US Environmental Protection Agency
Office of Pesticide Programs

Pesticide Registration (PR) Notice 2012-1
Material Safety Data Sheets as Pesticide Labeling

April 20, 2012

PESTICIDE REGISTRATION (PR) NOTICE 2012-1

April 9, 2012

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for the Registration of Pesticides

SUBJECT: Material Safety Data Sheets as Pesticide Labeling

I. Purpose and Applicability

This PR Notice updates and clarifies EPA's determination in PR Notice 92-4[1] that a Material Safety Data Sheet (MSDS) (also referred to as a Safety Data Sheet (SDS)) that accompanies a pesticide product is considered part of the pesticide's labeling but may accompany a pesticide product without notification to or approval by the Agency, provided such labeling is consistent with the 40 CFR Part 156 labeling requirements.

The Occupational Safety and Health Administration (OSHA) requires SDSs under its Hazard Communication Standard (HCS) (29 CFR 1910.1200) and is moving to align its HCS requirements with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA recently published its final rule[2], and will begin to accept SDSs that are prepared according to the final rule's requirements on May 25, 2012. EPA has not yet moved to amend its labeling regulations to reflect the GHS. There are differences between EPA's current requirements and the GHS related to classification criteria, hazard statements, pictograms, and signal words. Therefore, EPA is issuing this clarification of its policy in order to avoid potential inconsistencies between EPA-approved labels for pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the SDSs that OSHA requires for these chemicals under the HCS.

In brief, this guidance explains how registrants can ensure their FIFRA labeling and SDSs comply with both agencies' requirements.

While EPA recognizes that this guidance may require users of the SDS prepared for pesticide products to become familiar with two different systems, at least until the agencies' requirements are harmonized, it is necessary as an interim measure to ensure that the differences do not cause confusion and to provide regulated industry with a clear pathway to compliance with both agencies' requirements.

II. Effective Date

This guidance is effective immediately. At the time of issuing this PR Notice, however, EPA notes that final approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and OMB's regulations at 5 CFR part 1320, by the Office of Management and Budget (OMB) is pending for the information collection activities associated with the SDS as set out in the OSHA final rule. The OSHA

[1] PR Notice 92-4; Material Safety Data Sheets as Pesticide Labeling, October 9, 1992, available at http://www.epa.gov/PR_Notices/#1992.

[2] See 77 FR 17574-17896, March 26, 2012. More information regarding OSHA's HCS rulemaking can be found at http://www.osha.gov/dsg/hazcom/

Information Collection Request (ICR) is identified under OMB Control No. 1218-0072. Under the PRA, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it under the PRA, and the agency displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no employer can be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.

III. BACKGROUND

A. The GHS

The GHS is designed to provide a common and coherent approach to defining and classifying hazards and communicating hazard information on labels and safety data sheets. It is based on major existing systems for industrial chemicals, pesticides, consumer chemicals and chemicals in transport, but implementation of the GHS would require some changes in all existing systems in order to achieve harmonization. The primary goal of GHS is better protection of human health and the environment by providing chemical users and handlers with enhanced and consistent information on chemical hazards. The GHS includes standardized:

- hazard classification criteria for:
  - physical hazards (e.g., flammability);
  - human health hazards (e.g., acute toxicity (oral, dermal, inhalation)); and
  - environmental hazards (e.g., aquatic toxicity);

- hazard communication for:
  - label elements (pictograms, signal words, and hazard statements); and
  - SDS (format and content).

In addition, the GHS provides guidance on other label elements that should be included for a regulatory system to be considered consistent with the GHS, including product and supplier identifiers and additional precautionary statements. Lists of precautionary statements other than hazard statements are included in Annex 3 of the GHS, for use by competent authorities.

EPA, OSHA, the Department of Transportation, the Consumer Product Safety Commission, the State Department and other U.S. agencies participated in the development of the GHS, which was formally adopted by the UN Economic and Social Council in 2003.

