Center for Biocide Chemistries

February 9, 2022

VIA ELECTRONIC MAIL

Ed Messina
Director, Office of Pesticide Programs
U.S. Environmental Protection Agency
MC 7506C
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
messina.edward@epa.gov

Re: Petition to EPA to Issue Guidance on Minimum Labeling Requirements for Imported R&D Pesticide Samples

Dear Mr. Messina:

The American Chemistry Council's Center for Biocide Chemistries (CBC) hereby petitions the U.S. Environmental Protection Agency (EPA or the Agency) for guidance on the minimum labeling requirements for imported research and development (R&D) pesticide samples. CBC members have experienced problems with customs holds for registered and unregistered pesticide research samples. In both situations, the imported samples are often packaged in small containers (100 g – 500 g), where a full label does not fit on the face of the packaging. CBC has not identified any EPA regulations or Agency-wide guidance that specifically addresses minimum labeling requirements. There also is inconsistency among EPA regional offices with respect to the requirements. CBC therefore believes that Agency-wide guidance is needed.

This petition follows CBC's May 28, 2020, telephone conference with you and John Irving, then-Deputy Assistant Administrator of the Office of Enforcement and Compliance Assurance (OECA). Additionally, this petition follows CBC's July 24, 2020, letter to Mr. Irving, attached hereto as Attachment 1, in which CBC provided EPA with examples of company labels of imported research pesticide samples and guidance issued by EPA regional offices. As discussed below, CBC is aware that at least two EPA regional offices have developed memorandums outlining information that should be included on labels for imports of pesticide R&D samples. However, the memorandums differ with respect to the minimum information required. All interested parties, including importers, registrants, and EPA regional offices, would benefit if the Agency issues guidance, which can be applied across all regions, on the minimum labeling

requirements for registered and unregistered pesticides imported for R&D purposes, including labeling requirements with respect to small containers.

Part I of this petition describes the current regulatory landscape regarding labeling of imported pesticides for R&D uses. Part II of this petition presents CBC's proposed guidance for the applicable minimum labeling requirements.

I. Background

A. Labeling Requirements for Registered Pesticides are Addressed by EPA

EPA has addressed import requirements, including labeling requirements, for registered pesticides. For instance, in a Frequently Asked Questions document regarding the Agency's FIFRA imports program (the Imports Program FAQ), EPA states that "[p]esticides that are registered with EPA must be accompanied by an EPA [Notice of Arrival (NOA)] upon entry into the Customs Territory of the United States, *must bear a label/labeling that has been accepted by EPA and comports with 40 C.F.R. part 156*, and must meet the product composition standards established in its registration."[1]

EPA's labeling requirements for pesticides are provided at 40 C.F.R. Part 156. Under 40 C.F.R. § 156.10, every "pesticide product," defined as a pesticide in the particular form in which the pesticide is or is intended to be distributed or sold,[2] must bear a label that contains the following information:

a) The name, brand, or trademark under which the product is sold;
b) The name and address of the producer, registrant, or person for whom produced;
c) The net contents;
d) The product registration number;
e) The producing establishment number;
f) An ingredient statement;
g) Hazard and precautionary statements;
h) The directions for use; and
i) The use classification(s).

This provision also includes requirements regarding the placement and appearance of the required labeling.

Thus, EPA's position on labeling of imported registered pesticides for R&D uses is that the labeling should comply with the requirements of 40 C.F.R. Part 156.

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[1] EPA, FIFRA Imports Program Frequently Asked Questions at 2 (May 2021), available at https://www.epa.gov/sites/production/files/2021-05/documents/fifraimportfaqs.pdf (last accessed Dec. 8, 2021).

[2] 40 C.F.R. § 152.3.

B. Labeling Requirements for Unregistered Pesticides are not Addressed by EPA

Unlike registered pesticides, there is no clarity or consistency with respect to the minimum labeling requirements for imported unregistered R&D pesticides.[3] In EPA's Imports Program FAQ, the Agency states that "[p]esticides that are regulated by FIFRA but are not registered with EPA may be imported, with an EPA NOA, only under certain circumstances . . . *provided they are labeled appropriately*."[4] However, EPA does not address what constitutes appropriate labeling.

