

Multiple Products Packaged Together Registration Review Guidance

Updated September 15, 2021 – to address EPA comments from August meeting, has not been updated to address comments from HCPA (this will be addressed in the next revision)

SUMMARY

There is a federal registration/labeling compliance issue in the marketplace. With the challenges and complexities in determining which multiple products packaged together (*MPPT) require separate registration and/or EPA label review, POM has developed this quick guide as a reference document for State Lead Agencies (SLAs) and industry that brings together all currently available resources and answers FAQs about MPPT. The goal of this document is to provide the opportunity for consistency with packaging for industry and label reviews for SLAs.

The information contained in this document/guidance was developed by the State FIFRA Issues Research and Evaluation Group (SFIREG) and its working committees and is intended for state lead agencies responsible for administering and enforcing pesticide laws and regulations and is not endorsed or approved by US EPA.

Approaches regarding the labeling for MPPT are dependent on the specific issues of each case. Registrants should contact the appropriate division for additional information before submitting registrations or amendments that feature MPPT or before deciding whether such packaging requires registration.¹

** For the purpose of this document, the term "MPPT" will include all versions of kits, co-packs and multi-packs. Per Chapter 18 of EPA's Label Review Manual, MPPT often contain one or more FIFRA-regulated products or in some cases, FIFRA-regulated products along with one or more non-FIFRA products.*

BACKGROUND

There has been a proliferation of MPPT in the marketplace, likely on the order of hundreds of products. These could include:

- Multiple containers of the same pesticide product
- Different pesticide products
- Pesticide(s) plus non-pesticide(s)

Examples of terms used by industry include: kit, pak/pack, multi-pack, co-pack, value pack, twin pack, combo/combination pack, pallet, pallet pak/pack, cube, cube pack, season pak/pack

Examples of types of pesticides/uses/markets:

- disinfectants/sanitizers (e.g. first aid kits, pool/spa kits, home cleaning kits, home brewing kits)
- fungicides/insecticides, including conventional pesticides and biopesticides (e.g. crop treatments, seed treatments, golf/turf, residential indoor/outdoor)
- herbicides/algaecides (e.g. crop treatments, golf/turf, aquatic, residential indoor/outdoor)
- repellents (including skin-applied)

¹ US EPA Label Review Manual 18.IV.A, page 18-2

Some products are simply multiple pesticide products (same or different) packaged together, without the addition of a new name and with each pesticide label completely visible from the outside of the package.

- According to existing EPA guidance, EPA's registration and label review requirements do not apply to these products.
- The package may include a "boot" with partial label information, but the full pesticide label is also visible.

Other products are sold/marked under a new name (different from the name of each pesticide product inside), and/or each pesticide label is not completely visible from the outside of the package.

- Based on existing EPA guidance, these products require separate EPA registration and/or label review by EPA (at least for kits).
- Based on preliminary product reviews, many marketed products may require separate registration and/or label review with EPA.
- Primary registrants, supplemental distributors, and/or third parties (e.g. retailers) are creating/selling/distributing these products. In some cases, third party retailers may be unlawfully producing and marketing their own kits, etc. which include other companies' EPA-registered pesticides (and even unregistered pesticides).

Examples of marketplace issues:

- Package/labeling (particularly kits) has a name that is different from the name(s) of the pesticide(s) inside, and the combination package does not have its own unique EPA Reg. No.
- Deviations in outer packaging labeling content (e.g. additions, omissions, formatting changes) compared to EPA stamped label(s) for the pesticide(s) inside.
- Pesticide label(s) not visible, or not completely visible, from outside of package.
- Supplemental distributors marketing combination products (particularly kits), presumably without oversight of the primary registrant(s).
- Third party sellers (any business other than a registrant or supplemental distributor) marketing their own combinations (particularly kits), presumably without registrant/distributor oversight.
 - a. Example: various combinations of herbicides/algaecides packaged with adjuvants
 - b. Example: home brewing cleaning kits (packages include a sanitizer)
- Unregistered (and non-exempt) pesticide included within package.
- Retailers opening packages and separately selling the products inside.

