

HED



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OFFICE OF
 PREVENTION, PESTICIDES AND
 TOXIC SUBSTANCES

Memorandum

Subject: 000100-00656. Application for amended registration of Armor, EPA Reg. No. 100-656. Removal of Restriction Against Using Treated Mushroom Compost as Fertilizer.

DP Barcode:	D242379	PRAT Case:	192399
Submission No.:	S536201	Caswell No.:	167B
Chemical No.:	121301✓	Class:	Insecticide
Trade Name:	Armor	EPA Reg No.:	100-656
40 CFR:	§180.414		
MRID No.:	444567-01		
	444567-02		

TO: Arnold Layne/George LaRocca, PM Team 13
 RD (7505C)

FROM: William D. Wassell, Chemist
 RAB3/HED (7509C)

William D. Wassell

THRU: Stephen C. Dapson, Branch Senior Scientist
 RAB3/HED (7509C)

Stephen C. Dapson 9/22/99

Background:

The petitioner, Novartis Crop Protection, Inc. has submitted an application for an amended registration of Armor Insect Growth Regulator (EPA Reg. No. 100-656). In this amended registration request, Novartis proposes to remove a restriction from the label against the use of spent mushroom compost (SMC) as fertilizer.

Tolerances are established (40 CFR §180.414) for residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its metabolite melamine (1,3,5-triazine-2,4,6-triamine) in or on a variety of commodities. Information concerning the metabolism of cyromazine in/on plants and livestock were recently presented to the HED Metabolism Assessment Review Committee (MARC). The Metabolism Committee has determined that the cyromazine metabolite melamine no longer needs to be included in the tolerance expression for cyromazine (Memo, J.B. Stokes & S.C. Dapson, 4/15/98, D245214). Currently established tolerances for cyromazine uses have been reassessed in light of this decision (Memo, J.B. Stokes and T. Morton, 4/5/99, D254881). Reassessed tolerance levels for residues of cyromazine range from 0.1 ppm (cotton, undelinted seed) to 7.0 ppm (leafy vegetables, except

Brassica, crop group). HED has recently recommended for establishment of the reassessed tolerances for residues of cyromazine in or on various commodities (Memo, W.D. Wassell, 7/14/99, PP#7E4905, D256716). HED has also recommended for the establishment of indirect or inadvertent residue tolerances for cyromazine in/on sweet corn commodities and radishes (tops and roots) at 0.5 ppm and cotton, undelinted seed at 0.1 ppm.

CONCLUSIONS/RECOMMENDATIONS:

RAB3 concludes that label restrictions that prohibit the use of spent mushroom compost (SMC) on some crops or to have plantback intervals for crops when SMC is spread into fields in which food or feed crops will be grown are not practical because the SMC may not be under the control of the mushroom growers. Based upon this conclusion and the results of previously submitted confined rotational crop studies, limited field rotational crop studies would be required for all crops other than those with cyromazine registered uses or inadvertent residue tolerances. Thus, RAB3 recommends against the proposed amended registration for Armor Insect Growth Regulator. RAB3 further suggests that the petitioner submit for review a protocol outlining the scope of the proposed limited field rotation crop studies.

DETAILED CONSIDERATIONS:

In conjunction with this label amendment, the petitioner has submitted residue data for residues of cyromazine in/on spent mushroom compost (SMC) (MRID No. 444567-02) and storage stability data (MRID No. 444567-01) for cyromazine in/on soil.

In the submitted magnitude of residue study, two field trials were conducted in the State of Pennsylvania. In these field trials, Armor 5SC (EPA Reg. No. 100-656) was applied at the rate of 5 ppm to mushroom compost during the preparation of the compost and at spawning. The spawning application usually takes place approximately 10 days after the compost preparation. After the mushrooms were harvested, the compost was removed from the mushroom house and transferred to the weathering site. Samples of spent mushroom compost were collected on the day the SMC was removed from the mushroom house, and at approximately 1, 3, 6, 9, and 12 months following removal of the SMC from the mushroom house. Samples were stored frozen when not actively in use and a majority of the samples were analyzed within 7 months of collection. These samples were analyzed for residues of cyromazine and its metabolite melamine using a modified version of Analytical Method AG-435, "Determination of Cyromazine and Melamine Residues in Soil by High Performance Liquid Chromatography". Our discussion concerning this study will be limited to the residue data for cyromazine as the HED Metabolism Assessment Review Committee has determined that residues of melamine are no longer of concern (Memo, J.B. Stokes & S.C. Dapson, 4/15/98, D245214). Method AG-435 is briefly described as follows:

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Samples are extracted by refluxing the sample material with 80% glacial acetic acid/10% methanol/10% 0.5 N Sodium acetate (aq). The extracts are cleaned by cation exchange chromatography followed by anion exchange chromatography. Samples are analyzed for residues of cyromazine and melamine by gas chromatography with a mass selective detector (GC/MSD).

The adequacy of the method was demonstrated by analysis of fortified control samples of SMC. The fortification levels ranged from 0.05 ppm to 2.0 ppm. The fortification recoveries ranged from 65% to 125% with an average of 87% (n = 27) and a standard deviation of 16%. RAB3 concludes Analytical Method AG-435 has been adequately validated for use in determining residues of cyromazine in/on spent mushroom compost. The results of the field trials are summarized in Table 1.