To promote greater safety for workers exposed to chemicals on the job, OSHA has revised the HCS to be consistent with the international system.

B. Current Requirements: Relationship between Pesticide Product Labels and SDS

Generally, every pesticide sold or distributed in the United States must be registered by EPA (FIFRA § 12(a)(1)(A)). In granting a registration, EPA must determine that the pesticide's "labeling" complies with the requirements of FIFRA (FIFRA § 3(c)(5)(B)). In Section 2(p)(2)(A), FIFRA defines "labeling" to include all written, printed, or graphic matter accompanying the pesticide at any time. One of FIFRA's requirements for labeling is that it not be false or misleading in any particular. (See definition of "misbranding" in FIFRA § 2(q)(1)(A)).

EPA regards SDSs for pesticides to be labeling when they accompany the pesticide. PR Notice 92-4 (October 1992) explains EPA's policy to allow SDSs to accompany pesticides so long as they do not obscure or conflict with the labeling approved by EPA. Should an SDS conflict with the approved labeling, it could be misleading to users of the pesticide and therefore cause the pesticide to be considered misbranded and unlawful for sale or distribution. See FIFRA §§ 2(q)(1)(A) and 12(a)(1)(E).

EPA has promulgated by rule several requirements for hazard communication on FIFRA labeling. See, e.g. 40 CFR Part 156, Subpart D.

Under the authority of the Occupational Safety and Health Act, OSHA has established requirements for workplace chemical hazard communication programs in the Hazard Communication Standard (HCS, codified at 29 CFR 1910.1200). OSHA's HCS requires employers to have chemical hazard communication programs that include labeling, SDSs, and worker training. FIFRA labels approved by EPA pre-empt OSHA's label requirements, but not the requirements for SDS and worker training (except for certified applicators and agricultural workers for whom EPA has training requirements).

In the past, there was minimal potential for inconsistency since OSHA did not prescribe specific hazard statements, signal words, or pictograms. OSHA has long required information on hazards that do not generally appear on pesticide labels (e.g., for chronic health effects), and this additional information is not inconsistent with the FIFRA label. However, SDSs that would comply with OSHA's revised HCS/GHS requirements could be viewed as inconsistent with the FIFRA labeling since some of the label elements (e.g., pictogram(s), signal word(s), and/or hazard statement(s)) could differ for the same hazards. For example, the GHS uses only two signal words, "danger" and "warning," while current pesticide labels may also bear the signal word "caution" for less severe hazards. The label of a chemical that has an oral LD_{50} of 550 mg/kg would bear the signal word "caution" under current FIFRA labeling practices[3] but would require the signal word "warning" under the GHS.

C. Consequences of Conflicting Requirements

EPA recognizes that conflicts between:

(a) FIFRA labels and SDSs for the same chemicals, and
(b) FIFRA labels and the labels of other chemicals in the workplace,

could mislead workers about hazards, in some instances perhaps creating the impression that pesticides are less hazardous when they are not. Confusion due to inconsistent labeling could result in increased risks to workers. The potential problem may be greatest in the pesticide manufacturing workplace, but workers and others also receive SDSs in other settings and may be confused about differing hazard information.

In addition, as pointed out by commenters on the OSHA proposed rule, it is important that the agencies implement coordinated approaches to regulation, so that regulated industry has a clear pathway to be in compliance with both agencies' requirements. Otherwise, SDSs prepared in compliance with the revised OSHA HCS might be subject to regulatory or enforcement action for misbranding under FIFRA.

[3]Environmental Protection Agency, Label Review Manual, Chapter 7: Precautionary Statements, http:/www.epa.gov/oppfead1/labeling/lrm

D. Stakeholder Concerns about Potential Inconsistencies

CropLife America (CLA) and the American Chemistry Council's (ACC's) Biocides Panel submitted comments to OSHA's proposed rule docket (OSHA-H022K-2006-0062) and testified at OSHA's March 2010 hearings urging that OSHA and EPA coordinate their approaches and that pesticides be exempted from the OSHA rule, at least until EPA updates its regulatory requirements to be consistent with the GHS. EPA and OSHA worked together to develop the guidance in this PR Notice to address these commenters' concerns.

