

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

CASWELL FILE
7/95

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

JUL 11 1989

MEMORANDUMOFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for the Use of Express
(DPX-L5300) on Wheat and Barley, PP#7F3540

FROM: J. Robert Tomerlin, Ph.D. *JR Tomerlin 7/10/89*
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THROUGH: Reto Engler, Ph.D. *Reto Engler*
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Health Effects Division (H7509C)

TO: L. Schnaubelt, Acting PM 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

Action Requested

Provide an estimate of exposure to Express (DPX-L5300) resulting from the proposed tolerances on wheat and barley.

Discussion

1. Toxicology Endpoint: The routine chronic TAS analysis used a reference dose (ADI) of 0.008 mg/kg body weight/day, based upon a NOEL of 0.79 mg/kg body weight/day and an uncertainty factor of 100 from a 1 year dog feeding study. This value has been approved by HED (9/14/88) and Agency (10/12/88) reference dose committees.
2. Residue Information: There are no published tolerances for Express. Food uses evaluated were proposed tolerances on wheat and barley (R. W. Cook memo, 6/29/89). Although wheat and barley are both major feed commodities, residues in meat and milk are not expected and ruminant animal feeding and poultry feeding studies are not required at this time. Such studies may be required if additional or higher tolerances are sought for animal feed items (R. W. Cook memo, 5/11/89). A summary of the residue information used in the analysis is attached as Table 1.
3. Exposure Analysis: The TAS chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The estimated TMRC for the overall U.S. population is 0.000073 mg/kg body weight/day, which represents 0.9 per cent of the ADI. The two most highly

Express (DPX-L5300) Dietary Exposure Analysis, page 2

exposed TAS population groups, children aged 1 to 6 and children aged 7 to 12, have estimated TMRCs of 0.000158 mg/kg body weight/day (2.0% of the ADI) and 0.000116 mg/kg body weight/day (1.4% of the ADI), respectively.

4. Comments: This analysis was done assuming that 100 per cent of the wheat and barley consumed would contain tolerance level residues of Express herbicide. Even under these stringent assumptions, exposure did not exceed 2 per cent of the ADI for the most highly exposed TAS population group.

Subsequent analyses may require consideration of residues in meat and milk, in which case the exposure profiles for the various TAS population groups may be considerably different.

Attachments

cc: TAS (Tomerlin, SACB), DEB, Caswell #419S, Gardner (TOX-HFASB)

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 419S

DATE: 06/08/89

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CHEMICAL	STUDY TYPE	EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
		lyr feeding- doq	Elevated serum bilirubin	ADI	SF -->100	No data gaps.		
Express (IN L5300)	NOEL=	0.7900 mg/kg	and AST levels, increased	OPP RfD= 0.008000				HED complete 09/14/88.
Caswell #419S	LEL=	25.00 ppm	urinary volume	EPA RfD= 0.008000				EPA verified 10/12/88.
CAS No. 101200-4B-0		8.1600 mg/kg	Evidence of oncogenicity					
A.I. CODE:		250.00 ppm	in rats (F; mammary car-					
CFR No. 180.	ONCO: Class C (HED NOTE)		inoma); negative mice.			No Q* calculated.		On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
24001AA	BARLEY	7F3540	0.050000	
24007AA	WHEAT-ROUGH	7F3540	0.050000	
24007GA	WHEAT-GERM	7F3540	0.050000	
24007HA	WHEAT-BRAN	7F3540	0.050000	
24007WA	WHEAT-FLOUR	7F3540	0.050000	

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/08/89

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
Express (IN L5300)	lyr feeding- dog		Elevated serum bilirubin	ADI	SF -->100		No data gaps.		HED complete 09/14/88.
Caswell #4195	NOEL=	0.7900 mg/kg	and AST levels, increased	OPP	RED= 0.008000				EPA verified 10/12/88.
CAS No. 101200-48-0		25.00 ppm	urinary volume	EPA	RED= 0.008000				
A.I. CODE:	LEL=	8.1600 mg/kg	Evidence of oncogenicity						
CFR No. 180.		250.00 ppm	in rats (F; mammary car-						
	ONCO: Class C (HED WTE)		inoma); negative mice.				No Q* calculated.		On IRIS.
POPULATION SUBGROUP		TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC		DIFFERENCE		EFFECT OF ANTICIPATED RESIDUES	
		CURRENT TMRC*	NEW TMRC**	AS PERCENT	OF RFD	AS PERCENT	OF RFD	ARC	BRFD
U.S. POPULATION - 48 STATES		0.000000	0.000073	0.917575	0.917575	0.917575	0.917575		
U.S. POPULATION - SPRING SEASON		0.000000	0.000072	0.895088	0.895088	0.895088	0.895088		
U.S. POPULATION - SUMMER SEASON		0.000000	0.000072	0.894900	0.894900	0.894900	0.894900		
U.S. POPULATION - FALL SEASON		0.000000	0.000076	0.944425	0.944425	0.944425	0.944425		
U.S. POPULATION - WINTER SEASON		0.000000	0.000075	0.935912	0.935912	0.935912	0.935912		
NORTHEAST REGION		0.000000	0.000078	0.969762	0.969762	0.969762	0.969762		
NORTH CENTRAL REGION		0.000000	0.000076	0.951638	0.951638	0.951638	0.951638		
SOUTHERN REGION		0.000000	0.000069	0.864075	0.864075	0.864075	0.864075		
WESTERN REGION		0.000000	0.000071	0.890050	0.890050	0.890050	0.890050		
HISPANICS		0.000000	0.000070	0.875425	0.875425	0.875425	0.875425		
NON-HISPANIC WHITES		0.000000	0.000075	0.939387	0.939387	0.939387	0.939387		
NON-HISPANIC BLACKS		0.000000	0.000064	0.801150	0.801150	0.801150	0.801150		
NON-HISPANIC OTHERS		0.000000	0.000070	0.877962	0.877962	0.877962	0.877962		
NURSING INFANTS (< 1 YEAR OLD)		0.000000	0.000025	0.309638	0.309638	0.309638	0.309638		
NON-NURSING INFANTS (< 1 YEAR OLD)		0.000000	0.000059	0.732088	0.732088	0.732088	0.732088		
FEMALES (13+ YEARS, PREGNANT)		0.000000	0.000052	0.645050	0.645050	0.645050	0.645050		
FEMALES 13+ YEARS, NURSING		0.000000	0.000065	0.818100	0.818100	0.818100	0.818100		
CHILDREN (1-6 YEARS OLD)		0.000000	0.000158	1.978700	1.978700	1.978700	1.978700		
CHILDREN (7-12 YEARS OLD)		0.000000	0.000116	1.446587	1.446587	1.446587	1.446587		
MALES (13-19 YEARS OLD)		0.000000	0.000084	1.053262	1.053262	1.053262	1.053262		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.000000	0.000064	0.795250	0.795250	0.795250	0.795250		
MALES (20 YEARS AND OLDER)		0.000000	0.000063	0.793075	0.793075	0.793075	0.793075		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.000000	0.000048	0.599262	0.599262	0.599262	0.599262		

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.



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Chemical: Tribenuron-methyl

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