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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (Seventh session, 14-16 July 2004, agenda item 3,a)

DEVELOPMENT OF GUIDANCE FOR IMPLEMENTATION

Precautionary Statements: Recent Experience Updating First Aid Statements on Pesticide Labels

Transmitted by the expert from the United States of America

In 2001, the U.S. Environmental Protection Agency (EPA) updated guidance regarding the format and content of first aid statements on all pesticide product labels. The guidance provided what EPA believes to be the most up-to-date, appropriate, and effective first aid language for pesticide product labels to ensure that they continue to adequately protect the public. The changes were required to be made by October 1, 2003.

BACKGROUND

EPA's regulations (40 CFR 156.10 (h)(iii)) require that pesticide products be labeled with first aid statements which provide important information concerning appropriate first aid response in the event of accidental exposure to a pesticide. First aid statements generally provide the initial first steps to take when accidental exposure occurs and may inform physicians and emergency responders of appropriate medical procedures for victims of poisoning.

First aid statements should be easy for all readers understand and include distinctions in treatment for children vs. adults, when appropriate. EPA's Precautionary Statements guidance provides generic first aid statements applicable to most all pesticide products. However, these statements may not always be medically appropriate for a particular product. There are situations where unique acute effects are identified that necessitate additions to the standard precautionary statements or changes to the generic first aid statements. For example, if a product is a cholinesterase inhibitor, or other class of pesticide, EPA may require an additional statement in the first aid section identifying the product as such. If the product contains an organophosphate (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the following phrase should be included in the first aid statement:

"Contains an (either organophosphate or N-methyl carbamate) that inhibits cholinesterase."

CHANGES RECOMMENDED BY THE CONSUMER LABELING INITIATIVE

In early 1996, EPA's Office of Pesticide Programs (OPP) began updating its standard first aid statements with the intention that the statements be easier to understand and medically up-to-date. At about the same time, EPA also began a Consumer Labeling Initiative (CLI), which had as its goal the

improvement of pesticide labels on consumer products. In the first phase of the CLI, interviews were conducted with users of household pesticides and non-pesticide products used to clean hard surfaces. Information from the interviews can be found in EPA's CLI Phase I Report, EPA-700-R-96-001, September 1996. Consumers indicated that the phrase "first aid" was easier to understand than "Statement of Practical Treatment" then required on pesticide labels. Further, stakeholders indicated that first aid information needs to be technically accurate. The CLI recommended that EPA encourage registrants voluntarily to use the term "first aid" in place of the term "Statement of Practical Treatment."

CURRENT GUIDANCE

Draft new first aid statements, which EPA believed to be clearer and more accurate, were shown to consumers in the summer of 1997 as part of the CLI consumer research. As a result of those interviews, additional changes were made. The revised statements were then reviewed by, among others, the American Red Cross, the American Association of Poison Control Centers, the Pesticide Program Dialogue Committee, and the Consumer Product Safety Commission. Many of those organizations provided suggestions which were incorporated. In the summer of 1998, EPA sponsored research on consumer's reactions to different formats for pesticide labels. For information on the research, see the CLI Phase II Report, EPA-742-R-99-004, October 1999. This research indicated that consumers clearly preferred important information, such as first aid statements, be placed within a box which sets that text apart from the rest of the label. The consumers interviewed also preferred that information not be presented in a narrative format, but rather be shown as brief statements, individually marked with a symbol such as a hyphen or other type "bullet" along the left margin. In addition, EPA urged that pesticide labels include an appropriate toll-free phone number to be contacted in case of a medical emergency near the

first aid statements.

Since first aid statements are intended to provide vital information to pesticide users, physicians, and emergency response personnel, EPA called for pesticide labels to be updated to reflect changes in medical procedures and treatment. Updated first aid statements (i.e., specific time frames and removing directions to induce vomiting) were provided to EPA by poison control centers and the medical community for use in updating the first aid statements.