E. Implementation Dates for OSHA Final Rule

The recently published OSHA final rule revising the HCS provides transition periods for employers, distributors, manufacturers and importers to come into compliance with the final rule after it comes into effect. Manufacturers and importers have until June 1, 2015 to come into compliance with the new SDS requirements.

IV. GUIDANCE

This PR Notice is intended to aid registrants in assuring that the SDSs for their products should not be considered inconsistent with the EPA-approved product labels by providing guidance on how a registrant may reconcile an SDS with its associated FIFRA label, as stated below.

EPA believes that generally explaining why the FIFRA label and the SDS contain different hazard communication will prevent users from being misled by the inconsistencies. To provide an adequate explanation so the labeling is not misleading, EPA recommends registrants include in their SDSs the FIFRA label information and a brief explanation for any differences between that information and the SDS information. Section 15 of the SDS ("Regulatory Information") is an appropriate place to insert this information.

Sample text that may be used to explain the differences between the SDS and FIFRA is contained in Unit III of this PR Notice.

V. IMPLEMENTATION

To follow the recommendation above, registrants should reprint the FIFRA hazard statements (e.g., "fatal if swallowed"), signal word, and symbol (if required) in Section 15 ("Regulatory Information") of the SDS. Other elements of the FIFRA label, such as directions for use, should not be included. The following statement may be used to introduce the FIFRA hazard information and explain the differences between the HCS and FIFRA classification and labeling systems.

> This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use. [Insert FIFRA label hazard information]

Examples of how this could be accomplished are included in the Attachment to this PR Notice.

The GHS provides that precautionary statements (in addition to the standardized label elements, as described in Unit I) should be included on the SDS. While the GHS does not prescribe these precautionary statements, it does contain examples of such statements that a competent authority may use and lists them in Annex 3 of the GHS document. OSHA's revised HCS would require SDSs to contain the GHS Annex 3 statements, but also provides flexibility in meeting this requirement so as to avoid inappropriate or unnecessarily redundant statements and allow for additional statements where appropriate and consistent with the GHS. EPA has reviewed the statements in Annex 3 of the GHS and generally believes that problems will not arise due to inconsistencies between the FIFRA precautionary statements (beyond the signal word and hazard statement) and those that would be required by OSHA under the revised HCS. Therefore, it would not be necessary to reprint these other FIFRA label statements (such as first aid statements, for example) in Section 15 of the SDS.

If the FIFRA label includes information on hazards not required to be included in the SDS, (e.g., a hazard statement based on toxicity to fish), EPA recommends that this information be included in Section 15 or, for ecological hazards, Section 12 of the SDS.

OSHA indicates that it does not enforce information requirements for Sections 12 through 15 of the SDS format specified by the GHS and the revised HCS, since those sections are not under OSHA's jurisdiction. These sections cover Ecological information (Section 12), Disposal considerations (Section 13), Transport information (Section 14) and Regulatory information (Section 15).

SDS preparers may include the relevant information in these sections voluntarily, for example, to achieve greater harmonization with the SDS requirements of other jurisdictions. To the extent that the SDS text covers information that is also included on the FIFRA label (e.g., with respect to disposal considerations), the information presented should be consistent with the FIFRA label. As noted above, Section 15 would be an appropriate place to include the FIFRA label hazard information that corresponds to the standardized hazard identification elements of the HCS (as revised to be consistent with the GHS), in order to avoid potential confusion due to differences between the SDS and FIFRA label. Information on ecological hazards could be included in Section 12 or Section 15. Disposal information in Section 13 should be consistent with the disposal instructions included on the FIFRA label.

