



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

pm52/23
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOV 29 1985

MEMORANDUM

SUBJECT: PP#5F3252/FAP#6H5479 [RCB Numbers 123 and 124].
DPX-Y6202 (Assure®) Herbicide on Cotton and
Soybeans. Evaluation of Amendment Dated
September 19, 1985 (Accession Number 073908).

FROM: Michael P. Firestone, Ph.D., Chemist
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Hazard Evaluation Division (TS-769C)

Michael P. Firestone

TO: Robert J. Taylor, Product Manager No. 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

CT

Background

E. I. du Pont de Nemours and Company has submitted this amendment, consisting of a cover letter from T. Catka of DuPont to R. Taylor of EPA, an addendum to Section D containing the results of a soybean processing study, and an addendum to Section F proposing tolerances for various processed soybean commodities in partial response to Deficiency 8 as cited in RCB's review of the original petition (see M. Firestone memo of September 25, 1985).

RCB has previously recommended against establishment of the proposed tolerances for cottonseed and soybeans because of numerous deficiencies involving the product chemistry (1a, 1b and 1c), proposed use (2), residues of concern in plants (3a), animal metabolism (4), analytical methodology (5), storage stability (6), residue data (7a and 7b), processing studies for soybeans and cottonseed (8), and levels of secondary residues in animal commodities (9) (see M. Firestone memos of September 25, 1985 and October 23, 1985).

Deficiencies involving the analytical methodology (5), storage stability (6), residue data (7a and 7b), and processing studies (8) will be restated below since they have important relevance to the current submission.

Deficiency 5

The proposed regulatory method (Method No. AMR-153-83 Revision A) is not considered adequate for enforcement purposes because it is not designed to quantitate residues of DPX-Y6202 Acid conjugates. Depending on the results from the requested residue studies (see Deficiencies 7 and 8), methodology for some of the phenol metabolites (free plus conjugates) may need to be submitted and reviewed for regulatory purposes.

The petitioner will need to develop such methodology along with appropriate validation data (fortification/recovery data, control values, representative chromatograms, etc.) for analysis of both cottonseed and soybeans.

Also, the petitioner will need to examine whether any other pesticides registered for use on soybeans and cotton will interfere with the analysis of DPX-Y6202 and its acid and phenol metabolites of concern (free plus conjugates).

At such time as RCB considers the methodology acceptable, it will be sent to EPA's Analytical Chemistry Laboratory (ACS, COB, BUD) for a method tryout (MTO).

Deficiency 6

Storage stability data will need to be generated for residues of DPX-Y6202 Acid and the three possible phenol metabolites of concern.

Deficiency 7a

Considering the lack of residue data reflecting residues of DPX-Y6202 Acid conjugates and the phenol metabolites, and considering limited storage stability of DPX-Y6202 in frozen samples, the petitioner will need to conduct new field trials for soybeans and cottonseed in which the parent compound, and its acid and phenol metabolites (both free and conjugated) are quantitated (i.e., reanalysis of reserve samples is not considered acceptable at this time).

Deficiency 7b

RCB can reach no conclusion regarding the acceptability of the supplemental cottonseed residue data submitted in a September 10, 1985 amendment until a detailed description of Method No. AMR-154-83A as well as representative chromatograms are submitted. If Method AMR-154-83A does not contain an acceptable hydrolysis step capable of releasing conjugated DPX-Y6202 acid residues, the supplemental cottonseed residue data will probably be considered inadequate (note: plant metabolism studies indicate that a hydrolysis step is needed to release conjugated DPX-Y6202 acid residues).

In any case, the petitioner will still be required to submit residue data for the following three phenol metabolites (free plus conjugates) cited under Deficiency 3a generated on treated cottonseed and soybeans:

- Phenol 1 = 4-(6-chloroquinoxalin-2-yl oxy) phenol;
- Phenol 2 = 6-chloroquinoxalin-2-ol;
- Phenol 4 = 2-(4-hydroxyphenoxy) propionic acid.

Deficiency 8

Since detectable residues occur in/on soybeans treated even at 1/2x the maximum proposed use rate, the petitioner will need to conduct cottonseed and soybean processing studies in which the treated samples to be processed contain field weathered detectable residues (this may require treatment at greater than 1x and/or PHI's less than 80 days), so that it can be determined quantitatively whether residues concentrate in any processed fractions.

Current Considerations

The results of a soybean fractionation study are presented in the current submission.

Soybeans from a Beaumont, TX field trial conducted during 1984 were processed at Texas A&M University into hulls, meal, full fattened flour, defatted flour, soapstock and oil. Analytical Method AMR-153-83 Revision A was used to analyze the seeds and all processed fractions, except Appendix A to the above method, which was used to analyze oil samples.

A discussion of Method AMR-153-83 Revision A is presented in RCB's review of the original petition (see M. Firestone memo of September 25, 1985). However, Appendix A was not included in the original submission (nor is it provided in the current submission). Presumably, Appendix A is an alternate extraction and/or cleanup procedure for oily samples; it needs to be submitted to RCB.