Lack of EPA registration results in administrative challenges for SLAs, and possible misbranding issues.

DEFINITIONS

1. Multiple Products Packaged Together (MPPT)

For the purpose of this document, the term "MPPT" will include all versions of kits, co-packs and multi-packs. This is new term; however, it is used in the US EPA Pesticide labeling Q&A website.

2. Kits

A kit includes multiple products and can contain one or more FIFRA-regulated products, along with, in some cases, one or more non-FIFRA products. Each product in the kit is separately

packaged and labeled – just as it would be if sold separately. The kit consists of an outer container, such as cardboard box, which houses the separately-packaged FIFRA and non-FIFRA products placed inside the outer container.²

The contents of a kit are not mixed together – an example of a kit would be for lice, where the kit includes a comb, shampoo (non-pesticide product) and a pesticide. Another example is a kit that includes different items for pool care.

EPA suggested we add pictures

3. Co-packs

Combo/Combination packs

A co-pack is when two or more pesticide products 1) are packaged in separate containers but sold together as a single unit or 2) are packaged in one container that keeps the chemicals separate until the consumer purchases the product and mixes the different pesticides together. Co-packs may direct the user to mix the two products together before application.

Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels must be duplicated and securely attached to the outermost container. (40 CFR 156.10(a)(4)(i))³

EPA suggested we add pictures

4. Multipacks

A multipack is when two or more pesticide products with the same EPA Registration Number are packaged together. Each container must bear the full pesticide label.

This could include different scents and different names but the same EPA Registration Number.

EPA suggested we add pictures

5. Shrink-Wrapped MPPT

When MPPT products are packaged together through shrink-wrapping so the entire container for the pesticide is visible to the consumer at the point of purchase.

EPA suggested we add pictures

Note: A new or amended registration is required by US EPA when there is a change in the directions for use or there is a new or alternate brand name for the MPPT.

² US EPA Pesticide labeling Q&A website, LCO7-106;10/29/07

³ US EPA Label Review Manual 18.IV.A, page 18-2

Distributor Products:

According to 40 CFR 152.132, the **distributor product must be exactly the same** as the basic registered product, except:

- The product name of the distributor product may be different (but may not be misleading);
- The name and address of the distributor may appear instead of that of the registrant;
- The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request);
- The establishment number must be that of the final establishment at which the product was produced; and
- Specific claims may be deleted, provided that no other changes are necessary.

This also applies to MPPT as well, the distributor product cannot do anything that the basic registered product cannot do, unless listed above.

Things to Look at During Inspections or Label Reviews

- If the full pesticide label (on the immediate container) cannot be seen through the outer package, the full pesticide label must be duplicated on the outer label (box, wrapping, etc.) for the MPPT.
- For a distributor product to be placed in a MPPT, the specific language (including the MPPT contents) must be on the basic registrant's master label
- When the pesticide product is sold with a non-pesticide or mixing agent (like an adjuvant), the two products can be sold together as a single unit only if the adjuvant is referred to in the Directions for Use on the Label.⁴

Frequently Asked Questions:

1. When does EPA not need to review the packaging of a MPPT?
If the approved label(s) is visible through the outer packaging (e.g. visible through shrink-wrap), or if the outer packaging is an exact replica of the approved label(s), EPA does not need to review the MPPT label.⁵
2. When does EPA require the review of a MPPT?
If the MPPT is sold under a separate name from its previously registered contents, the MPPT must be registered as a separate product and the kit label must be reviewed. 40 CFR 152.3 defines "pesticide product" as "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold." 40 CFR 156.10(b)(2)(ii) requires pesticide products to have unique names. Therefore, if the MPPT is considered anything more than the combination of separately named products (i.e., when the kit is marketed with its own distinct name), the MPPT must be registered.⁶
If the MPPT is being sold as a unique product requiring separate registration or the individual product labels are not visible from the outer container or the previously approved labels are not

⁴ US EPA Label Review Manual 18.IV.A, page 18-2

⁵ US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

⁶ US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

used on the outer container in their entirety without modification, EPA must review the labeling through the registration (in the case of a new product) or registration amendment process.⁷

