

SECTION 18s

General Guidance for Preparation of Use Directions/Labeling in Connection with Emergency Exemptions

INTRODUCTION

When the section 18 program was initiated, it was the practice that any directions for use as well as additional precautions or restrictions particular to an emergency exemption would be conveyed to the user by a copy of EPA's authorization letter. Recently many Applicants have submitted stand alone "labeling" for their emergency exemptions. These "labels" may contain a variety of components such as, the site to be treated, the application rate, and other basic use restrictions. Often these specially prepared section 18 "labels" are distributed to growers in lieu of or separate from the EPA authorization. EPA wants to ensure that all of the critical use conditions and necessary restrictions are captured in these section 18 labels, since the EPA authorization letter may not be distributed to growers. EPA has seen many section 18 labels that are inconsistent or incomplete as compared to the authorizing letter for the emergency program. Thus, this paper is intended to provide general guidance with respect to "labeling" in connection with emergency exemptions under section 18, as regulated in 40 CFR 166.

In most cases, the pesticide product authorized for use under an emergency exemption is already EPA-registered for other uses. It is understood in such cases that the product will be shipped bearing its EPA-accepted parent label. The special directions for use and any restrictions and precautions relating to the emergency exemption must be available to the user at the time of pesticide application. These directions for use, have increasingly been given by the states, in the form of additional section 18 "labeling". This practice is acceptable to EPA. Alternately, as in the past, the Applicant may distribute copies of the EPA emergency exemption authorization to growers. Either practice is permissible. (Please note that we do not intend to stamp as accepted any "labeling" in connection with a specific exemption.)

This guidance contains a sample section 18 label format, a general "Do" and "Don't" list for this topic, and a discussion about how to prepare a section 18 label for an unregistered chemical. In addition, to references specifically cited throughout this guidance, Applicants are advised to become familiar with PR Notice 2000-5, General Guidance for Mandatory and Advisory Labeling Statements, as well as guidance provided with respect to liability waivers under 24 (c) which has been provided upon request and is attached for your convenience.

Section 18 Labels for EPA Registered Products

In the case of an EPA registered product, it is the Applicant's option as to whether stand-alone section 18 use directions are prepared and distributed. Section 18 use information can be communicated to growers through either the authorizing letter prepared by EPA or separate section 18 use directions. **Either method is acceptable to EPA.**

If the Applicant chooses to use stand-alone section 18 use directions, a draft must be submitted with the application for an emergency exemption. In addition to other necessary data and information as specified in 40 CFR 166, the submission should consist of the following:

- the registered section 3 label + separate use directions for the 18

To follow is a sample format:

Sample format of use directions for a section 18

~Restricted Use Pesticide~ **“If required by EPA”**

These directions for use must be in the possession of the user at the time of application.

EMERGENCY EXEMPTION USE DIRECTIONS

STATE: **Name state(s) authorized**

CHEMICAL: **Chemical authorized
trade name**

CROP: **Site authorized**

PEST: **Pest authorized**

EFFECTIVE: **Effective Dates**

USE RATE: **Authorized Rate**

RESTRICTIONS: (Some examples follow)

- Do not make more than x applications or apply more than x ounces of product (x lb. a.i.) per acre per year.
- The Pre-harvest Interval (PHI) is xx days.
- **Trade Name** may be applied by ground equipment only.
- Applications should be made in xx gallons of water.
- Applications through any type of irrigation system (chemigation) are prohibited.

All Applicable Directions, Restrictions and Precautions on the Registered Product Label for Trade Name (EPA Registration Number xxx-xx) are to be Followed.

Any adverse effects resulting from the use of Trade Name under this emergency exemption must be immediately reported to the **Name Agency to which the exemption is authorized**

Company Name (Registrant)
Address

Note that the information in the above sample format relates directly to the emergency use. Agency resources have already been expended on the acceptance of the section 3 label(s), therefore, repetition and/or replication of wording appearing on the registered label, other than what is presented in the example format is not appropriate. Should an application be received with use directions that are significantly inconsistent with the sample format, the Applicant will be asked to resubmit the proposed section 18 use directions or distribute the EPA approval letter instead of separate use directions.