VI. SCOPE OF THIS PR NOTICE

The PR Notice provides general guidance to EPA and to pesticide registrants and applicants, and the public. This guidance is not binding on either EPA or any outside parties, and the EPA may depart from the guidance where circumstances warrant and without prior notice. Registrants may propose alternative approaches to the recommendations in this PR Notice, and the Agency will assess them for appropriateness on a case-by-case basis and will respond in writing if requested.

VII. PAPERWORK REDUCTION ACT NOTICE

The information collection activities associated with revising an SDS as prescribed by the OSHA final rule are addressed in the analyses accompanying the OSHA final rule. At the time of OSHA's proposed rule, OSHA prepared an information collection request (ICR) that revised the existing Hazard

Communication ICR, which is identified under OMB Control No. 1218-0072. The approach provided in the EPA guidance for pesticide registrants, however, was not considered by OSHA at the proposed rule stage, and is therefore not captured specifically by the ICR that was prepared for the final rule.

The guidance presented in this PR Notice affects the information collection activities addressed in the OSHA final rule related ICR revision because this PR Notice describes how pesticide registrants can ensure they comply with both agencies' requirements when they prepare the SDS as required by the OSHA final rule. Specifically, this PR Notice provides guidance on what could be included in the SDS in terms of draft explanatory text and the use of FIFRA hazard information as available on the EPA-approved label of the registered product. Although using the approach identified in this PR Notice is entirely optional, EPA recognizes that the approach involves an information collection activity covered by the PRA. As such, EPA and OSHA are collaborating on a subsequent revision to OSHA's ICR to ensure that it addresses the activities in the EPA guidance. EPA intends to solicit public comment on an ICR revision that addresses the information collection activities and related burden estimates associated with the EPA guidance as part of its release of that guidance. After public comments are considered by both agencies, OSHA intends to ask OMB to revise its ICR approval, identified under OMB Control No. 1218-0072, to capture the information collection activities and burden adjustments, if any, related to EPA's guidance. OSHA will publish a separate notice in the **Federal Register** that will announce the result of OMB's reviews.

VIII. FOR FURTHER INFORMATION CONTACT

If you have questions or need further assistance with regard to the guidance presented in this PR Notice, please contact Mary Frances Lowe of the Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (703) 305-5689; fax number: (703) 308-2962; e-mail address: *lowe.maryfrances@epa.gov*.

IX. SIGNATURE

Director, Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

Date: 4/9/12

Attachment

Attachments to PR Notice 2012-1

This Attachment presents two hypothetical examples of how Section 15 of the SDS could be revised in accordance with this PR Notice.

For each example, there is a table that provides information on the data used for classification, and the expected resulting classification categories, pictogram, signal word, and hazard statement under current FIFRA policies and under the revised OSHA HCS. The table would not appear in the SDS and is provided in the example as background information.

The hazard information in the third column of the table in each example would be presented in Section 2 of the revised SDS. The FIFRA information that could be inserted into Section 15 of the SDS is presented below the table in each example.

