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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 168

[EPA-HQ-OPP-2009-0607; FRL-9360-8]

RIN 2070-AJ53

Labeling of Pesticide Products and Devices for Export; Clarification of Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revising the regulations on the labeling of pesticide products and devices intended solely for export. Specifically, EPA is restructuring the current regulations to clarify which provisions apply under various circumstances. EPA is also increasing specificity in the regulations by requiring that people who transfer unregistered pesticide products between registered establishments operated by the same producer within the United States must also comply with the requirements of this part if those products are intended solely for export at the time of such transfer. EPA believes that this requirement is necessary to ensure appropriate handling of such products as they move in commerce before they actually leave the United States.

DATES: This final rule is effective [*insert date 60 days after date of publication in the Federal Register*]. The compliance date for the requirement to label unregistered pesticide products

intended solely for export that are being shipped between registered establishments operated by the same producer is January 21, 2014.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2009-0607, is available either at <http://www.regulations.gov>, or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What Action is the Agency Taking?

The Agency is revising the regulations on the labeling of pesticide products and devices intended solely for export. The revisions will clarify the labeling requirements and assist in compliance. Unregistered pesticide products that are intended solely for export but that are shipped between registered establishments in the United States operated by the same producer under 40 CFR 152.30(a) must comply with the labeling requirements in 40 CFR part 168.

B. What is the Agency's Authority for taking this Action?

EPA is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., to regulate the sale, distribution, and use of pesticide products and devices through a licensing (registration) scheme. This action is issued under the authority of section 25(a) of FIFRA, 7 U.S.C. 136w(a), to carry out the provisions of section 17(a) of FIFRA, 7 U.S.C. 136o(a).

In addition, because it is recognized that regulations written in a clear and easily readable style can save time and effort for the federal government and for persons affected by the regulation, agencies are specifically directed to use plain language in writing or revising regulations. For example, Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), says that regulations must be "simple and easy to understand, with the goal of minimizing uncertainty and litigation..." (Sec. 1, Par. (b)(12)). Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996), requires agencies that are reviewing existing regulations take the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The Plain Writing Act of 2010, 5 U.S.C. 301 note, requires Federal agencies to use "clear government communication that the public can understand and use." Executive Order 13563, entitled *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011), states that "[our regulatory system] must ensure that regulations are accessible, consistent, written in plain language, and easy to understand."

C. Does this Action Apply to Me?

You may be potentially affected by this action if you export a pesticide product, a pesticide device, or an active ingredient used in producing a pesticide. The inclusion of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document might apply to them. Potentially affected entities may include, but are not limited to: Pesticide and other agricultural chemical manufacturing (NAICS code 325320), e.g., Pesticides manufacturing, Insecticides manufacturing, Herbicides manufacturing, Fungicides manufacturing, etc.

D. What are the Incremental Costs and Benefits of this Action?

EPA did not quantify the potential costs or benefits from these revisions, which are qualitatively discussed in this unit. EPA has determined that there are minimal costs for industry to comply with the requirement that the unregistered pesticide product or device intended solely for export that is shipped between registered establishments operated by the same producer must be labeled in compliance with 40 CFR part 168, particularly the required statement “Not Registered for Use in the United States.” This determination was made given that most of the labeling requirements for export pesticide products already appear in other existing requirements, and the burden of adding the additional statement to unregistered products or devices intended solely for export that are shipped between registered establishments operated by the same producer would be negligible. EPA believes that this labeling change may be easily accomplished using commonly available word processing software; in addition, this label change does not require label submission to or approval by EPA, and shall be phased in as part of normal business operations. As such, EPA has concluded that the per firm and industry level impact of the rule is not significant.

Benefits are derived from the additional protection of public health and the environment that may result from ensuring appropriate handling of such unregistered pesticide products as they move in commerce before they actually leave the United States. Requiring that unregistered pesticide products and devices intended solely for export that are shipped between

establishments operated by the same producer be labeled according to the current regulations in §168.65, prevents them from inadvertently entering the U.S. market and provides compliance assistance. This requirement further protects public health and the environment by ensuring safe and appropriate handling of such products as they move in commerce before they actually leave the United States.

II. Background

A. Summary of the Proposed Rule

EPA published a notice in the **Federal Register** of April 6, 2011 (76 FR 18995) proposing to revise the regulations on labeling of pesticide products and devices intended solely for export. EPA proposed to include a specific indication that these requirements also apply to unregistered pesticide products intended solely for export when they are shipped between registered establishments in the United States operated by the same producer according to 40 CFR 152.30(a) before they are actually exported from the United States.

