US EPA ARCHIVE DOCUMENT

2-15-95

MEMORANDUM

Subject: EPA Reg. #: 59639-ON; Trumpet EC Insecticide

TO: Robert Forrest, PM # 14 Attn: Beth Edwards
Insecticide/Rodenticide Branch
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist DLR 2-15-95
Registration Support Branch
Precautionary Review Section
Registration Division (7505C)

Registrant: Valent USA Corp.
1333 California BLVD # 600
Walnut Creek CA 94596

FORMULATION FROM LABEL:

Active Ingredient(s):	% by Wt.
*Naled	85%
Inert Ingredient(s):	15%

*1,2-dibromo-2,2-dichloroethyl-dimethyl phosphate

Action Requested:

Waive all acute toxicity data requirements.

PRS Recommendations:

PRS has no objection to waiving the acute toxicity data requirements for this product.

The registrant cites data from other naled products which have similar concentrations and for which toxicity data are available.

These include: Dibrom 14 Concentrate, 85% Naled (EPA Reg. #. 59639-19) and Naled Technical, 92.5% (EPA Reg. # 59639-43). The present formulation, Trumpet EC, contains 85% Naled.

The registrant proposes the following toxicity categories for this product:

	TOXICITY Cat.
Acute oral	II
Acute dermal	II
Acute inhalation	II
Eye irritation	I
Dermal "	I
Dermal sens.	na

The dermal LD_{50} on technical Naled (92.5% AI) was found to be TOX I (I. Mauer memo of 12/3/85, # 004838). RD summarized the toxicity categories of Dibrom 14 (85% AI) in its memo of 6/12/86; the category I for inhalation was subsequently changed to TOX II in the I. Mauer memo of 6/24/86; # 005217). Trumpet EC contains 85% AI and thus lies between Dibrom EC and the Naled technical. A comparison of the three formulations reveals the similarities of these products (see the attached confidential appendix).

For the purpose of this response PRS considers the composition of these products to be toxicologically equivalent.

Bases for the Waivers:

The formulations noted above possess pHs of 2.0 or less; Trumpet EC has a Ph of 2.1, close enough to waive the requirements for eye and skin irritation and dermal sensitization. The product would be placed in TOX category I for these routes of exposure; accordingly the requirement for acute eye and skin irritation and dermal sensitization are waived.

The acute oral and dermal toxicity data requirements are waived because there are acceptable data from the other two products, Dibrom 14 and the Naled technical. Therefore, the acute toxicity data profile for Trumpet EC is complete and is summarized as follows:

	TOXICITY Cat.
Acute oral	II
Acute dermal	II
Acute inhalation	II
Eye irritation	I
Dermal "	I
Dermal sens.	na

Precautionary Labeling Review:

Signal Word: Danger! Acceptable.

Precautionary Statement:

Begin second sentence with "Due to corrosive nature, may be ...".

Statement of Practical Treatment:

If Swallowed: Drink a large quantity milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Note to PM:

Criterion for Toxicity Category I:

The finding of corrosivity of the eye and the skin places this product in Toxicity Category I (40 CFR 152.70).

Criterion for Child-Resistant packaging:

The finding of TOX I meets the requirement for child resistant packaging pursuant to 40 CFR 157.22(a)(4). If classified for Restricted Use only, CRP is not required.

Criterion for Restricted Use classification:

The finding of corrosivity of the eye and the skin meets the criterion for a "Restricted Use" classification (certified applicators only) pursuant to 40 CFR 152.170(b)(iv). PM Team must decide if alternative labeling is sufficient to offset the hazard and the requirement for Restricted Use Classification.

CONFIDENTIAL APPENDIX FORMULATION INERT INGREDIENTS

59639-ON; Trumpet EC Insecticide

Valent USA Corp.
1333 California BLVD # 600
Walnut Creek CA 94596

Product	Reg. No.	%Naled	% Impurities	% XRAS	% Emuls.
Dibrom 14	59639-19	85%	[redacted]		
Trumpet EC	" -ON	86.7			
Naled Tech.	" -43	92.45			

For the purpose of this response PRS considers the composition of these products to be toxicologically equivalent.

INERT INGREDIENT INFORMATION IS NOT INCLUDED