EPA further states that all R&D pesticides, including unregistered pesticides, "must comply with all pesticide import requirements, including submission of an EPA NOA, production establishment registration and reporting requirements, *and all applicable labeling requirements*."[5] Again, the Agency does not specify the applicable labeling requirements for imported unregistered R&D pesticides.

Similarly, EPA's regulations do not specifically address the minimum labeling requirements for imported unregistered R&D pesticides. Under the Agency's FIFRA regulations, unregistered pesticides may be imported only if the import meets the conditions of one of the exceptions in 40 C.F.R. § 152.30, which includes the following:

a) A pesticide transferred between registered establishments operated by the same producer;
b) A pesticide transferred between registered establishments not operated by the same producer.
c) A pesticide distributed or sold under an experimental use permit;
d) A pesticide transferred solely for export;
e) A pesticide distributed or sold under an emergency exemption;
f) A pesticide transferred for purposes of disposal; and
g) Existing stocks of a formerly registered product.

Under each of these conditions, with the exception of the existing stocks condition, the regulations state that the product "must be labeled in accordance with Part 156."[6] However, R&D pesticides are not specifically exempted under this provision. CBC submits that EPA should directly address whether the Part 156 labeling requirements apply to unregistered R&D pesticides.

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[3] CBC recognizes that EPA has referenced certain labeling requirements for unregistered pesticides in various non-binding materials. *See, e.g.*, EPA, Importing and Exporting Pesticides and Devices, available at https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices (last accessed Dec. 16, 2021) (stating that unregistered pesticides must be labeled with an EPA establishment number). However, CBC maintains that the Agency has not issued a single guidance document addressing the applicable minimum labeling requirements for unregistered R&D pesticides.

[4] Imports Program FAQ at 2.

[5] *Id.* at 3.

[6] *See* 40 C.F.R. § 152.30.

C. Labeling Requirements for Small Containers

This situation is further complicated by the fact that imported R&D pesticide samples are often packaged in small containers (100 g – 500 g), and a full label does not fit on the face of the packaging.

EPA's Label Review Manual includes information on labeling of small containers. Specifically, the Agency states that, when a container is too small to contain all required label text, "it is permissible to have text located on accompanying pamphlets or other collateral material."[7] EPA further states that the Agency "historically has required" the following information to appear on the label of small containers:[8]

a) Ingredient statement;
b) Signal word;
c) Skull and crossbones (when required);
d) Child hazard warning;
e) EPA Registration Number;
f) EPA Establishment Number;
g) The phrase "RESTRICTED USE PESTICIDE" (if so classified); and
h) A reference statement to any accompanying pamphlets.

It should be noted that this section of the Label Review Manual does not reference EPA's labeling regulations. CBC urges EPA to specifically address whether the Agency's guidance on small container labeling applies to imported registered and unregistered R&D pesticides.

D. Guidance From EPA Regional Offices Regarding Labeling of R&D Pesticides

In the absence of Agency-wide direction on minimum labeling requirements for imported R&D pesticides, CBC is aware of two EPA regional offices that have developed memorandums on this issue.

EPA Region 5 issued a memorandum addressing unregistered R&D pesticides being imported into the U.S. (included in Attachment 1). This memorandum states that the following information should be submitted with the NOA:

> 1) A true and correct copy of the label on the immediate container of the R&D pesticide, which must be affixed to the immediate container at the time of importation. The label, at a minimum, must include:
>
> a) An ingredient statement;
> b) The statement, "For Research and Development Purposes Only;"
> c) The statement, "Not for Sale;"

[7] EPA, Label Review Manual at 18-3 - 18-4, available at https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf (last accessed Dec. 16, 2021).

[8] *Id.* at 18-3.

d) The foreign manufacturer's complete address and EPA Establishment Registration Number; and
e) Net contents of the R&D pesticide within the container.

2) The following additional information should be submitted as an addendum to Item #18 on the NOA and signed by a duly delegated officer of the importing company (not the broker) specifying:

a) That the R&D pesticide is being imported to determine its value for pesticidal purposes or to determine its toxicity or other properties, and no benefit of pest control is expected to result;
b) A brief description of the anticipated research and development activity with a projected date of completion;
c) The specific points of distribution en route to the R&D pesticide's ultimate destination;
d) The R&D pesticide's ultimate destination (U.S. address);
e) Provisions for disposing of leftover stocks of the R&D pesticide; and
f) A statement that the label provided to U.S. EPA is a true and correct representation of the label that will accompany the R&D pesticide throughout its distribution and analysis in the U.S.