EXAMPLE #1

Hazard Data	FIFRA Classification/Typical Hazard Labeling, as outlined in EPA Label Review Manual	OSHA HCS Requirement for Section 2 of SDS
Signal Word[4]	WARNING	DANGER
Acute toxicity, oral LD_{50} 200 mg/kg	(Category II) May be fatal if swallowed	(Category 3) Skull and crossbones Toxic if swallowed
Acute toxicity, dermal LD_{50}1500 mg/kg	(Category II) May be fatal if absorbed through skin	(Category 4) Harmful in contact with skin
Acute toxicity, inhalation LC_{50} 1.5 mg/l (dust/mist)	(Category III) Harmful if inhaled	(Category 4) Harmful if inhaled
Skin irritation/corrosion—severe erythema or edema at 72 hrs	(Category II) Causes skin irritation	(Category 2) Causes skin irritation
Serious eye damage/eye irritation—irritant, clearing in 8-21 days	(Category II) Causes substantial but temporary eye injury	(Category 2A) Causes serious eye irritation
Sensitization	Not classified (NC)	Not classified (NC)
Germ cell mutagenicity	Not labeled (NL)	NC
Carcinogenicity	NL	NC
Reproductive/developmental toxicity	NL	NC
Specific target organ toxicity, single exposure	NL	NC
Specific target organ toxicity, repeated exposure	NL	NC
Aspiration hazard	NL	NC
Environmental (aquatic) toxicity, acute. documented fish kills, $LC_{50} \leq$ 1ppm	This pesticide is extremely toxic to fish	Not within OSHA's jurisdiction, therefore not required on SDS. Optional GHS aquatic toxicity symbol and hazard statement: Very toxic to aquatic life

FIFRA information for SDS Section 15 (Regulatory Information)

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

WARNING
May be fatal if swallowed or if absorbed through skin
Harmful if inhaled.
Causes skin irritation
Causes substantial but temporary eye injury

This pesticide is extremely toxic to fish[5]

[4] Both the current EPA FIFRA and OSHA HCS requirements specify that only one signal word should appear, and that the signal word should be determined based on the most severe classification category,

[5] If the SDS preparer voluntarily chooses to include information on environmental toxicity in the SDS, this statement could be included in SDS Section 12, Ecological information, or in Section 15.

EXAMPLE #2

Hazard Data	FIFRA Classification/Typical Hazard Labeling, as outlined in EPA Label Review Manual	OSHA HCS Requirement Section 2 of the SDS
Signal word	WARNING	DANGER
Acute toxicity, oral LD_{50} 350 mg/kg	(Category II) May be fatal if swallowed	(Category 4) Exclamation Mark Harmful if swallowed
Acute toxicity, dermal LD_{50}3000 mg/kg	(Category II) Harmful if absorbed through skin	Not classified (NC)[6]
Acute toxicity, inhalation –not toxic at limit dose tested	(Category IV) No required hazard labeling	NC
Skin irritation/corrosion—moderate irritation/erythema at 72 hrs	(Category III) No hazard statement	NC[7]
Serious eye damage/eye irritation—irritant, clearing in 8-21 days	(Category II) Causes substantial but temporary eye injury	(Category 2A) Exclamation mark Causes serious eye irritation
Sensitization	(Skin sensitizer) Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals	(Category 1 Skin sensitizer) May cause an allergic skin reaction
Germ cell mutagenicity	Not labeled (NL)	NC
Carcinogenicity	NL	NC
Reproductive/developmental toxicity—effects on lactation (data show likelihood of toxic levels in breast milk)	NL	May cause harm to breast-fed children
Specific target organ toxicity, single exposure (containing $\geq$ 4% methanol)	POISON Skull and crossbones Methanol may cause blindness	(Category 1) Health hazard symbol Causes damage to eyes
Specific target organ toxicity, repeated exposure	NL	NC
Aspiration hazard	NL	NC
Environmental (aquatic) toxicity, acute LC_{50} > 1mg/but $\leq$ 10 mg/l	NL	Not within OSHA's jurisdiction and therefore not required on SDS—Optional GHS hazard statement: Toxic to aquatic life

FIFRA information for SDS Section 15 (Regulatory Information)

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

POISON
Skull and crossbones
WARNING

[6] The GHS classification would be Category 5, (May be harmful in contact with skin). OSHA did not adopt this category/building block of the GHS and therefore it would not be required to be included on the label or the SDS.
[7] The GHS classification would be Category 3, (Causes mild skin irritation). OSHA did not adopt this building block and therefore it would not be required to be included on the label or the SDS.

May be fatal if swallowed
Harmful if absorbed through skin
Causes substantial but temporary eye injury
Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals
Methanol may cause blindness