ОСТ 2 5 1995

MEMORANDUM

SUBJECT: Exposure Assessment - Use of Cloransulam-methyl on Soybeans.

FROM: Charles Lewis
Special Review and Registration Section II

TO: R. Griffin
Risk Characterization and Analysis Branch

THRU: Mark I. Dow, Ph.D, Section Head
Special Review and Registration Section II

Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

The Occupational and Residential Exposure Branch (OREB) has been requested by the Risk Characterization and Analysis Branch (RCAB) to provide an exposure assessment for the proposed use of cloransulam-methyl on soybeans. The assessment is attached.

DP Barcode: D219680

Pesticide Chemical Code: 129116

EPA Reg. No.: 62719-ETL

PHED: Yes

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I. INTRODUCTION:

A. Background:

The proposed use is for control of broadleaf weeds in soybeans. Applications can be made with groundboom sprayers; preplant incorporated, preemergence, and postemergence. Maximum use rate is 0.0392 lb ai/A. The product, FirstRate, is a water soluble granule packaged in water soluble pouches. One application per year is permitted.

OREB has not previously completed an exposure assessment for use of cloransulam-methyl.

No endpoint of concern has been provided.

B. Purpose:

OREB has been requested by RCAB to provide an exposure assessment for the proposed use of cloransulam-methyl on soybeans.

II. DETAILED CONSIDERATIONS:

The registrant, DowElanco, has submitted an exposure assessment based on the Pesticide Handlers Exposure Database, Version 1.1 (PHED). OREB used the same version of PHED along with the use information provided by DowElanco to develop its exposure assessment.

Assumptions

One application/year @ 0.0392 lb ai/A;
Typical soybean farm is 400 A (DowElanco);
Applicator treats 200 A/day (DowElanco);
Chemical handled/day = 7.84 lbs ai.

The DowElanco estimates of exposure differ slightly from those of OREB because of PHED data selection. OREB has relied on a more conservative approach[1] resulting in a higher unit of exposure value for mixer/loaders (94.2790 μg/lb ai handled) than that of DowElanco (9.2306 μg/lb ai handled).

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[1] OREB Science Peer Review. Water dispersible granule formulations will be treated as a dry flowable, open mixing/loading.

Mixer/loaders

According to WPS, handlers must wear long-sleeved shirt, long pants, shoes plus socks, and waterproof gloves. The label currently requires this PPE.

Based on PHED and the information provided by DowElanco, estimated exposure for mixer/loaders of cloransulam-methyl is 10.6 μg ai/kg bw/day.

Applicators

With applicators wearing the same PPE as mixer/loaders, estimated exposure is 1.7 μg ai/kg bw/day.

III. CONCLUSIONS:

OREB has estimated the exposure for mixer/loaders and applicators using FirstRate for weed control in soybeans (TABLE 1). TABLE 2 contains the estimates of exposure calculated by DowElanco.

TABLE 1. OREB estimated total exposure (μg ai/kg bw/day) for mixer/loaders and applicators using FirstRate for weed control in soybeans.	
Task	Estimated Exposure (μg ai/kg bw/day)
Mixer/loader	10.6
Applicator	1.7

TABLE 2. DowElanco estimated total exposure (μg ai/kg bw/day) for mixer/loaders and applicators using FirstRate for weed control in soybeans.	
Task	Estimated Exposure (μg ai/kg bw/day)
Mixer/loader	1.0
Applicator	2.0

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CALCULATIONS

Mixer/loaders

94.2790 μg ai/lb handled (PHED 1.1, DF.OPN.AIR.AB.MLOD., long-sleeved shirt, long pants, gloves) x 7.84 lb ai/day ÷ 70 kg bw = 10.56 μg ai/kg bw/day.

Applicators

15.3644 μg ai/lb handled (PHED 1.1, BRUCE. APPL., long-sleeved shirt, long pants, gloves) x 7.84 lb ai/day ÷ 70 kg bw = 1.72 μg ai/kg bw/day.

cc.   C. Lewis, OREB
      K. Hicks, RD (PM25)
      Chemical File (129116)
      Correspondence File

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          SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, gloves
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PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				
		Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	16.575	35.7906	109.9166	17.5482	16
NECK.FRONT	Lognormal	8.055	13.9106	102.7059	5.8389	16
NECK.BACK	Lognormal	.5665	3.8954	152.6005	1.1169	16
UPPER ARMS	Lognormal	5.82	7.6751	122.0349	5.7753	16
CHEST	Lognormal	7.1	9.0525	56.739	8.0221	16
BACK	Lognormal	5.325	5.6578	29.4726	5.3841	16
FOREARMS	Lognormal	2.42	3.5317	74.0267	2.8683	16
THIGHS	Lognormal	21.01	143.7991	232.209	31.365	16
LOWER LEGS	Other	4.76	27.1469	246.6433	8.3813	16
FEET						0
``NDS	Lognormal	10.6667	11.1217	30.8631	10.5675	16
`TAL DERM:		93.2463	82.2982	261.5814	96.8676	