A significant new use pattern (food use for products with only non-food uses; tree use vs vegetable crop; etc) may require additional precautions/ restrictions (worker protection statements, environmental, etc.). Proposed precautions/restrictions should be included on the use directions submitted with the emergency exemption application.

Below is a list of “Do’s” and “Don’ts” for section 18 use directions.

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The following list summarizes the “**Do’s**” for emergency exemption use directions:

- **The Use Directions:** Include a copy of the draft use directions with the emergency exemption request. The Agency does not anticipate that any section 18 use directions need be longer than 2 pages, with 1 page being perfectly adequate in most cases.
- **The Use:** Make it **prominently** clear that the use is in connection with (an) emergency exemption(s) authorized under the provisions of section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.
- **The Effective Period:** **Prominently** state the effective period for the emergency exemption. Note in the case of crisis exemptions, if a specific exemption request has been submitted to EPA, state the intended use season. If only a crisis exemption will be submitted the use season is limited to 15 days (refer to 40 CFR 166.45(b)).
- **The State(s):** **Prominently** list the state(s) which has (have) been authorized the use.
- **The Product Name:** State the product name.
- **Placement of EPA Registration Number:** Only include the EPA registration number for the product parenthetically in a statement such as the following: “All applicable directions, restrictions, and precautions on the registered product label for Product X (EPA Reg. No. X-XX) are to be followed”.
- **Registrant Information:** List the name and address of the registrant.
- **Directions for Use:** State the directions for use authorized in the emergency exemption(s). This includes, but is not limited to, number of applications per season; pre-harvest interval (PHI), rate, and any restrictions/precautions specific to this use.

- **Statement of Possession:** Include a statement which indicates that the use directions must be in the possession of the user at the time of application.
- **Adverse Effects Statement:** State that any adverse effects resulting from the use of Product X under this emergency exemption must be immediately reported to the State of Y Department of Agriculture (or appropriate authorized Applicant).
- **Specificity of Language:** Remember only language specific to the emergency exemption should appear on the section 18 use directions.
- **Required Revisions:** Ensure that any changes or additional restrictions/precautions cited in EPA's emergency exemption authorization are added to the use directions.

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The following is a list of “Don’ts” for section 18 use directions:

- **Claims of Efficacy:** **Do not** include claims of efficacy not specified in the emergency exemption.
- **Placement of EPA Registration Number:** **Do not** place the EPA Reg. No. in such a way that gives the impression to the user that this is a registered use.
- **Specificity of Language:** Only include language specific to the emergency exemption on the section 18 use directions. **Do not** edit the current section 3 label by inserting the crop for which a section 18 is being requested. As noted above, the Agency does not anticipate the section 18 use directions will be any longer than 2 pages. If a modified section 3 label is submitted, the applicant will be asked to provide use directions in accordance to this guidance document or to use the EPA authorization as use directions. Including the parent section 3 label **along with** the section 18 use directions is acceptable.

Section 18 Labels for New Chemicals and Unregistered Products

Emergency exemptions for new chemicals and unregistered products are a special case. As we have communicated in the past, submission of emergency exemption requests for new chemicals is strongly discouraged. We have stressed the difficulty of processing these requests and setting tolerances if needed when a chemical's full toxicity data base has not been completely reviewed and an FQPA assessment has not been completed. In this case, as well as in the case in which the Applicant proposes use of a new product formulation of a registered active ingredient, this Agency must review the section 18 label for inclusion/appropriateness of all language as required in 40 CFR Part 156. This is one of the factors that contributes to the difficulty in processing an emergency exemption application for an unregistered chemical in a time schedule that meets the growers' needs.

In those unusual cases where it may be possible for the Agency to grant an exemption for a new chemical/unregistered product, the Applicant is responsible for ensuring that full and complete labeling is attached to the product for shipping purposes and for use in accordance with the emergency exemption (refer also to 40 CFR 152.30(e)). Such labeling must be submitted with the request to EPA for evaluation and authorization prior to use. A detailed program outlining the plans for the return of unused/unopened material to the manufacturer and/or other disposition of unused material should also be provided by the Applicant at the time the request is submitted.

Please refer to the EPA Label Review Manual for a sample format.