To improve comprehension by consumers and medical personnel, EPA provided examples of what it believes to be the most up to date and appropriate first aid statements. The statements for each route of exposure (oral, dermal, inhalation, and eye) are the same for EPA's current toxicity categories I-III for acute toxicity and eye and skin corrosion/irritation because EPA concluded that the same immediate responses to exposure would be appropriate. These standard first aid statements are expected to be used unless they are medically incorrect for a specific product.

EPA determined that product labels should direct the user to call a poison control center when there is an incident. Poison control centers in the United States are more likely to have information on effective treatment for pesticide exposures. EPA expects the phrase "Call a poison control center or doctor immediately for treatment advice" to appear as the first line in the statements for the ingestion route of exposure. However, for the other routes of exposure, the phrase should be placed in one of the following three locations in the first aid statements:

- 1. at the top;
- 2. at the end; or,
- 3. for each route of exposure.

(Note: The word "immediately" may be deleted for all routes of exposure except for ingestion.)

Today among the emergency response community, inducing vomiting, as a standard first aid instruction, is no longer universally recommended. For some chemicals, inducing vomiting may actually be harmful. From the information gathered from the U.S. poison control centers and the medical community, the following examples are instances where vomiting especially should <u>not</u> be induced, unless advised to do so by a poison control center or doctor:

- 1) pesticides containing zinc phosphide;
- 2) pesticide products which are corrosive (pH \leq 2 or \geq 11.5); and,
- 3) products containing $\geq 10\%$ petroleum distillates.

The need to induce vomiting for products having any of these characteristics should be weighed against the potential danger of doing so. If necessary, the poison control center will tell the person calling how to induce vomiting; the label need not do so.

Regarding contact lenses, lens wearers are instructed to first rinse eyes with water, remove contact lenses, and then continue to rinse eyes. Several organizations and doctors commented that it is preferable to reduce the amount of contaminant first, then remove the contacts, and then rinse more thoroughly. In some cases of exposure, the eye muscles tend to hold the eye shut, so removing contacts first may not actually be possible. In EPA's revised language, the words "hold eye open" are included to reduce consumer confusion.

IMPLEMENTATION

U.S. EPA issued the PESTICIDE REGISTRATION (PR) NOTICE 2001-1 regarding changing First Aid statements on pesticide labels on January 2, 2001. Companies had until October 1, 2003 to change their labels. They were given specific instructions as to how to comply in the PR Notice. Label changes required submission and processing of an amendment to the registration. Companies could not allow labels with the new First Aid statements to enter channels of trade until they received the acceptance of their amendment from the U.S. EPA.

REFERENCE

EPA's guidance for the use of first aid response statements on pesticide labels and examples are found in the document, "PESTICIDE REGISTRATION (PR) NOTICE 2001-1" which is located on the OPP Website at: http://www.epa.gov/PR_Notices/

Annex I provides a comparison of the EPA statements with the statements in ST/SG/AC.10/2004/8.

ANNEX I

SAMPLE COMPARISONS OF FIRST AID PRECAUTIONARY STATEMENTS

US EPA Pesticide Precautionary Statements: First Aid	GHS Precautionary Statements ("Response")
General information to include either near the first aid statement or emergency phone number: Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
Acute Toxicity (Oral)	Acute Toxicity (Oral)
EPA/OPP Categories I-III (oral LD_{50} up to 5000mg/kg) If swallowed: -Call a poison control center or doctor immediately for treatment adviceHave person sip a glass of water if able to swallowDo not induce vomiting unless told to by a poison control center or doctorDo not give anything to an unconscious person. Category IV No statements required. However, the registrant may choose to use categories I- III statements.	Categories 1-2 IF SWALLOWED: Immediately call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible. Induce vomiting (if conscious). [If knowledge of the chemical indicates this action is not contraindicated.] Give water/nothing to drink. Give a slurry of activated charcoal. [If ingestion of a solid water soluble substance.] Category 3 IF SWALLOWED: Immediately call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible. Give water/nothing to drink. Induce vomiting (if conscious). [If knowledge of the chemical indicates this action is not contraindicated.] Category 4 IF SWALLOWED: Immediately call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible. Give water/nothing to drink. Category 5 Call a Poison Control Center/doctor/physician if you feel unwell. Show container/label/Safety Data Sheet when possible.