B. Public Comments on the Proposed Rule

EPA has considered the comments received on the proposed rule, and provided responses in a Response to Comments document, which is available in the docket for this rule under document ID No. EPA-HQ-OPP-2009-0607-0015. Only the key comments and the Agency's responses are discussed in this rule.

1. *Labeling terms.* Commenters called attention to inconsistencies in the use of the terms “label,” “labeling,” and “supplemental labeling” in the proposed regulations. EPA has revised the regulatory text according to the definitions of these terms in FIFRA section 2(p) to eliminate the inconsistencies.

2. *Foreign language labeling.* Commenters indicated that the proposed regulations addressing foreign languages on labeling did not explicitly allow for an exception when the predominant or official language of the importing country is English. The regulatory text has been revised so that labeling text is only required to appear in a foreign language if English is not the predominant or official language in the importing country, as well as the country of final destination, if known.

3. *Formulation modifications.* One commenter supported EPA's proposal to remove the list of formulation modifications and allow a broader range of changes that can be made to a registered pesticide product intended solely for export while it may still be considered to be "registered" for purposes of section 17(a) of FIFRA, i.e. any changes that are permitted under notification or non-notification. The Pesticide Registration Manual and the Pesticide Registration Notice 98-10 provide more information and guidance on the permitted changes.

4. *Human hazard and precautionary statements.* One commenter disagreed with the use of "appropriate" and "inappropriate" in the description of the statements; EPA had selected those terms because a literal translation of the U.S. human health and precautionary statements might not convey the correct level of caution in the importing country. EPA has revised the regulatory text to require "true and accurate" translations of the English statements in the human hazard and precautionary statements.

5. *Amplification of the phrase "Not Registered for Use in the United States."* Several commenters assumed that amplification of the phrase was required and maintained such amplification was not necessary. EPA agrees that the phrase "Not Registered for Use in the United States," a FIFRA requirement for unregistered pesticide products, is sufficient to comply with this rule if the exporting company prefers not to use any further optional amplification.

Another commenter suggested that including the phrase on device labeling would create a competitive disadvantage in the marketplace. However, EPA believes that the ability to include explanatory text such as “because pesticide devices are not required to be registered” should resolve this potential concern.

6. *Shipping between registered establishments operated by the same producer.* Several commenters discussed potential problems associated with the proposed requirement that when unregistered pesticide products intended solely for export are shipped between registered establishments operated by the same producer, the products are required to have labeling that complies with 40 CFR part 168. One issue raised by a commenter related to the many steps in the production process for pesticide products. One commenter suggested the new requirement be added to 40 CFR 152.30 instead of part 168 while another believed the new requirement was not even necessary. After considering the comments, EPA believes that it is more appropriate to retain the new requirement in §168.70 instead of adding it to 40 CFR 152.30.

III. The Final Rule

With the exception of the modifications discussed in the previous unit, EPA is finalizing the rule in essentially the same form as the proposed rule. This rule will clarify, restructure, add specificity to the current regulations and will also add an extra margin of safety when shipments of unregistered pesticides and devices that are intended solely for export move between registered establishments operated by the same producer prior to being exported. The regulations at 40 CFR 152.30(a) currently allow the transfer of an unregistered pesticide between registered establishments operated by the same producer, and require the transferor to follow the labeling requirements in 40 CFR part 156. EPA believes that requiring the registration status information from 40 CFR 168.70(b)(3) on the label when such products are intended solely for

export at the time of the transfer will result in safer and more appropriate handling and distribution of unregistered pesticide products and devices. EPA also believes that this requirement will help to prevent unregistered pesticide products and devices intended solely for export from inadvertently entering the U.S. market.