Additionally, an EPA regional office issued a document, included in Attachment 1, regarding procedures for review of NOAs submitted by importers of R&D pesticides. This document differs from the Region 5 memorandum and states that importers should submit a completed NOA along with the following information:

1) A true and correct copy of the label to be placed on the R&D pesticide which includes:

a) The statement, "For Research and Development Purposes Only;"
b) The statement, "Not for Sale;"
c) The name of the pesticide;
d) An ingredient statement listing the names of active ingredients and percentages for all active and (if applicable) inert ingredients for the pesticide;
e) Net weight of the pesticide;
f) Minimal directions for use, First Aid statements, Human Hazard and precautionary statements, and Environmental Hazard and Precautionary statements; and
g) Foreign manufacturer's address and the EPA Establishment Number.

2) An addendum to Item #18 on the NOA form, signed by a duly delegated officer of the importing company (not the broker) specifying:

a) That the R&D pesticide is being imported to determine its value for pesticidal purposes or to determine its toxicity or other properties and no benefit of pest control is expected to result;

b) A brief description of the anticipated research and development activity with a projected date of completion;
c) The specific points of distribution en route to the R&D pesticide's ultimate destination;
d) The R&D pesticide's ultimate destination (U.S. address);
e) Provisions for disposing of leftover stocks of the R&D pesticide; and
f) A statement that the label provided is a true and correct representation of the label that will accompany the R&D pesticide throughout its distribution and analysis in the U.S.

II. Proposed Guidance

CBC urges EPA to issue guidance that can be applied across all EPA regions addressing minimum labeling requirements for imported registered and unregistered R&D pesticides. We have provided below proposed minimum labeling requirements and additional information that should be included in the requested guidance.

A. Registered Pesticides

Registered pesticides should be imported under FIFRA. An EPA-approved FIFRA label should be affixed to the packaging. If a full label does not fit on the face of the packaging, the importer should follow EPA's guidance in the Label Review Manual regarding labeling of small containers.[9]

B. Unregistered Pesticides

The importer should determine whether the chemical substance is a "pesticide" as that term is defined under FIFRA. Under FIFRA, a "pesticide" is defined as (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer.[10] Chemicals that meet the statutory definition of a pesticide should be imported under FIFRA. Under FIFRA, unregistered pesticides may be imported only if the import meets the conditions of one of the exceptions in 40 C.F.R. § 152.30.

Chemicals that may have pesticidal use but are not intended for any pesticidal R&D purpose, and chemicals that are intended for use in R&D that is designed to determine whether the chemicals are in fact pesticides, are not pesticides as that term is defined under FIFRA.[11] If the material being imported falls within this R&D exclusion or otherwise does not meet the FIFRA definition of a pesticide, it likely should be imported under the Toxic Substances Control Act (TSCA).[12] If such chemicals are not on the TSCA inventory, small quantities can be imported under the TSCA R&D exemption, in accordance with 40 C.F.R. §§ 720.36 and 720.78. For significant new uses,

[9] *See* EPA, Label Review Manual at 18-3 - 18-4.

[10] 7 U.S.C. § 136(u).

[11] *See* Imports Program FAQ at 3.

[12] 15 U.S.C. § 2601 *et seq.*

small quantities can be imported under the TSCA R&D exemption, in accordance with 40 C.F.R. § 721.47.

Importers of unregistered pesticides must submit a true and correct copy of the label. The label, at a minimum, must include [CBC to discuss]:

a) An ingredient statement;[13]
b) The statement, "For Research and Development Purposes Only";
c) The statement, "Not for Sale in the USA";
d) The foreign manufacturer's complete address and EPA Establishment Registration Number (if the foreign establishment of the manufacturer is registered with U.S. EPA, pursuant to Section 7(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136e(a));
e) Net contents of the pesticide within the container;
f) Product Identifier or Product Name; and
g) The statement, "See Label Insert".[14]

If the container is too small to contain all required label text, it is permissible to have text located on accompanying pamphlets or other collateral material.

III. Conclusion

For the foregoing reasons, CBC urges EPA to issue guidance addressing the minimum labeling requirements for imported R&D pesticides, including with respect to small containers.

Thank you for your attention to this matter.

