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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 01-OCT-2004

SUBJECT: Indoxacarb in/on *Brassica*, Sweet Corn, Cotton, Fruiting Vegetables, Lettuce (head and leaf) and Pome Fruits. **Request for Livestock Petition Method Validation (PMV)**. MRID#s 46308003 & 46308004. DP# 306822. Chemical# 067710. Decision# 347540.

FROM: Sarah J. Levy, Chemist *Sarah J. Levy*
Registration Action Branch 1 (RAB 1)
Health Effects Division (HED) (7509C)

THRU: P.V. Shah, Ph.D., Branch Senior Scientist *P.V. Shah*
RAB1/HED (7509C)

TO: Frederic Siegelman, Ph.D., Chief
Analytical Chemistry Laboratory (ACL)
Biological and Economics Analysis Division (7503C)

HED received a Section 3 registration request for application of indoxacarb ((S)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl][4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno [1,2-e][1,3,4] oxadiazine-4a(3H)-carboxylate) to *Brassica*, sweet corn, cotton, fruiting vegetables, lettuce (head and leaf) and pome fruits. In a memo dated 19-JAN-2000, HED reviewed the residue chemistry data submitted in support of this request (Memo, S. Levy; D244253). Tolerances for indoxacarb residues have since been established in 40 CFR 180.564 in/on various raw agricultural commodities (RACs) and meat and milk products.

Since then, the petitioner has submitted a poultry feeding study, as well as supporting method validation data (MRID 46116302). The liquid chromatography (LC)/mass spectrometry (MS)/MS Method (Dupont Method AMR 12739, modified) was successfully validated using hen muscle, liver, skin and fat, and whole eggs, egg yolk, and egg white, and is adequate for data collection (46116302.der1). A revised method, Dupont Method AMR 12739, Revision No. 1 (MRID 46308004), was submitted to the Agency which incorporated the minor findings of the independent laboratory validation (ILV - MRID 46308003).

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Note to ACL: the petitioner has not submitted a Section F for poultry tolerances. However, based on the submitted poultry feeding study, HED recommended (Memo, S. Levy, 22-SEP-2004; D297936) that tolerances be established for the combined residues of the insecticide indoxacarb + its R-enantiomer, IN-JT333, IN-KT319, IN-JU873, IN-KG433, and IN-KB687 in/on the following RACs:

Egg	0.20 ppm
Poultry, fat	0.20 ppm
Poultry, meat	0.06 ppm
Poultry, meat byproducts	0.06 ppm

The following volumes contain the LC/MS/MS Method (Dupont Method AMR 12739, Revision No. 1) and the ILV, which are appended to this memorandum as Attachments 2 and 3, respectively:

MRID 46308004 Stry, J. (2004) Analytical Method for the Determination of DPX-MP062 and Metabolites IN-KB687, IN-KG433, IN-KT319, IN-JU873, and IN-JT333 in Poultry Skin, Liver, Muscle, and Eggs. Lab Project Number: DuPont-12739. Unpublished study prepared by Dr. Specht & Partner and DuPont. 158 p.

MRID 46308003 Connolly, P. (2004) Independent Laboratory Validation of the Analytical Method, DuPont-12739, "Analytical Method for the Determination of DPX-MP062 and Metabolites IN-KB687, IN-KG433, IN-KT319, IN-JU873, and IN-JT333 in Poultry Skin, Liver, Muscle, and Eggs. Exygen Project Number: P0000493. Unpublished study prepared by Exygen Research. 53 p.

RAB1 has conducted a preliminary review of the ILV. Acceptable recoveries were obtained by the laboratory. RAB1 requests that ACL conduct a PMV on the submitted analytical methods.

Samples should be run in duplicate per the experimental design specified in Attachment 1. Please complete and return this attachment as part of your report. Also, please include with your report, copies of the standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Any deficiencies in the method, as written, should also be noted and reported. Please comment on the length of time necessary to complete a set of samples.

One of the purposes of conducting a PMV is to determine whether all necessary instructions are included in the submitted method. For this reason, we are requesting that laboratory staff scientists have minimal contact with the petitioner during this PMV. Any problems encountered should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

Please obtain the necessary analytical reference standards from the EPA Repository. If the analytical reference standard of indoxacarb and its metabolites are not available from the Repository, then please contact the Registration Manager at E.I. du DuPont de Nemours and Company (Richard Carver, 302-451-4517) directly requesting several hundred milligrams of each standard along with the required MSDS be provided directly to ACL. In your final report

please note which standards are available from the Repository as of (date).

The Registration Division (RD) Product Manager for indoxacarb is Ann Hanger. She should be contacted directly concerning the priority for completion of the PMV.

- Please address your written reports to: Karen Whitby, Ph.D., Chief, Registration Action Branch 1, Health Effects Division (7509C).

Attachment 1: Experimental Design for PMV

Attachment 2: Proposed Enforcement Method, MRID# 46308004.

Attachment 3: ILV, MRID# 46308003.

Attachment 4: Bean Sheet (D308834)

cc (with Attachment 1 only): S. Levy, A. Hanger (RD-7505C)
RDI: RAB1 Chemists (29-SEP-2004), P.V. Shah (01-OCT-2004)
S. Levy:806T:CM#2:(703)305-0783:7509C:RAB1

METHOD: MRID 46308004 Stry, J. (2004) Analytical Method for the Determination of DPX-MP062 and Metabolites IN-KB687, IN-KG433, IN-KT319, IN-JU873, and IN-JT333 in Poultry Skin, Liver, Muscle, and Eggs. Lab Project Number: DuPont-12739. Unpublished study prepared by Dr. Specht & Partner and DuPont. 158 p.

Please: (i) Indicate the limit of detection and quantitation; (ii) Do not use control values for recovery calculations; and (iii) Do not report control values as zero; if less than the limit of detection, report as such.

Commodity	Chemical Added	ppm Added	ppm Found	Percent Recovery
Poultry liver	Indoxacarb	0.00		
		0.010		
		0.020		
		0.060		
	IN-JT333	0.00		
		0.010		
		0.020		
		0.060		
	IN-KT319	0.00		
		0.010		
		0.020		
		0.060		
	IN-JU873	0.00		
		0.010		
		0.020		
		0.060		
	IN-KG433	0.00		
		0.010		
		0.020		
		0.060		
IN-KB687	0.00			
	0.010			
	0.020			
	0.060			

Egg	Indoxacarb	0.00		
		0.010		
		0.10		
		0.20		
	IN-JT333	0.00		
		0.010		
		0.10		
		0.20		
	IN-KT319	0.00		
		0.010		
		0.10		
		0.20		
	IN-JU873	0.00		
		0.010		
		0.10		
		0.20		
	IN-KG433	0.00		
		0.010		
		0.10		
		0.20		
IN-KB687	0.00			
	0.010			
	0.10			
	0.20			



13544

R102889

Chemical:	Indoxacarb
PC Code:	067710
HED File Code	11000 Chemistry Reviews
Memo Date:	10/01/2004
File ID:	DPD306822
Accession Number:	412-05-2000

HED Records Reference Center
10/21/2004