IV. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA submitted a draft of this final rule to the FIFRA Scientific Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The FIFRA SAP waived its review of this final rule on June 7, 2012 because this action is administrative and does not contain scientific issues that require the FIFRA SAP's consideration. USDA waived the opportunity to review the final rule on June 19, 2012 because clarification and restructuring of the current regulations are administrative actions with no scientific or policy issues.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and was therefore not submitted to the Office of Management and Budget for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new significant information collection burden that would require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The

information collection requirements contained in the existing regulations (40 CFR 168.65), are already approved by OMB under OMB control number 2070-0027 (EPA ICR No. 0161); since there is no new significant burden, it was not necessary to amend the ICR. Burden is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 are displayed in the **Federal Register** and are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act, 5 U.S.C. 551-553, or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201. A small business that manufactures pesticides and other agricultural chemicals as defined by NAICS code 325320 has 500 or fewer employees (based on the Small Business Administration size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The small entities directly

regulated by this final rule are small manufacturers of pesticides which export unregistered pesticide products or devices.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA has determined that the cost is minimal to comply with the requirement that an unregistered pesticide product intended solely for export that is transferred between registered establishments under § 152.30(a) must be labeled with the statement “Not Registered for Use in the United States.” This is because existing requirements already call for labeling that includes most of the provisions in 40 CFR part 168, and the burden of adding the additional statement in that limited context would be negligible. EPA believes this labeling change may be easily accomplished using commonly available word processing software; in addition, this label change does not require label submission to or approval by EPA, and can be phased in as part of normal business operations by January 21, 2014. EPA concluded that the per firm and industry level impact of the final rule is insignificant.

EPA believes that increasing the specificity of the current regulations will minimally affect all manufacturers of pesticide products and devices intended solely for export, not just those manufacturers that are small entities. The more specific indication that “Not Registered for Use in the United States” will be required for unregistered pesticide products and devices intended solely for export that are shipped between establishments operated by the same producer; this is the identical labeling information that is already required before an unregistered pesticide product or device intended solely for export is in fact exported to another country.

D. Unfunded Mandates Reform Act (UMRA)

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 for State, local or tribal governments or the private sector. This action imposes no enforceable duty on any State, local or tribal governments or the private sector because the action is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices intended solely for export and to not result in expenditures of \$100 million or more. Since no State, local, or tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this rule is not expected to affect State, local, and tribal governments individually, much less in the aggregate. Therefore, this action is not subject to the requirements of sections 202 or 205 of UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments since no small government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action contains no regulatory requirements that might affect State or local governments since no State or local government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and the State and local governments, EPA specifically solicited comment on the proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because this action is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices. Since no Indian tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this action has no tribal implications. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks, nor is it an “economically significant regulatory action” as defined in Executive Order 12866. The clarification and restructuring of current regulations for the export of unregistered pesticide products and devices do not present a disproportionate risk to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866 nor will it affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to NTTA section 12(d), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note). Thus, NTTAA does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

The clarification and restructuring of current regulations for the export of unregistered pesticide products and devices increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

VI. Congressional Review Act (CRA)

Pursuant to the CRA, 5 U.S.C. 801 et seq., EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Information collection requirements.

40 CFR Part 168

Environmental protection, Administrative practice and procedure, Advertising, Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 11, 2013.

James Jones,

Acting Assistant Administrator for Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.* , 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.* , 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.* , 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

§ 9.1 [Amended]

2. In the table to § 9.1, under the center heading “Statements of Enforcement Policies and Interpretations,” remove the entire entry for “168.65.”

PART 168—[AMENDED]

3. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136-136y .

4. Revise the heading for subpart D to part 168 to read as follows:

Subpart D--Export Policy and Procedures for Exporting Pesticides

§168.65 [Removed and reserved]

5. Remove and reserve §168.65.

6. Add §168.66 through §168.71 to subpart D to read as follows:

Sec.

168.66 Labeling of pesticide products and devices intended solely for export.

168.67 Definitions.

168.68 Applicability.

168.69 Registered export pesticide products.

168.70 Unregistered export pesticide products.

168.71 Export pesticide devices.

§168.66 Labeling of pesticide products and devices intended solely for export.

(a) This subpart describes the labeling requirements applicable to pesticide products and devices that are intended solely for export from the United States under the provisions of FIFRA section 17(a). The requirements for pesticide production reporting, recordkeeping and inspection and purchaser acknowledgement provisions can be found in the following parts:

(1) Pesticide production reporting requirements under FIFRA section 7 are located in part 167 of this chapter (as referenced in §168.85(b));

(2) Recordkeeping and inspection requirements under FIFRA section 8 are located in part 169 of this chapter (as referenced in §168.85(a));

(3) Purchaser acknowledgement statement provisions under FIFRA section 17(a) are located in §168.75.

(b) The labeling of pesticide products and devices intended solely for export must comply with the requirements in §156.10(a)(4) of this chapter.