Sincerely,

Komal K. Jain
Executive Director, CBC

Enclosure

[13] 40 C.F.R. § 156.10(g).

[14] Registered pesticide products only.

Center for Biocide Chemistries

Attachment 1

July 24, 2020

Submitted via Email

John Irving
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
Environmental Protection Agency
Irving.john@epa.gov

RE: Information on the Imports of Biocides for Research and Development

Dear Mr. Irving,

I am responding to our May 28, 2020, telephone conference regarding challenges with the imports of biocides. We discussed a number of topics, and in several instances, EPA requested additional information and examples. While our efforts to collect the information you requested are still ongoing, we are providing information related to the imports of research samples so that we might make progress on this one key area. We believe the information provided below, as well as the attachments to this letter, underscore the need for EPA Headquarters to develop guidance materials that can be used by all nine regional offices and industry.

Research Samples

As noted in our May 8, 2020, letter and May 28th conference call, CBC members primarily experience issues with customs holds for registered and unregistered pesticide research samples. In both instances, the samples imported for research and development are often packaged in small containers (100 g – 500 g) where a full label does not fit on the face of the packaging.

EPA requested information on the specific instances where an import of a pesticide research sample was held. Unfortunately, CBC members have not maintained adequate past records, so we were unable to obtain specific examples. We, however, are providing the following information to illustrate how some companies label imported research samples:

1. A template used by some registrants for labeling of unregistered research samples (Attachment A);
2. Examples of labels of unregistered research samples (Attachment B); and

3. Photos of research sized samples of registered products where the center panel of the label is affixed directly to the container, and the full (folded) label is inserted into a clear plastic sleeve, also affixed to the container (Attachment C).

It is important to note that there is no industry standard, nor could CBC find specific labeling or import rules under EPA's regulations for imports of R&D samples. CBC is aware, however, of two examples of regional offices developing memos outlining information that should be included on the labels for imports of unregistered pesticide R&D samples.[1,2] CBC believes that EPA should develop guidance on the key elements needed on a product label for pesticides (both registered and unregistered) that are imported in small packs and in small quantities for research purposes that can be applied across all regions. Such guidance will be beneficial to both industry and EPA.

Letter of Intent

For imports of unregistered pesticide research samples, a "Letter of Intent" is transmitted to EPA by the importer to address the requirements under 40 CFR §§ 152.30 and 172.3. While a Letter of Intent is necessary to communicate certain elements set forth under the regulations, there is no specific format or standard language to the letter. Unfortunately, this often results in significant back and forth with EPA regional staff on the language that is to be included in the Letter of Intent.

EPA requested examples of a Letter of Intent, and in particular, examples of submissions where the letter was considered acceptable but then later rejected by the same EPA Regional Office. We are providing the following:

1. A copy of a Letter of Intent that was deemed acceptable in 2011 by EPA Region 4 (Attachment D).
2. A copy of the same 2011 Letter of Intent with red-lined changes later required by EPA Region 4 for another import (Attachment E).

CBC again asks that EPA Headquarters, in collaboration with the regional offices, develop a template Letter of Intent to support an efficient review process.

CBC continues to internally discuss and review the feedback from our May 28th meeting and will follow up with additional information on the other areas we discussed accordingly. In the meantime, please feel free to contact me at Komal_Jain@americanchemistry.com or (202) 249-6212 if you have any questions.

[1] *See* Attachment F. U.S. EPA-Region 5 Memorandum: Unregistered Research and Development Pesticides (R&D pesticides) Being Imported into the United States.

[2] *See* Attachment G. Procedures for Review of Notices of Arrival (EPA Form 3540-1) Submitted by Importers of Research and Development Pesticides.

Sincerely,

Komal K. Jain
Executive Director
Center for Biocide Chemistries

Cc: Ed Messina, Office of Pesticide Programs
Royan Teter, Office of Enforcement and Compliance Assurance

Attachments (7)

Attachment A

UNREGISTERED *INSERT PRODUCT TYPE (i.e. INSECTICIDE, ANTIMICROBIAL)*

Insert Product Name

Chemical Name (Active Ingredient):
Insert Chemical Name……..……*0.00*%
Inert ingredients……..Balance

UNREGISTERED ***INSERT PRODUCT TYPE***

Update as appropriate: CAUTION: Avoid all direct contact. Use eye protection and proper Personal Protection Equipment. In case of contact, flush skin or eyes with plenty of water or move to fresh air. In case of poisoning, contact a Poison Control Center or physician. Keep out of the reach of children. Do not reuse container. Discard according to local trash disposal regulations.

NOT REGISTERED IN THE UNITED STATES. NOT FOR SALE.

Net Contents: *Insert Number* Lot No. *Insert Number*

EPA Establishment Number: *Insert Number*

Insert Company Name and Address

Attachment B

NOT USEPA REGISTERED FOR USE IN THE USA
FOR RESEARCH PURPOSES ONLY. NOT FOR SALE OR COMMERCIAL USE.
THIS PRODUCT IS INTENDED FOR EXPERIMENTAL RESEARCH AND
EVALUATION ONLY BY AUTHORIZED LABORATORIES.

Product Code No. CL 322,250

Pesticide metabolite for research test purposes

INGREDIENT STATEMENT:

3-bromo-5-(4-chlorophenyl)-4-cyano-1H-pyrrole-2-carboxylic acid* :	94.9%
Other ingredients:	5.1%
Total:	100.0%

*CAS no. 890044-32-3

CAUTION – substance not yet fully tested

KEEP OUT OF REACH OF CHILDREN

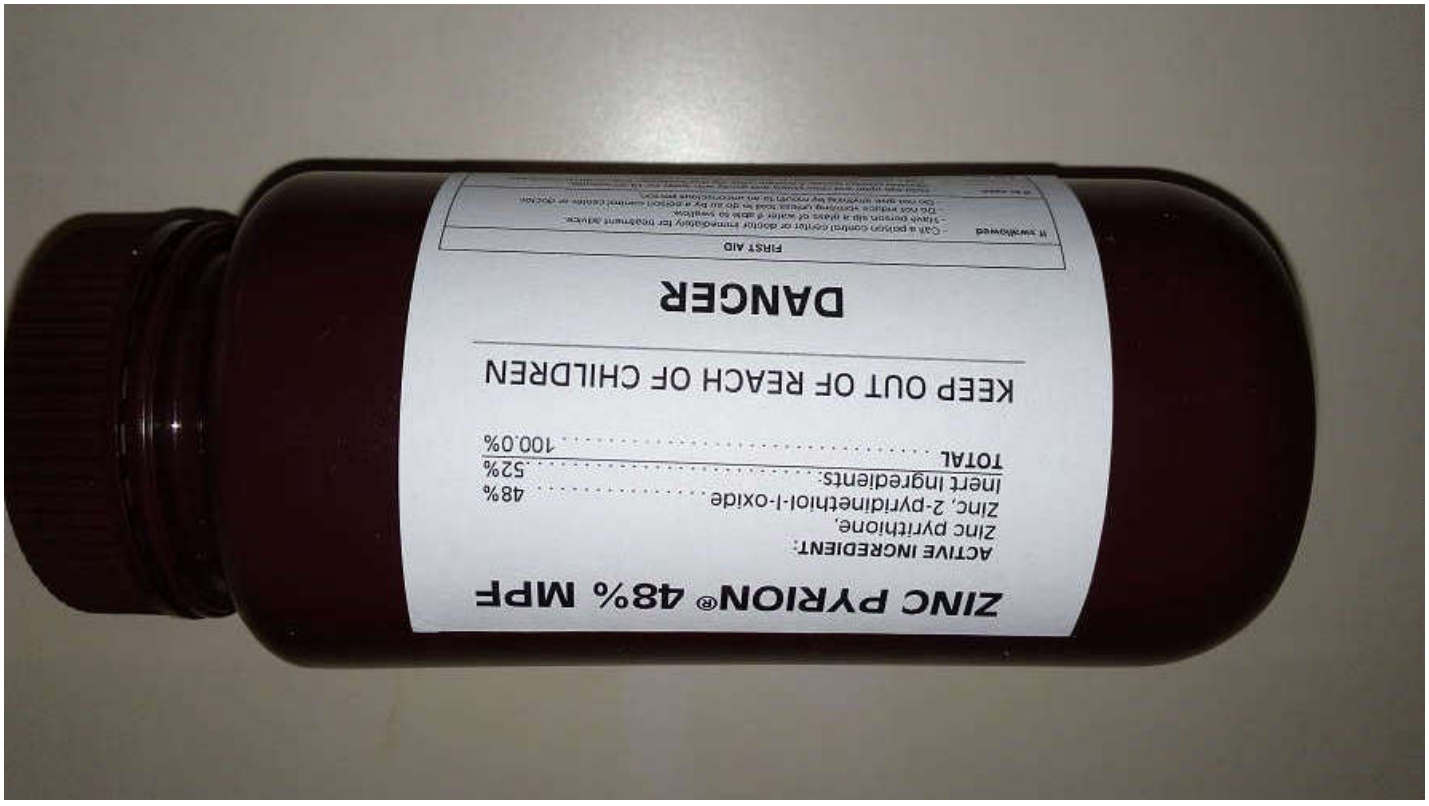
Refer to enclosed SDS for first aid, precautionary statements and storage and disposal

