2 for a listing of bridged data .

	<u>NEU 1161I</u>	<u>NEU 1161 I RTU</u>
Canola Oil	89.5 %	1.00 %
Naturally Occurring Pyrethrins	0.5 %	0.01 %

The Toxicity Categories of NEU 1161I (File Symbol 67701-L) are III and IV for all routes of exposure.

2. Based on the toxicity data for this end-use product and the knowledge that all inert ingredients used in this product are already cleared by the Agency for food-use, and an exemption from the requirement of a tolerance has been issued for the active ingredient, Pyrethrins under 40 CFR §180.128 in or on all raw agricultural commodities when applied as a pest control agent or post-harvest pest control agent in accordance with good agricultural practices (40 CFR 180.128), all requirements for toxicity testing are satisfied. (See CBI Appendix.)

cc: S. Cerrelli, P. Zubkoff, BPPD Subject File
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Table 1: Summary of NEU 11611 RTU (Canola Oil + Pyrethrins) File Symbol 67702- A

Guideline	Study	Result	MRID #
151-B-10	Product Identity	A See CBI Appendix	440769-01
151-B-11	Manufacturing Process	A See CBI Appendix	440769-01
151-B-12	Discussion of formation of unintentional ingredients	A See CBI Appendix	440769-01
151-B-13	Preliminary Analysis	A See CBI Appendix	440769-02
151-B-15	Certification of limits	A See CBI Appendix	440769-02
151-B-16	Analytical methods	A See CBI Appendix	440769-02
151-17	Physical/Chemical Properties		
a	color	A White	440971-03
b	physical state	A White, opaque liquid, no inclusions at room temperature	440971-03
c	odor	A Faint pyrethrin odor	440971-03
d	melting point	N/A Technical material is liquid	Administrative
e	boiling point	N/A a.i. is mixture of naturally occurring substances	Administrative
f	density	A 0.989 ± 0.001 g/ml @ 20.0°C (n=3)	440971-03
g	solubility	A Technical is insoluble in water & ethanol; soluble in mineral oil; end product is dispersible in water	
	vapor pressure	Product specific waiver requested a.i. of product < 0.1 mm Hg @ 19.5°C#	
	pH dissociation constant	A 6.70 ± 0.04	440971-03
	octanol/water partition coefficient	N/A Toxicology studies do not indicate need for information	Administrative
l	pH 1% solution	A 6.63 ± 0.11	440971-03
	stability	A stable#	440971-03
	oxidizing or reducing	N/A Waiver granted	Administrative
k	flammability / flash pt.	A 48°C (Cleveland Open Cup Method)# product contains no combustible fluids	440971-03 see CBI Note
	explosibility	N/A Waiver granted	Administrative
	storage stability	A Canola oil shows no change @ 54°C for 1 month Pyrethrins show no change @ 54°C for 1 month	440971-03 440971-03
	viscosity	A 2.7 ± 0.1 centipoise (Brookfield viscometer / #1)	440971-03
n	miscibility	N/A Product specific waiver requested / product is not to be diluted with hydrocarbons	Administrative

Table 2. Listing of NEU 1161I Bridging Data to Support NEU1161I RTU (File Symbol 67702- A)

Toxicology				
Tolerance	Tolerance Petition			8F4747
152-10	Acute Oral (rat)	Acceptable	LD ₅₀ > 2000 mg/kg Toxicity III	440769-04
152-11	Acute Dermal (rat)	Acceptable	LD ₅₀ > 2000 mg/kg Toxicity III	440769-05
152-12	Acute Inhalation (rat)	Acceptable	LD ₅₀ > 2.36 mg/L air Toxicity IV	441577-01
152-13	Primary Eye (rabbit)	Acceptable	Draize = 3.3 Minimally Irritating Toxicity IV	440769-06
152-14	Primary Dermal (rabbit)	Acceptable	Primary Irritation Index = 2.5 Moderately Irritating Toxicity III	440769-07
152-15	Hypersensitivity	Waiver Granted	8,9 Soybean Oil	Administrative
152-16	Hypersensitivity Incidents	Waiver Granted	4, no known incidents	Administrative
152-17	Genotoxicity	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
152-18	Immune Response	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
152-20	90 Day Feeding	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
152-21	90 Day Dermal	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
152-22	90 Day Inhalation	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
152-23	Teratogenicity	Waiver Granted	1, 2, 3, 4, 5, 6, 7	Administrative
Ecotoxicity				
154-6	Avian Acute Oral	Waiver Granted	1, 2, 3, 4, 5, 6, 7, 10	Administrative
144-7	Avian Acute Diet	Waiver Granted	1, 2, 3, 4, 5, 6, 7, 10	Administrative
154-8	Freshwater Fish	Waiver Granted	1, 2, 3, 4, 5, 6, 7, 10	Administrative
154-9	Freshwater Invert	Waiver Granted	1, 2, 3, 4, 5, 6, 7, 10	Administrative
154-10	Non-Target Plant	Waiver Granted	1, 2, 3, 4, 6, 6, 7, 10	Administrative
154-11	Bee	Waiver Granted	1, 2, 3, 4, 5, 6, 7, 10	Administrative

- 1 Known low toxicity and risks of canola oil
- 2 Known natural occurrence and abundance of canola oil
- 3 Widespread use of canola oil as edible fats and oils
- 4 FDA GRAS status of canola oil as an edible fat or oil in human food 21 CFR §184.1555(c)
- 5 Non-toxic mode of action of canola oil
- 6 Anticipated low volume use in pesticide products
- 7 Data are available in the open literature for canola oil
- 8 Reregistration Eligibility Decision (RED): Flower and Vegetable Oils EPA 738-R-93-031 December 1993
- 9 Anticipated low exposure from proposed use patterns
- 10 Pyrethrin component is eligible for formulator's exemption provided that labeling is commensurate with other pyrethrin products