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MEMORANDUM

TO: John S. Sanders, Chief **HSM-98008**
Worker Health and Safety Branch

FROM: Michael H. Dong, Staff Toxicologist
Worker Health and Safety Branch [original signed by Michael Dong]

DATE: September 22, 1998

SUBJECT: SUMMARY OF REVIEW CRITERIA USED FOR SB-950 DATA
EXEMPTION

The review criteria that have been used by this Branch since 1991 for exempting or waiving the SB-950 health effects data requirements are summarized below:

1. As indicated in the attached spreadsheet, the criteria or bases used can be subsumed under four categories: (a) the Proposition 65 safe harbor level; (b) other safe levels including apparent NOEL (no observed effect levels) from related toxicity data, or those set forth by this Branch for defining default insignificant exposure (Donahue, 1996); (c) naturally occurring in abundance (as evidence of a level generally recognized as safe); and (d) minimal or low contact. In terms of their use, these criteria are not mutually exclusive.
2. Of the 246 products reviewed, 53.3% (i.e., 131/246) were determined to be with *insignificant* human exposure either under initial (current) label specifications or subject to apparent or minor label amendments intended to be consistent with the label specifications required for other similar uses.
3. Another 66 (26.8%) of the 246 products were subsequently considered to have *insignificant* human exposure either after specific label amendments were made or upon review of further information/data provided by the registrants.
4. Altogether, 81.2% (i.e., 160/197) of the insignificant exposure calls were based on minimal or low contact (category D). The distributions for the other review criteria are: Proposition 65 (category A), 0.5%; other safe levels (category B), 24.9%; and natural occurrence (category C), 14.2%.

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5. Products considered here (under similar context) but not on the SB-950 list that Karen Fletcher's group (of Registration) is currently working with are: Nuosept 145; 20,25-diazacholestenol dihydrochloride chemosterilant; Tektamer 38; and resmethrin (Scourge 4%, Scourge 18%).

References

Donahue JM, 1996. Parameters Defining Insignificant Exposure. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation, January 26.

Attachments

cc: John H. Ross

CRITERIA USED FOR DATA EXEMPTION/WAIVER

DATA EXEMPTION/WAIVER REQUEST	total	initially	finally	criteria				remark
				A	B	C	D	
4-aminopyridine (4-nitropyridine)	3		3				3	bird repellent
alkyl-propylenediamine (oil)	5	5					5	per closed system
ancymidol	1		1		1			
bendiocarb	1	1					1	with conditions
biobor jf (dioxaborinane)	1							significant exposure; an antimicrobial (with boric acid as a.i.)
borate (wood preservative)	6	2	2				4	2 products canceled
borax (ants)	4	4					4	
borax (carpets/fleas)	5		1			1	1	insignificant for 1(M7 Mop On); 3 products especially for carpet
borax (fungicide)	2	2					2	
borax (wood preservative paste)	1		1				1	trade name: CuRap 20
boric acid (bird control)	2		2				2	trade names: SafeCide IC and SafeCide Bait
boric acid (crack/crevice)	6	6				6	6	1 product (Victor Liquid) is also an ant killer
boric acid (fiber insulation)	1		1				1	trade name: In-Cide
boric acid (in 1992)	41	40					40	
boric acid (insecticide)	4	2					2	ok: Jecta Terminator, CB Mop Up; not ok: Krystal, PT 240D
bromadiolone	16		16		16		16	with conditions
chloroneb	3		2				2	1 product canceled
chlorophacinone	6	6					6	with conditions
chromic acid	10	3					3	the other 7 products: not by WHS alone due to Prop 65 level
compound 1080 (sod. fluoroacet.)	1	1					1	USDA product
diazacholestenol dihydrochloride	1							bird repellent; significant exposure; not on SB 950 list
diclofop-methyl	1		1					criteria not clear as not finalized by this reviewer
diphacinone (in 1992)	37	24	8		32		5	products: significant or for manufacturing use
diphacinone (those after 1992)	7	6					6	
formaldehyde (poultry, 1998)	1		1	1				per label amendments
formaldehyde (sterilant)	1		1				1	per label amendments
hexaflumuron	1	1					1	
IBA (indole-butyric acid)	16	16				16	16	biochemical products
m-44 cyanide	1	1					1	USDA product
Magnacide 461, 434, 407(oil)	3	1	2				1	per closed system for 407; the other 2 products: criteria not clear
methiocarb	1							more information now available for re-consideration
NAF-46W (pheromone)	1		1				1	
nicotine (Smoke Generator)	1							significant exposure

CRITERIA USED FOR DATA EXEMPTION/WAIVER (Cont'd)

Nuosept 145 (Cosan 145)	1							not on the SB 950 list
oleic acid sulfonates	3	3						3 concurring with EPA
piperalin (Pipron)	1							significant exposure; re-consideration pending further data
resmethrin (Scourge 4%, 18%)	2							significant exposure; PPE suggested; not on the SB 950 list
rotenone (prior to 1992)	13	1						1 no further decision on the other 12 products
sabadilla alkaloids	1	1				1	1	
sulfotep (greenhouse)	1							significant exposure; see note below
Tektamer 38	1		1					1 not on the SB 950 list
tenn-cop (copper salt)	1	1				1	1	1 with conditions
toluidine hydrochloride (birds)	4		4				4	4 USDA product
toluidine hydrochloride (birds)	2		2				2	2 CDFA product
tomahawk (pirimiphos-methyl	1	1					1	
X-cide 370, 107, 105 (oil)	3							no closed system; no longer registered in California
X-cide380, 320, 402 (oil)	3	3				3	3	3 per closed system
Z-9 tricosene	2							sex attractant; significant exposure
zinc phosphide	16		16				16	16 with conditions
					1	49	28	160
total	246	131	66					
% insignificant exposure calls								
per initial review:		53.3%						
to this date:		80.1%						
A. Prop 65 Safe Harbor Level	1		0.5%					
B. Other (Policy) Safe Level	49		24.9%					
[C. Natural Occurrence*	28]		14.2%					
D. Minimal/low contact	160		81.2%					
*usually also with low contact								

CRITERIA USED FOR DATA EXEMPTION/WAIVER (Cont'd)

Trade Names for Selected Products									
4-aminopyridine									
Avitrol Mixed Grains									
Avitrol Corn Chops									
Avitrol Whole Corn									
Magnacide 461, 434, 407									
alkyl amino aminopropane hydroxyacetate (a.i.)									
alkyl dimethyl benzyl ammonium chloride (a.i.)									
20,25-diazacholestenol dihydrochloride									
(chemosterilant for pigeons (trade name?))									
methiocarb									
Mesurol									
3-chloro-p-toluidine hydrochloride									
Compound DRC-1339 Concentrate - Feedlots									
1330 Gull Toxicant 98% Concentrate									
Compound DRC-1339 98% Concentrate - Livestock Depredations									
Compound DRC-1339 95% Concentrate - Pigeons									
Feral Pigeon and Crow Bait									
Starling and Blackbird Bait									
Z-9 Tricosene									
Musca-Cide Fly Bait									
Apache Fly Bait									
Notes									
1. Denial for sulfotep was based on limited (inconclusive) WH&S data; additional clothing (e.g., gloves) was recommended for harvesters.									
2. Products considered but not on the SB-950 list that Karen Fletcher (of Registration) is currently working with are as follows:									
20,25-diazacholestenol dihydrochloride chemosterilant									
nuosept 145 (Cosan 145)									
resmethrin (Scourge 4%, Scourge 18%)									
Tektamer 38									
3. The common product names borax, borate, and boric acid might have been used here interchangeably or loosely for a few cases.									