NET CONTENTS: 0.035 ounces (1 gram)
Expiry date : January 27, 2020

Batch Nr.:1547-20
EPA Est. No.: 43813-BEL-001

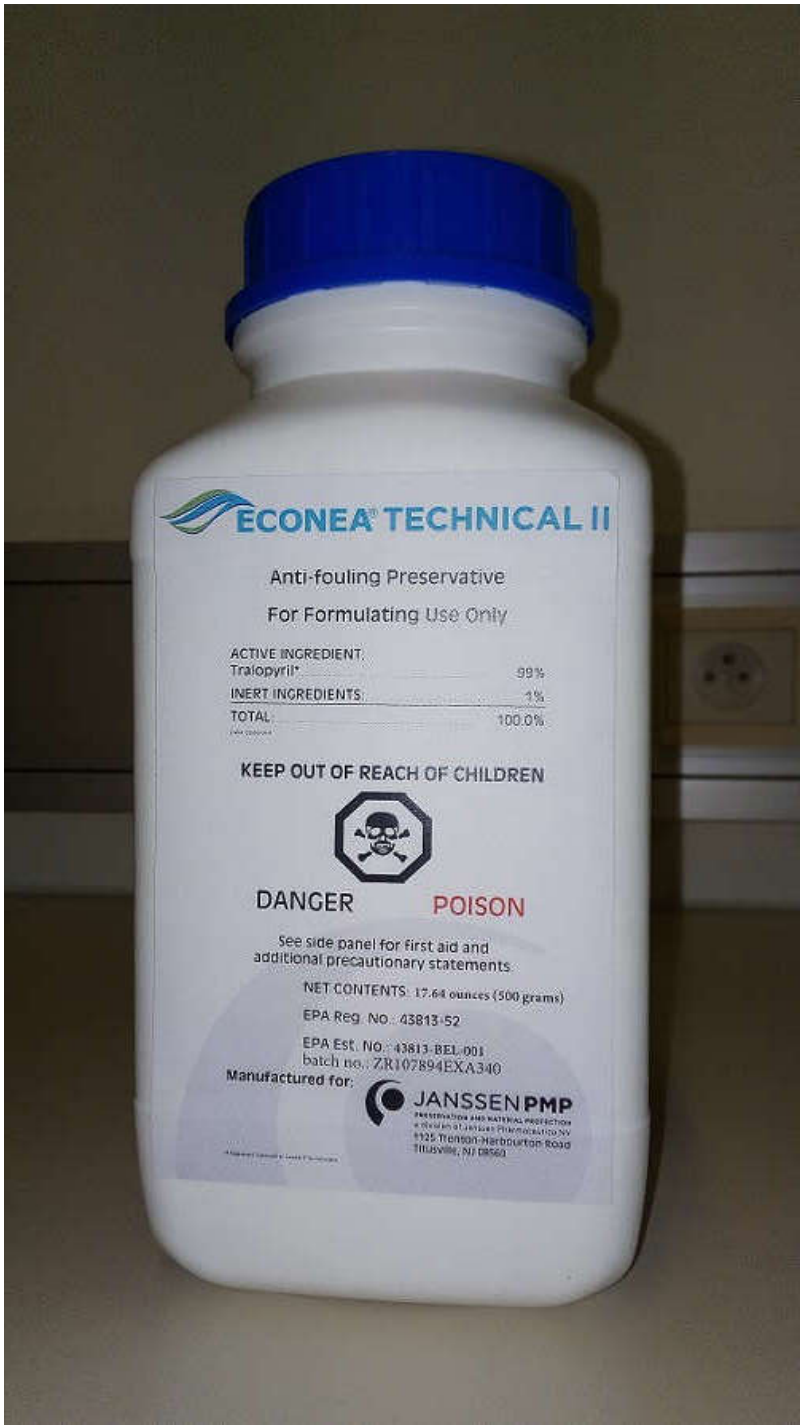
Manufactured for : JANSSEN PMP PRESERVATION AND MATERIAL PROTECTION a division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Attachment C




ZINC PYRION® 48% MPF
ACTIVE INGREDIENT:
Zinc pyrithione,
Zinc, 2-pyridinethiol-1-oxide 48%
inert ingredients
TOTAL
KEEP OUT OF REACH OF CHILDREN
DANGER

For Formulating Use Only
ACTIVE INGREDIENT:
Trioxysulf 99%
INERT INGREDIENTS 1%
TOTAL 100.0%
KEEP OUT OF REACH OF CHILDREN
DANGER
POISON
See side panel for first aid and
additional precautionary statements
NET CONTENTS 12.64 ounces (500 grams)
EPA Reg. No. 43813-52
EPA Est. No. 43813-BEL-001
batch no.: ZR107894EXA340
Manufactured for:
JANSSEN PMP
ECONFA TECHNICAL
FSC
MIX
Paper from
responsible sources
FSC® C113380
contains recycled film


ECONEA® TECHNICAL II
Anti-fouling Preservative
For Formulating Use Only
ACTIVE INGREDIENT:
Tralopyril* 99%
INERT INGREDIENTS: 1%
TOTAL: 100.0%
KEEP OUT OF REACH OF CHILDREN
DANGER
POISON
See side panel for first aid and additional precautionary statements
NET CONTENTS: 17.64 ounces (500 grams)
EPA Reg. NO.: 43813-52
EPA Est. NO.: 43813-BEL-001
batch no.: ZR107894EXA340
Manufactured for:
JANSSEN PMP

LOI Example #1

[redacted]

April 28, 2011

To Whom It May Concern:

[redacted] doing business at [redacted] and with Laboratory facilities [redacted], intends to import a biocide product in order to perform testing required to support the registration of the biocide in Europe.

The biocide product to be imported is:
[redacted]

The biocide will be evaluated by chemical testing and samples will be sent to Product Safety Labs in Dayton, NJ, for testing. The projected date of completion is when the aforementioned biocides have either been used up in testing or have exceeded shelf life of two years.

A total of five 0.5 liter samples of [redacted] are being sent in one box from [redacted]

The samples will be conveyed by common carrier. Panalpina will broker the package at its port of entry, John F. Kennedy International Airport, Queens, NY 11422, USA. Panalpina's U.S. address is: Panalpina Inc., 1000B Castle Road, Secaucus, NJ 07094.

From the package's port of entry, it will be transported to its ultimate destination by common carrier. The package's ultimate destination is [redacted], USA and will be delivered to me at this address.

Any unused biocide product that exceeds the 2 year shelf life will be disposed of as hazardous waste.

The label/s provided for the test samples is a true and correct representation of the label that will accompany each test sample throughout their distribution and testing in the United States of America.

[redacted]

A more simpler version of the LOI that was acceptable in 2011. See Example 2 for added revisions.

LOI Example #2

[redacted]

March 9, 2020

To Whom It May Concern:

[redacted], doing business at [redacted], intends to import one biocide product to determine its toxicity and other chemical properties. One sample of [redacted] is being sent from [redacted] These laboratory tests are exempt from the requirements for an Experimental Use Permit under 40 CFR § 172.3(1)(i) and (2). No benefit of pest control is expected to result.

The product to be imported is:
[redacted]

a. CAS-No.: [redacted]
b. Net contents: 8.5 Fl. Ounces

Research will be conducted, solely in a laboratory setting. This material will be used as an internal standard to validate the analytical method for measuring active ingredient content. This sample will be evaluated using existing test methods along with experimental methods. The sample will be tested by methods that may include, but may not be exclusive to: pH, and percentage of the active ingredient. The projected date of completion is when the aforementioned biocide either has been used up, or has exceeded the expiration date of May 29, 2021.

The port of departure is London Heathrow Airport (LHR). The port of entry is Atlanta International Airport (ATL). From the package's port of entry, it will be transported to its ultimate destination by common carrier. The package's ultimate destination is [redacted] and will be delivered to me at this address.

Any unused biocide products that exceed the above expiration date will be received and transported by Hazmat Environmental Group Inc., 60 Commerce Drive, Buffalo, New York 14218, U.S. EPA ID Number NYD980769947 and disposed by Clean Harbors El Dorado, LLC., 309 American Circle, El Dorado, AR 71730 U.S. EPA ID Number ARD069748192.

The labels provided for the test samples are a true and correct representation of the label that will accompany each test sample throughout their distribution and testing in the United States of America.

[redacted]

Red writing indicates changes in LOI over the last few years, most changes within last couple years in which Region 4 has been adding requirements regularly.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5 (LC-8J)
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MEMORANDUM

Subject: Unregistered Research and Development Pesticides (R&D pesticides) Being Imported into the United States

From: United States Environmental Protection Agency (U.S. EPA), Region 5

To: Importer or Broker-Filer

The U.S. EPA-Region 5 is requesting the following information on the importation of unregistered pesticides for research and development (R&D pesticides) into the United States. U.S. EPA is requesting this information in order to more fully document the declared R&D nature of the R&D pesticides, to ensure that imported R&D pesticides are not diverted into the channels of trade, and to more closely monitor the transportation, R&D use, and proper disposal of these types of unregistered pesticides.

The following information should be submitted with the Notice of Arrival of Pesticides and Devices (NOA), EPA Form 3540-1.

1) A true and correct copy of the label on the immediate container of the R&D pesticide, which must be affixed to the immediate container at the time of importation. The label, at a minimum, must include:

a) An ingredient statement,
b) The statement, "For Research and Development Purposes Only,"
c) The statement, "Not for Sale,"
d) The foreign manufacturer's complete address and EPA Establishment Registration Number (if the foreign establishment of the manufacturer is registered with U.S. EPA, pursuant to Section 7(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136e(a))
e) Net contents of the R&D pesticide within the container.

2) The following additional information should be submitted as an addendum to Item #18 on the NOA and signed by a duly delegated officer of the importing company (not the broker!) specifying:

a) That the R&D pesticide is being imported to determine its value for pesticidal purposes or to determine its toxicity or other properties, and no benefit of pest control is expected to result,
b) A brief description of the anticipated research and development activity with a projected date of completion,
c) The specific points of distribution en route to the R&D pesticide's ultimate destination,
d) The R&D pesticide's ultimate destination (U.S. address),
e) Provisions for disposing of leftover stocks of the R&D pesticide,
f) A statement that the label provided to U.S. EPA is a true and correct representation of the label that will accompany the R&D pesticide throughout its distribution and analysis in the U.S.

Procedures for Review of Notices of Arrival (EPA Form 3540-1)
Submitted by Importers of Research and Development Pesticides
Revised March 9, 2020

In order to fully document the "Research and Development" (R&D) nature of the pesticide, ensure that the importer maintains control of the product throughout the R&D process, and to ensure that the R&D pesticide does not enter the channels of trade, the importer must submit a completed NOA to EPA for review as well as:

1) A true and correct copy of the label to be placed on the R&D pesticide which includes:
   a) The statement, "For Research and Development Purposes Only";
   b) The statement "Not for Sale";
   c) The name of the pesticide;
   d) An ingredient statement listing the names of active ingredients and percentages for all active and (if applicable) inert ingredients for the pesticide;
   e) Net weight of the pesticide;
   f) Minimal directions for use, First Aid statements, Human Hazard and Precautionary statements, and Environmental Hazard and Precautionary statements;
   g) Foreign manufacturer's address and the EPA Establishment Number, and

2) An addendum to item #18 on the NOA form, signed by a duly delegated officer of the importing company (not the broker) specifying:
   a) That the R&D pesticide is being imported to determine its value for pesticidal purposes or to determine its toxicity or other properties and no benefit of pest control is expected to result;
   b) A brief description of the anticipated research and development activity with a projected date of completion;
   c) The specific points of distribution en route to the R&D pesticide's ultimate destination;
   d) The R&D pesticide's ultimate destination (U.S. address);
   e) Provisions for disposing of leftover stocks of the R&D pesticide;
   f) A statement that the label provided is a true and correct representation of the label that will accompany the R&D pesticide throughout its distribution and analysis in the U.S.