(c) The labeling of pesticide products and devices intended solely for export must comply with this regulation no later than January 21, 2014.

§168.67 Definitions.

Terms used in this subpart have the same meanings as in the Act and as in §152.3 of this chapter, unless otherwise defined in this section.

Export pesticide device means a device, as defined in FIFRA section 2(h), that is intended solely for export from the United States to another country.

Export pesticide product means a pesticide product, as defined in §152.3 of this chapter, that is intended solely for export from the United States to another country.

§ 168.68 Applicability.

This subpart applies to all export pesticide products and export pesticide devices that are exported for any purpose, including any research purpose.

§ 168.69 Registered export pesticide products.

(a) Each export pesticide product that is registered under FIFRA section 3 or FIFRA section 24(c) must bear labeling approved by EPA for its registration and comply with the requirements of §168.66(b).

(b) For the purposes of this subpart, a registered export pesticide product is considered to be any of the following:

(1) A pesticide product of composition, packaging and labeling as described in its registration under FIFRA section 3;

(2) A pesticide product that has been modified in compliance with the notification or non-notification provisions of §152.46 of this chapter, and any associated procedures issued under §156.10(e) of this chapter, regardless of whether such modification has been made for the pesticide product's registration under FIFRA section 3;

(3) A pesticide product initially registered by a State under FIFRA section 24(c), and whose Federal registration has not been disapproved by EPA under §162.164 of this chapter.

(c) The text of the labeling of the export pesticide product must be provided in English and, if applicable, the following foreign languages:

(1) The predominant or official language of the country of final destination, if known; and

(2) The predominant or official language of the importing country.

§168.70 Unregistered export pesticide products.

(a) Any export pesticide product that does not meet the terms of §168.69 is an unregistered export pesticide product for purposes of this subpart.

(b) Each unregistered export pesticide product must bear labeling that complies with all requirements of this section and §168.66(b).

(1) The labeling must comply with all of the prominence and legibility requirements of §156.10(a)(2) of this chapter.

(2) The labeling must comply with all the language requirements in §§168.69(c) and 156.10(a)(3) of this chapter.

(3) The labeling must bear the following information:

(i) The name and address of the producer, in accordance with the requirements of §156.10(c) of this chapter;

(ii) The net weight or measure of contents, in accordance with the requirements of §156.10(d) of this chapter;

(iii) The pesticide producing establishment number, in accordance with the requirements of §156.10(f) of this chapter;

(iv) An ingredients statement, in accordance with the requirements of §156.10(g) of this chapter, except that:

(A) The ingredients statement need not appear in a second language besides English if English is the official or predominant language in the importing country and the country of final destination, if known; and

(B) An export pesticide product intended solely for research and development purposes, (and which bears the statement "For research and development purposes only. Not for distribution, sale, or use," or similar language) may bear coded ingredient information to protect confidentiality.

(v) Human hazard and precautionary statements in accordance with the requirements of subpart D of part 156 of this chapter. The statements must be true and accurate translations of the English statements.

(vi) The statement "Not Registered for Use in the United States of America," which may be amplified by additional statements accurately describing the reason(s) why the export pesticide product is not registered in the United States, or is not registered for particular uses in the United States.

(c) This section also applies to all unregistered pesticide products and devices that are intended solely for export and that are transferred, distributed, or sold between registered establishments operated by the same producer according to §152.30(a) of this chapter if:

(1) The transfer, distribution or sale occurs between a point in the United States and a point outside the United States, or

(2) The transfer occurs within the United States solely for the purpose of export from the United States.

§168.71 Export pesticide devices.

(a) Each export pesticide device sold or distributed anywhere in the United States must bear labeling that complies with all requirements of this section and §168.66(b).

(b) The labeling of each export pesticide device must meet all of the prominence and legibility requirements of §156.10(a)(2) of this chapter.

(c) The labeling must also comply with all the language requirements in §168.69(c) and §156.10(a)(3) of this chapter.

(d) The labeling must bear the following information:

(1) The name and address of the producer, meeting the requirements of §156.10(c) of this chapter;

(2) The producing establishment number, meeting the requirements of §156.10(f) of this chapter;

(3) The statement “Not Registered for Use in the United States of America,” which may be amplified by additional statements describing the reason why the export pesticide device is not registered in the United States, such as “because pesticide devices are not required to be registered in the United States.”

(e) An export pesticide device is not required to bear an ingredients statement.