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95% C.I. on Mean: Dermal: [-5059.0451, 5582.2079]


                                    Number of Records: 16
Data File: MIXER/LOADER            Subset Name: DF.OPN.DERM.AB.LO.MLOD




                      << Specifications >>
          Subset Specifications for DF.OPN.DERM.AB.LO.MLOD



With Total lb ai Mixed Less than 10
{  set originated from DF.OPN.DERM.AB.MLOD
With Dermal Grade Uncovered Equal to "A" "B" or
With Dermal Grade Covered Equal to "A" "B"
Subset originated from DF.OPN.MLOD
With Mixing Procedures Equal to 1 and (open mixing)
With Solid Type Equal to 2 (dry flowable)
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Water dispersible granule formulation treated as dry flowable, open mixing/loading, as per science peer review decision.

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SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				
		Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	16.575	35.7906	109.9166	17.5482	16
NECK.FRONT	Lognormal	8.055	13.9106	102.7059	5.8389	16
NECK.BACK	Lognormal	.5665	3.8954	152.6005	1.1169	16
UPPER ARMS	Lognormal	5.82	7.6751	122.0349	5.7753	16
CHEST	Lognormal	7.1	9.0525	56.739	8.0221	16
BACK	Lognormal	5.325	5.6578	29.4726	5.3841	16
FOREARMS	Lognormal	2.42	3.5317	74.0267	2.8683	16
THIGHS	Lognormal	21.01	143.7991	232.209	31.365	16
LOWER LEGS	Other	4.76	27.1469	246.6433	8.3813	16
FEET						0
HANDS	Lognormal	10.6667	11.1217	30.8631	10.5675	16
TOTAL DERM:		93.2463	82.2982	261.5814	96.8676	

95% C.I. on Mean: Dermal: [-5059.0451, 5582.2079]

Number of Records: 16

Data File: MIXER/LOADER   Subset Name: DF.OPN.HAND.AB.LO.MLOD

<< Specifications >>
Subset Specifications for DF.OPN.HAND.AB.LO.MLOD

With Total lb ai Mixed Less than 10
Subset originated from DF.OPN.HAND.AB.MLOD
With Hand Grade Equal to "A" "B"
Subset originated from DF.OPN.MLOD
With Mixing Procedures Equal to 1 and (open mixing)
With Solid Type Equal to 2 (dry flowable)
Subset originated from MLOD.FILE

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SUMMARY STATISTICS FOR INHALATION EXPOSURES

EXPOSURE	DISTRIB. TYPE	NANOGRAMS PER LB AI MIXED				
		Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Lognormal	632.0859	1032.7422	113.3869	674.5318	16

95% C.I. on Geo. Mean: [107.4181, 4235.7221]
Number of Records: 16
Data File: MIXER/LOADER   Subset Name: DF.OPN.AIR.AB.LO.MLOD

<< Specifications >>
Subset Specifications for DF.OPN.AIR.AB.LO.MLOD

..th Total lb ai Mixed Less than 10
Subset originated from DF.OPN.AIR.AB.MLOD
With Airborne Grade Equal to "A" "B"
Subset originated from DF.OPN.MLOD
With Mixing Procedures Equal to 1 and
With Solid Type Equal to 2
Subset originated from MLOD.FILE

CALCULATIONS

93.2463 ug/lb ai mixed - 10.5675 ug/lb ai mixed = 82.6788 ug/lb ai mixed
                                        (dermal unit exposure
                                          w/o hands)

82.6788 ug/lb ai mixed + 10.5675 ug/lb ai mixed = 93.2463 ug/lb ai mixed
                                        TOTAL dermal unit exposure

93.2463 ug/lb ai mixed + 1.0327 ug/lb ai mixed = 94.2790 ug/lb ai mixed
                      (inhalation)   **TOTAL UNIT EXPOSURE**
                              (combined dermal and inhalation)

Groundboom - Open Cab - long pants long sleeves gloves

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves   **(GROUNDBOOM APPLICATION)**

TCH CATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
AD (ALL)	Lognormal	.78	2.5874	139.8663	.9707	31
NECK.FRONT	Lognormal	.3	1.5763	167.9503	.3296	23
NECK.BACK	Lognormal	.242	.9753	181.4416	.2219	27
UPPER ARMS	Lognormal	1.455	1.6914	88.749	1.1637	32
CHEST	Lognormal	1.42	1.8282	95.4874	1.2005	40
BACK	Normal	1.775	2.0057	88.3183	1.3235	40
FOREARMS	Lognormal	.605	2.7301	419.1055	.564	32
THIGHS	Lognormal	1.146	3.3025	180.0273	1.2698	31
LOWER LEGS	Other	.714	2.2285	167.1842	.8001	33
FEET						0
HANDS						0
AL DERM:		8.4399	8.437	18.9254	7.8438	

95% C.I. on Mean: Dermal: [-141.4485, 179.2993]

Number of Records: 42

Data File: APPLICATOR   Subset Name: BRUCE1.APPL

ADD INHALATION	CHANGE HEAD	LB AI TO KG AI	EXIT

<< Specifications >>
Subset Specifications for BRUCE1.APPL

With Dermal Grade Uncovered Equal to "A" "B" .
ubset originated from BRUCE.APPL
  :h Application Method Equal to 2 3 and (Groundboom Tractor, Groundboom Truck)
  th Cab Type Equal to 1 2 (Open Cab)
{ et originated from APPL.FILE

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED				
		Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	3.51	14.5427	256.3981	3.1175	60
NECK.FRONT	Lognormal	.6225	1.5156	134.3626	.5743	48
NECK.BACK	Lognormal	.484	1.5962	277.5153	.3815	55
UPPER ARMS	Lognormal	1.3095	1.627	95.5501	1.0466	22
CHEST	Lognormal	2.13	6.0169	190.4768	2.0825	59
BACK	Lognormal	2.485	6.384	193.3835	2.2369	59
FOREARMS	Lognormal	.968	3.8282	263.411	1.0872	47
THIGHS	Other	.382	3.82	360.4738	.796	25
LOWER LEGS	Other	.833	2.1745	152.035	.9379	44
FEET	Lognormal	1.048	20.3196	211.3742	1.9643	9
HANDS	Lognormal	13.6511	43.3524	188.4279	6.2868	21
TOTAL DERM:		19.9926	27.4231	105.1771	20.5115	

95% C.I. on Mean: Dermal: [-1363.2173, 1573.5715]

Number of Records: 65
Data File: APPLICATOR
Subset Name: BRUCE2.APPL

ADD INHALATION	CHANGE HEAD	LB AI TO KG AI	EXIT

<< Specifications >>   Subset

Specifications for BRUCE2.APPL

With Hand Grade Equal to "A" "B" "C" and
 th Hand Measuring Method Equal to 1 2
   set originated from BRUCE.APPL
   ch Application Method Equal to 2 3 and (Groundboom Tractor, Groundboom Truck)
W h Cab Type Equal to 1 2 (Open Cab)
S. set originated from APPL.FILE

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SUMMARY STATISTICS FOR INHALATION EXPOSURES

DISTRIB. TYPE		NANOGRAMS PER LB AI SPRAYED				
		Median	Mean	Coef of Var	Geo. Mean	Obs.
Lognormal		915.7671	1673.8958	156.4139	637.7581	22

EXPOSURE
(ALL)
FROM

C.I. on Geo. Mean: [30.3269, 13411.6863]
Number of Records: 22
Data File: APPLICATOR   Subset Name: BRUCE3.APPL

<< Specifications >>
Subset Specifications for BRUCE3.APPL

With Airborne Grade Equal to "A" "B"
   oset originated from BRUCE.APPL
with Application Method Equal to 2 3 and (Groundboom Tractor, Groundboom Truck)
With Cab Type Equal to 1 2 (Open Cab)
Subset originated from APPL.FILE

CALCULATIONS

hands

8.4399 ug/lb ai sprayed + 6.2868 ug/lb ai sprayed = 14.7267 ug/lb ai sprayed
                                                    TOTAL dermal unit exposure

14.7267 ug/lb ai sprayed + 0.637 ug/lb ai sprayed = 15.3644 ug/lb ai sprayed
                            (inhalation)   **TOTAL UNIT EXPOSURE**
                                          (combined dermal and inhalation)

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Equal
ed f

**PHED version 1.1 used

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9/29/95

NOTE:

TO: OREB

FROM: R. Griffin
        Registration Section/RCAB   305-5715

In support of a tolerance petition (5F04560) for cloransulam-methyl
(aka XDE-565) on soybean, the following data package has been
submitted:

1. Estimation of exposure/risk to workers from use of
    cloransulam-methyl.   MRID 437154-01

A subordinate bean (D219680) has been set up for OREB review.

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