The following fortification/recovery data are presented in the current amendment (note: all samples were fortified with DPX-Y6202 and its acid metabolite (DPX-Y6202 Acid; alternate designation IN-B6729) at 0.02 ppm and either 0.05 or 0.10 ppm):

Sample	Percent Recovery	
	DPX-Y6202	DPX-Y6202 Acid
soybeans	95, 93	90, 82
hulls	80, 87	110, 90
desolventized meal	95, 89	115, 82
full fat flour	80, 87	72, 55
defatted flour	115, 94	85, 48
crude oil	87, 82	67, 55, 91, 62
refined oil	150, 108	75, 62
refined bleached oil	110, 83	75, 75, 108
refined bleached deodorized oil	65 71	121, 121
soapstock	a	185, ^a 176 ^a

- a) Soapstock samples were fortified with both DPX-Y6202 and its acid metabolite (IN-B6729). DPX-Y6202 is reportedly converted to DPX-Y6202 Acid in soapstock due to residual NaOH present. No DPX-Y6202 was found in fortified soapstock. However, soapstock samples fortified with only DPX-Y6202 Acid yielded recoveries of 80 percent. Thus, the actual recovery of total (DPX-Y6202 plus its acid metabolite) residues averages approximately 90 percent.

Control values for DPX-Y6202 and its acid metabolite were all ≤ 0.02 ppm in all samples analyzed.

Soybeans were treated at rates of 2, 4 and 8 oz ai/A and harvested at 72 days after treatment (note: maximum proposed application rate = 4 oz ai/A; minimum proposed PHI = 80 days).

DPX-Y6202 residue levels were < 0.02 ppm in all soybean and processed fraction samples. Tabularized below are the results for residues of DPX-Y6202 Acid (IN-B6729):

Fraction	DPX-Y6202 Acid Residue Levels (ppm)/Concentration Factors		
	2 oz ai/A	4 oz ai/A	8 oz ai/A
soybeans	<0.020	0.022	0.062
hulls	0.033	0.073 (3.3x)	0.070 (1.1x)
desolventized meal	0.027	0.064 (2.9x)	0.190 (3.1x)
full fattted flour	0.049	0.088 (4.0x)	0.157 (2.5x)
defatted flour	0.088 ($>4.4x$)	0.095 (4.3x)	0.180 (2.9x)
crude oil	<0.020	<0.020 (-)	<0.020 (-)
refined oil	<0.020	<0.020 (-)	<0.020 (-)
soapstock	0.090	0.226 (10.3x)	0.448 (7.2x)

Based on the above results, and a previously proposed tolerance of 0.05 ppm for residues of DPX-Y6202 and its acid metabolite in soybeans, the petitioner has proposed the following tolerances on various soybean processed food and feed commodities:

Commodity	Proposed Tolerance (ppm)
soybean hulls	0.2
soybean meal	0.5
soybean flour	0.5
soybean soapstock	1.0

RCB's Comments/Conclusions re: Deficiency 8

a. With regard to the soybean processing study:

- i. The data are considered inadequate since they do not reflect residues of DPX-Y6202 Acid conjugates and the three possible phenol metabolites of concern.

- ii. Depending on resolution of the issue of storage stability (see Deficiency 6), either reanalysis of reserve samples should be performed (in which case information concerning the length of storage between harvest, processing, and analysis should be submitted), or a new soybean processing study will be needed in which analysis includes DPX-Y6202, its acid metabolite (free plus conjugates) and Phenols 1, 2 and 4 (free plus conjugates).
 - iii. The petitioner should submit a copy of Method AMR-153-83 Revision A Appendix A which was not included in the original petition.
- b. The petitioner will still need to conduct a cottonseed processing study in which the treated samples contain field weathered detectable residues (this may require treatment at exaggerated rates and PHI's of less than 80 days), and the residues to be analyzed for include DPX-Y6202, its acid metabolite (free plus conjugates), and its three possible phenol metabolites of concern (free plus conjugates).

At this time, Deficiency 8 remains unresolved.

Other Considerations

An International Residue Limit Status sheet is included with this review as Attachment 1. Since no Codex, Canadian or Mexican limits/tolerances have been established for DPX-Y6202 on cotton or soybeans, there are no compatibility problems at this time.

Recommendation

At this time, RCB continues to recommend against establishment of the proposed DPX-Y6202 tolerances for cotton, soybeans and processed soybean fractions for the reasons cited under Deficiencies 1a, 1b, 1c, 2, 3a, 4, 5, 6, 7a, 7b, 8 and 9 in RCB's previous review of PP#5F3252 (see M. Firestone memo of October 23, 1985) and also cited in this review.

Attachment 1: International Residue Limit Status Sheet

cc: R.F., Circu, MPFirestone, EAB, EEB, PMSD/ISB, FDA,
 PP#5F3252/FAP#6H5479
 RDI:JHOnley-11/20/85:RDSchmitt-11/21/85
 RCB:TS-769:MPFirestone:CM#2:Rm800b:557-7484
 typed by Kendrick contractor-11/26/85:edited by MPF-11/27/85

INTERNATIONAL RESIDUE LIMIT STATUS

J. Lives
11/1/85CHEMICAL: DPX-Y6202 (Assure®)PETITION NO.: 5F.3252/6H5479

CCPR NO.: _____

REVIEWER: Michael P. FirestoneCodex Status☒ No Codex Proposal Step
6 or above

Residue (if Step 9): _____

Crop(s) Limit (mg/kg)CANADIAN LIMIT

Residue: _____

Crop(s) Limit (ppm)

none

Proposed U.S. TolerancesResidue: ethyl 2-[4-(6-chloroquinoxalin-
2-yl oxy) phenoxy] propanoate ("Assure")
and its corresponding acid metabolite,
2-[4-(6-chloroquinoxalin-2-yl oxy)
phenoxy] propanoic acid.Crop(s) Tol. (ppm)soybeans 0.05
cotton 0.05soybean hulls 0.2
soybean meal 0.5
soybean flour 0.5
soybean soapstock 1.0MEXICAN TOLERANCIA

Residue: _____

Crop(s) Tolerancia (ppm)

none

Notes: