

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

28/JUL/2004

MEMORANDUM

Subject: Name of Pesticide Product: GF-881 Manufacturing Use Concentrate
EPA Reg. No./File Symbol: EPA File Symbol 62719-LNE
DP Barcode: 305274
Decision #: 211685
PC Code: 119031 Benzenesulfonamide, 2-(2,2-difluoroethoxy) -
N-(5,8-dimethoxy[1,2,4]triazolo[1,5c]pyrimidin-2-yl)
-6(trifluoromethyl) (DE-638, Penoxsulam)

From: Tracy Keigwin *TK* *SCA*
Technical Review Branch
Registration Division (7505C)

To: Philip Errico, PM 23
Herbicide Branch
Registration Division (7505C)

Applicant: Dow AgroSciences LLC .
9330 Zionsville Road
Indianapolis, IN 46268

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FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
119031 Penoxsulam	50
<u>Inert Ingredient(s):</u>	<u>50</u>
Total:	100%

ACTION REQUESTED: PM requests review of response from Dow Agrosciences LLC with regard to EPA File Symbol 62719-LNE.

BACKGROUND: Dow AgroSciences LLC has submitted a response to our review concerning EPA File Symbol 62719-LNE. Originally an acute inhalation waiver request was submitted to support this product and was denied. It cited the (then) unacceptable acute inhalation toxicity study submitted to support EPA File Symbol 62719-UOO and additionally had a different pH and formulation from the technical product. The response from Dow rebutted the previous review and requested that the acute inhalation study that was submitted to support the registration of EPA File Symbols 62719-LNN and 62719-LRU (MRID 45830819) be considered in support of EPA File Symbol 62719-LNE. They have requested a toxicity 4 classification for this product in spite of the toxicity 3 classification of MRID 45830819, based on the physical limitations to aerosol generation of the test substance.

RECOMMENDATIONS: We can not agree to the acute inhalation toxicity 4 classification for EPA File Symbol 62719-LNE. In their rebuttal Dow references a product that would represent an approximate 1:1 dilution of the proposed product. Under normal circumstances the citation of a study with a lower percent active ingredient than the proposed product would be unacceptable. However, as Dow pointed out, the acute inhalation toxicity of penoxsulam is relatively low, and the cited study was a liquid of high viscosity (like the proposed product). However, the cited study was given a toxicity III classification for acute inhalation based on the highest attainable aerosol concentration of 0.74mg/L. While we understand that Dow believes this is due to the physical limitations to the aerosol generation for this product, we will not override a previous Agency decision (awarding a toxicity 3 classification for this study) for a less protective toxicity 4 classification. EPA File Symbol 62719-LNE will receive a toxicity 3 classification for acute inhalation toxicity.

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The acute toxicity profile for EPA File Symbols 62719-LNE is as follows:

Acute oral toxicity	IV	Cited	MRID 45830813
Acute dermal toxicity	IV	Cited	MRID 45830816
Acute inhalation toxicity	III	Cited	MRID 45830819
Primary eye irritation	IV	Cited	MRID 45830821
Primary skin irritation	IV	Cited	MRID 45830824
Dermal sensitization	No	Cited	MRID 45830827

The precautionary labeling for EPA File Symbol 62719-LNE is as follows:

PRECAUTIONARY LABELING: (Note that the registrant has included some voluntary precautionary language on the label which is in *italics*, below)

Hazards to Humans and Domestic Animals

CAUTION

Harmful if inhaled. Avoid breathing spray mist. *Avoid contact with eyes or clothing.* Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and Handlers of this should wear:

Long-sleeve shirt and long pants

Shoes + Socks

FIRST AID

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: *Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center for treatment advice.*

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HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.