



Department of Pesticide Regulation



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MEMORANDUM

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HSM-04002

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[original signed by J. Goodbrod]

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SUBJECT: HOELON® 3EC LABEL EVALUATION (TRACKING ID NO. 202762)

Bayer Cropscience LP is requesting a Section 3 label amendment for their product “Hoelon® 3EC Herbicide” (Tracking ID No. 202762). This product was originally approved for Section 3 Registration in California on October 17, 2000 and is to be used to control a wide variety of annual grassy weeds in barley and wheat. Because of its intended agricultural uses, it is subject to Worker Protection Standard (WPS) label requirements under Title 40, Code of Federal Regulations, Part 170 (40 CFR 170). Application is permissible via both aerial and ground means as either a pre-plant, pre-emergent, or post-emergent herbicide. It is a restricted use pesticide consisting of 34.7% diclofop in an emulsifiable concentrate formulation.

A Reregistration Eligibility Decision (RED) for diclofop was completed by the U.S. Environmental Protection Agency (U.S. EPA) in September of 2000 and comments were accepted until February of 2001 (U.S. EPA, 2000). In the course of developing the RED, certain environmental and human health hazards associated with the use of products containing diclofop were identified. As a result, U.S. EPA proposed and adopted a list of measures intended to mitigate the risk of exposure to this pesticide by workers and handlers. The product label changes necessary to implement these mitigation measures are listed in Table 11 of the RED. The label amendments proposed by the registrant in this registration action consist of revised personal protective equipment (PPE) statements in order to be in compliance with the RED. The Registration Branch has requested that Worker Health and Safety (WHS) Branch review this proposed label amendment in order to determine whether or not the revisions to the PPE section are appropriate and acceptable. This registration action is being reviewed by only the WHS Branch. It has not been reviewed by the Medical Toxicology (MT) Branch.

On January 15, 2004, in an Evaluation Memorandum (tracking ID no. 202762) from you and I (Joe Frank and James Goodbrod) to Rachel Kubiak of the Registration Branch, WHS recommended against registration of the amended Hoelon® 3EC proposed label. This decision was due to the lack of an evaluation and review of the acute toxicity data and proposed label by MT, and as a consequence, the absence of an assignment of acute toxicity categories and a determination of dermal sensitization status.



According to Branch policy, WHS's recommendation for registration is contingent on the review and findings of the MT Branch. In assessing precautionary language on proposed pesticide labels, WHS relies on toxicity category designations of the formulated product as determined by the MT Branch. In the case of the subject product, a MT review and determination was not available. Having re-reviewed the Hoelon 3EC label, this time based on the acute toxicity categories assigned by the U.S. EPA in the RED for technical diclofop, WHS finds inconsistencies in label language.

According to the U.S. EPA's evaluation of the data, the acute toxicity categories for diclofop are as follows: **oral = II, dermal = III, inhalation = IV, primary eye irritation = III, and primary dermal irritation = IV** (U.S. EPA, RED Diclofop-Methyl, September, 2000. table 7b, p.28). Dermal sensitization data was inconclusive in that the Buehler test indicated a negative response and the guinea pig maximization test demonstrated moderate to severe sensitization.

Since MT has neither reviewed acute toxicity data nor assigned acute toxicity categories for this product, the best information available to WHS (for the purposes of this label review) is EPA's evaluation of the acute toxicity data in the diclofop RED. Although the acute toxicity data evaluated in the RED is for the active ingredient (diclofop), not the formulated product (Hoelon 3EC), WHS nevertheless considers this data and the acute toxicity category assignments (in the absence of an MT review) an adequate basis for its label review. The "Precautionary Statements" on the proposed label, normally reviewed by MT, are considered by WHS to be inconsistent with the RED-assigned acute toxicity categories (see table 1 in this memo) and inadequate for this product label.

Because WHS considers this deficiency in precautionary label language to pose a potential exposure issue and possible health concern, registration of the proposed label is not recommended. WHS recommends that the registrant refer to the table in 40 CFR 156.70 (c) and the EPA Label Review Manual 3rd Ed., Chapt. 7, Part III D for guidance on appropriate language for precautionary statements for each acute toxicity category designation and each route of exposure.

The signal word on the proposed label is "DANGER". This would constitute over-labeling, but would be adequate and acceptable to WHS, based on RED tox category designations. The word "POISON" and the "skull and crossbones" would not be required. All first aid statements are also appropriate and acceptable. The revised PPE statements are consistent and in compliance with the RED and acceptable to WHS. The WPS-required precautionary label language is also appropriate for a category II product and in compliance with the RED and 40 CFR Part 156 (subpart K) and Part 170. This includes the restricted entry interval (24 hrs), and early entry PPE. Dermal sensitization is not addressed in the "Precautionary Statements" but WHS

considers this potential exposure issue adequately mitigated by the required PPE on the label. The subject product contains petroleum distillates in the formulation and this hazard is appropriately identified and addressed in the “Ingredients” and “Note to the Physician” sections of the label.

In order for WHS to consider registration of this product label:

- 1) acute toxicity category designations for the formulated product must be assigned by MT, and, based on these categories, WHS will determine acceptability of the proposed label language, or;
- 2) if the toxicity categories assigned in the RED are to be used, the registrant must make appropriate revisions to the proposed label language.

Table 1: Hoelon® 3 EC, Proposed Label Precautionary Statements

Route of Exposure	Acute Toxicity Category for a.i. (from diclofop RED)	Precautionary Statement on Proposed Label	Required Precautionary Statement (40 CFR 156.70 (c))
Oral	II	Harmful if swallowed. Do not take internally. (under-labeled, unacceptable)	May be fatal if swallowed.
Dermal	III	Harmful if absorbed through skin. Do not get on skin or clothing. Avoid contact with spray mist. (adequate - acceptable)	Harmful if absorbed through skin. Avoid contact with skin or clothing.
Inhalation	IV	Avoid inhalation of spray mist (over-labeled –acceptable)	No precautionary statement required
Primary Dermal Irritation	III	Harmful if absorbed through skin. Do not get on skin or clothing. Avoid contact with spray mist. (adequate - acceptable)	Avoid contact with skin or clothing.
Primary Eye Irritation	IV	Corrosive. Causes irreversible eye damage. Do not get in eyes. (over-labeled - acceptable)	No precautionary statement required
Dermal sensitization	Buehler test – No Guinea pig maximization test - Moderate/severe	No statement addressing dermal sensitization present (may be under-labeled – data inconclusive)	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.