Field Trial ID	Interval ¹ (days)	Average Cyromazine Level (ppm)
NE-IR-601-94	0	0.11
	33	0.10
	91	0.085
	182	<0.05
	280	0.10
	371	0.05
NE-IR-602-94	0	0.11
	33	0.074
	91	0.08
	182	0.06
	280	0.08
	371	<0.05

¹Interval between the day compost was removed from the mushroom house and the day sampled.

To demonstrate the stability of residues of cyromazine in SMC, the petitioner submitted the results of a storage stability study for cyromazine and melamine in/on soil following frozen storage (MRID No. 444567-01). We note this study was completed prior to the effective date of the Agency's Good Laboratory Practice Standards. Our discussion of this study will be limited to the data for cyromazine only, since the HED Metabolism Assessment Review Committee has determined that residues of melamine are not of concern. In this

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study, two field treated soil samples were analyzed for residues of cyromazine (and melamine) by Analytical Method AG-435 at 0-days and after approximately 5-months storage. Method AG-435 is described above. Results of fortification recovery experiments were not reported in the submitted study report. The results of the study show that residues of cyromazine are stable in soil for a period of approximately 5-months during frozen storage. We note that there was some variation of residue levels of cyromazine in the study. Cyromazine residue levels actually increased in the study by 20 to 25%. We suspect this was due to analytical variation.

Novartis has stated in their submission that approximately 280,000 lbs of SMC would be spread per acre of crop land. They provided 2 references for this figure. The references are: 1. USDA, Natural Resources Conservation Center, West Chester, PA; and 2. Water Quality Resource Management Plans and Mushroom Farm Environmental Management Plans, USDA/NRCS, West Chester, PA. Based upon this figure and the 0-day residue levels of cyromazine in/on SMC, this translates to an application rate of 0.031 lbs ai/A.

Confined rotational crop data have been submitted to the Agency previously. The results of the confined rotational crop studies are summarized in the following table.

Commodity	Study Type	Application Rate (lbs ai/A)	Planting Interval (Days)	Residues Levels (ppm ²)
lettuce	S	0.05	30	<0.009
lettuce	R	1.50	spring	<0.01
sugar beets tops roots	S	0.05	30	<0.009 <0.009
sugar beets tops roots	R	1.50	spring	<0.01 <0.01
wheat grain straw hulls	S	0.05	30	<0.009 0.112 0.078
wheat grain stalks hulls	R	1.50	fall	<0.01 0.04 <0.01

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Table 2. ¹⁴ C-Cyromazine Rotational Crop Studies				
Commodity	Study Type ¹	Application Rate (lbs ai/A)	Planting Interval (Days)	Residues Levels (ppm ²)
carrots immature tops roots mature tops roots	R	1.50	spring	0.03 0.19 0.05 <0.02
soybeans immature stalks pods beans	R	1.50	spring	0.02 0.05 0.03

¹ S = Soil Uptake. (PP#5F3180, RCB# 331, Study# ABR 82003, C. Deyrup, 2/8/85). R = Rotation from Tomatoes. Fall planting of winter wheat followed in the spring by soybeans, carrots, lettuce, and sugar beets (PP#6F3332, Accession # 260663, Study# ABR 85009, submitted 12/16/85).

² Residues levels are for total radioactive residues (TRR) and are reported as cyromazine equivalents.

The study with the application rate of 0.05 lbs ai/A is closest to that of the projected application rate when SMC would be spread into fields in which food or feed crops would be grown. Thus, we will use these data to determine if there would be uptake of residues into crops. The wheat straw sample (containing 0.112 ppm TRR) was extracted and analyzed for residues of cyromazine and melamine. The sample contained 0.065 ppm cyromazine. Residues in the wheat hull sample were not identified. Based upon these data, projected residue levels in wheat straw, based upon an application rate of 0.031 lbs ai/A, would be 0.04 ppm. Thus, we conclude there would be uptake of residues of cyromazine into grain crops.

The petitioner has provided residue data for cyromazine in SMC from various time intervals (see Table 1). These data show that residue levels in SMC do decrease slightly over time although it is apparent that there were some problems obtaining a homogeneous sample in this study. Concerning the practicality of label restrictions that prohibit the use of SMC on some crops or to have plantback intervals for crops when SMC is spread into fields in which food or feed crops will be planted, RAB3 concludes that label restrictions that prohibit the use of spent mushroom compost (SMC) on some crops or to have plantback intervals for crops when SMC is spread into fields in which food or feed crops will be grown are not practical because the SMC may not be

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under the control of the mushroom growers. Based upon this conclusion and the results of the previously submitted confined rotational crop studies, limited field rotational crop studies would be required for all crops other than those with cyromazine registered uses or inadvertent residue tolerances. Thus, RAB3 recommends against the proposed amended registration for Armor Insect Growth Regulator. RAB3 further suggests that the petitioner submit for review a protocol outlining the scope of the proposed limited field rotation crop studies.

cc: W.D. Wassell, RAB3 Reading File.

RDI: RAB3 Chemistry Team: 9/17/99; S. Dapson: 9/17/99



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031607

Chemical: *CYROMAZINE*
Tebuthiuron

PC Code: 105501 *121301*
HED File Code ~~13000~~ *Tox Reviews 11000* *Chemical Review*
Memo Date: ~~01/31/75~~ *09-17-99*
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