Requirements for Section 18 Labels for Unregistered Chemicals:

- **Compliance with 40 CFR Part 156:** The labeling which will be used in connection with an emergency exemption for a product which is not registered by EPA must comply with 40 CFR Part 156, as specified in **40 CFR 152.30(e)**.
- **Shipping the Product:** Complete labeling must accompany all shipments of the product.
- **Emergency Exemption Statement:** A statement indicating that the use is in connection with an emergency exemption(s) authorized under the provisions of section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, must be included.
- **Exact Authorized Use:** A statement reflecting the exact authorized use of the emergency exemption, such as "For control of pest X on crop Y" must **prominently** appear.
- **Unused Product:** Include a statement which indicates that any unused, unregistered product must either be returned to the manufacturer or distributor (unopened

containers) or disposed of in accordance with Resource Conservation and Recovery Act regulations following the expiration of the emergency exemption.

- **Use Period:** The effective period for the emergency exemption must be given, unless the EPA authorization will also be distributed to users. Should subsequent exemptions be authorized this could be stickered over with the new use period/yr.
- **Method of Disposal:** The method of disposal must appear on the label.
- **Claims of Efficacy:** Any claims of efficacy not specified in the emergency exemption may **not** be included on the label.
- **Required Revisions:** Ensure that any changes or additional restrictions/precautions cited in EPA's emergency exemption authorization are added to the use directions.

Other:

- **Authorized States:** The state(s) which has (have) been authorized the use and the emergency exemption number(s) are encouraged to be listed but are not required.

Attachment Referenced on Page 1: Sample Liability Waiver under Section 24(c)

MANUFACTURER'S SPECIAL CONDITIONS AND DISCLAIMER FOR USE OF
DESSICATOR ON DRY BULB ONIONS.

NKAMBE, INC. INTENDS THAT SECTION 24(c) LABEL BE DISTRIBUTED ONLY BY THE NDU ONION ASSOCIATION (NOA) ONLY TO END USERS AND/OR GROWERS WHO AGREE IN WRITING TO THE TERMS AND CONDITIONS REQUIRED BY THE NOA INCLUDING A WAIVER AND RELEASE FROM ALL LIABILITY AND INDEMNIFICATION BY THE USER AND/OR GROWER OF NKAMBE, NOA, AND OTHERS FOR FAILURE TO PERFORM AND CROP DAMAGE FROM USE OF DESSICATOR ON DRY BULB ONIONS. IF SUCH TERMS AND CONDITIONS ARE UNACCEPTABLE, RETURN DESSICATOR AT ONCE UNOPENED.

THIS PRODUCT WHEN USED ON DRY BULB ONIONS MAY LEAD TO CROP INJURY, LOSS, OR DAMAGE. NKAMBE RECOMMENDS THAT THE USER AND/OR GROWER TEST THIS PRODUCT IN ORDER TO DETERMINE ITS SUITABILITY FOR SUCH INTENDED USE. THE NDU ONION ASSOCIATION AND NKAMBE MAKE THE PRODUCT AVAILABLE TO THE USER AND/OR GROWER SOLELY TO THE EXTENT THE BENEFIT AND UTILITY, IN THE SOLE OPINION OF THE USER AND/OR GROWER OUTWEIGH THE EXTENT OF POTENTIAL INJURY ASSOCIATED WITH THE USE OF THIS PRODUCT. THE DECISION TO USE OR NOT USE THIS PRODUCT MUST BE MADE BY EACH INDIVIDUAL USER AND/OR GROWER ON THE BASIS OF POSSIBLE CROP INJURY FROM DESSICATOR, THE SEVERITY OF WEED INFESTATION, THE COST OF ALTERNATE WEED CONTROLS, AND OTHER FACTORS. BECAUSE OF THE RISK OF CROP DAMAGE, ALL SUCH USE IS AT USER'S AND/OR GROWER'S RISK.

The indemnification statement MAY NOT require a user to be a member of the Ndu Onion Growers Association.

The following type of statements is unacceptable:

Neither the Ndu Onion Growers Association nor the manufacture, Nkambe, Inc., recommended the use of Dessicator on Dry Bulb Onions because of the risk of crop damage.