US EPA/OPP Acute Toxicity (Dermal)

EPA/OPP Categories I-III (LD 50 up to 5000 mg/kg)

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

Category IV

Statement is not required. Registrants may use toxicity category I-III statements if they choose.

GHS Acute Toxicity (Dermal)

Categories 1-2

IF ON SKIN: Wash with plenty of soap and water/appropriate cleansing agent specified by the manufacturer. Remove/Take off immediately all contaminated clothing. Call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible. Wash/Decontaminate removed clothing before reuse.

Category 3

IF ON SKIN: Wash with plenty of soap and water/appropriate cleansing agent specified by the manufacturer. Remove/Take off immediately all contaminated clothing. Call a Poison Control Center/doctor/physician if you feel unwell. Wash/Decontaminate removed clothing before reuse.

Category 4

IF ON SKIN: Wash with plenty of soap and water/appropriate cleansing agent specified by the manufacturer. Call a Poison Control Center/doctor/physician if you feel unwell. Show container/label/Safety Data Sheet when possible. Wash contaminated clothing before reuse.

Category 5

Call a Poison Control Center/doctor/physician if you feel unwell.

US EPA/OPP Acute Toxicity (Inhalation)

EPA/OPP Categories I-III (LC 50 up to 2 mg/l)

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.

Category IV

Statement is not required. Registrants may use toxicity category I-III statements if they choose.

GHS Acute Toxicity (Inhalation)

Categories 1-2

IF INHALED: Remove victim to fresh air and keep at rest. Keep in half-upright position if breathing is difficult. Immediately call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible.

Category 3

IF INHALED: Remove to fresh air and keep at rest. Keep in half-upright position if breathing is difficult. Immediately call a Poison Control Center/doctor/physician. Show container/label/ Safety Data Sheet when possible.

Category 4

IF INHALED: Remove to fresh air and keep at rest. Keep in half-upright position if breathing is difficult. Call a Poison Control Center/doctor/physician. Show container/label/ Safety Data Sheet when possible.

Category 5

Call a Poison Control Center/doctor/physician if you feel unwell. Show container/label/Safety Data Sheet when possible.

US EPA/OPP Eye Corrosion/Irritation

<u>Categories I-III (from corrosion to corneal involvement or irritation clearing within 7 days or less)</u>

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

<u>Category IV (minimal effects clearing within 24 hours)</u>

Statement is not required. Registrants may use toxicity Category I-III-3 statements if they choose.

GHS Eye Damage/Irritation

Category 1

IF IN EYES: Hold eyes open and rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a Poison Control Center/doctor/physician. Show container/label/Safety Data Sheet when possible.

Category 2A

IF IN EYES: Hold eyes open and rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Show container/label/Safety Data Sheet when possible.

Category 2B

IF IN EYES: Hold eyes open and rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Show container/label/Safety Data Sheet when possible.

US EPA/OPP Skin Corrosion/Irritation

<u>EPA/OPP Categories I-III (corrosion up to moderate irritation at 72 hours)</u>

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

Category IV (mild or slight irritation at 72 hours)

Statement is not required. Registrants may use toxicity Category I-III statements if they choose.

GHS Skin Corrosion/Irritation

Category 1 A-C

IF ON SKIN: Remove/Take off immediately all contaminated clothing under the shower and wash skin with plenty of soap and water/other cleansing agent specified by the manufacturer.

IF IN EYES: Hold eyes open and rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF SWALLOWED: Rinse mouth. Do not induce vomiting.

IF INHALED: Remove to fresh air. Keep at rest in half-upright position if breathing is difficult.

Call a Poison Control Center/ doctor/ physician. Show container/label/ Safety Data Sheet when possible.

Category 2

IF ON SKIN: Wash with plenty of soap and water/other cleansing agent specified by the manufacturer. If skin irritation occurs, seek medical advice/attention. Show container/label/Safety Data Sheet when possible.

Category 3

If skin irritation occurs, seek medical advice/attention. Show container/label/Safety Data Sheet when possible.