The regulation at 40 CFR 152.3 states that the “pesticide product” includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and labeling of any “non-pesticide” which is part of the package. This means that EPA reviews and accepts or disapproves of the non-pesticide that is packaged with the pesticide.⁸

3. What is required on the outer package of a MPPT?

EPA may allow, if appropriate, a subset of the approved label to appear on the outer container. In all cases, the following items are required to be fully visible either through the outer packaging or on the outer container:

- Product Name.
- Registration Number.
- Ingredient Statement.
- Signal Word.
- Keep out of reach of children statement.
- Precautionary Statements.
- The full directions for use or a referral statement to read the labels on the containers in the box for full directions for use, including mixing or sequential use of the products.
- Name and address of producer or registrant.
- Net weight.
- If highly toxic, skull and crossbones, “poison,” and a statement of practical treatment in case of poisoning.
- Use classification (e.g. Restricted use).
- Establishment Registration.⁹

4. If a pesticide product is included within a kit, what is required on the immediate pesticide container within the MPPT?

If this were an appropriately-registered co-pack/kit product, full labeling would have to be present on the pesticide packaging, and the First Aid, ingredients, and precautionary statements, along with the product name and registration number, would have to appear on the outer packaging, with a referral to additional directions for use inside the packaging. And if the kit requires a new name or changes to the directions for use compared to the product(s) when used alone, it would need a new registration, potentially with additional product-specific data.

5. Can a distributor product be included within a MPPT that contains X,Y and Z, if the master label only identifies MPPT combinations of A, X and Y?

⁷ US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

⁸ US EPA Label Review Manual 18.IV.A, page 18-2

⁹ US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

If the stamped master label for the parent product includes MPPT language, then the supplemental distributor of that basic product can also have it, provided it mirrors the master label for the basic product. A supplemental distributor company cannot take one component and then make their own MPPT with it if it is not what the basic master label allows.

6. Does my MPPT require state registration if the individual pesticide is already registered in that state? States have different registration laws regarding which products require registration. It is recommended to connect with the registration department in each state to clearly identify if your product (as a MPPT) requires registration. [AAPCO State Lead Agencies - Points of Contact](#)

7. EPA has accepted the ABN or Supplemental Distributor product for my basic product that includes the word “kit”. Therefore, it must be OK to sell this product as a kit, right?

Not necessarily. Upon receiving the request for an ABN or 8570-5 form, EPA does not review the name of the product to confirm that it aligns with the basic product’s approved label.

Ultimately, if the basic master label does not include kit language, a distributor cannot include the pesticide product in a kit (see Q&A #6 and distributor product details above). If the ABN includes “kit” within the name, see Q&A #1 & 2 as to when EPA reviews kit contents. The review for kit contents may not be included in the master label that is available to SLAs on EPA’s PPLS. SLAs should confirm with the Project Manager at EPA for the basic product that the required review of kit content has been satisfied and the review is within EPA’s label folder for this specific pesticide product.

8. I want to sell a MPPT that includes a pesticide and market it for my small business. The MPPT would include non-pesticides and a pesticide. Can I do this?

Yes, but in order to package a MPPT that includes a pesticide you would need the following:

- i. Agreement with the basic registrant (would this be considered a supplemental distribution – if boxed, shrink-wrapped, etc...)
- ii. EPA Establishment Number
- iii. Language approving the use of a kit on the master label

9. If I shrink-wrap my MPPT together, does it require federal or state registration?

If the approved label(s) is visible through the outer packaging (e.g. visible through shrink-wrap), or if the outer packaging is an exact replica of the approved label(s), EPA does not need to review the MPPT label. If, however, the MPPT is sold under a separate name from its previously registered contents, the MPPT must be registered as a separate product and the MPPT label must be reviewed. 40 CFR 152.5 defines “pesticide product” as “a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold.” 40 CFR 156.10(b)(2)(ii) requires pesticide products to have unique names. Therefore, if the MPPT is considered anything more than the combination of separately named products (i.e., when the MPPT is marketed with its own distinct name), the MPPT must be registered.¹⁰

¹⁰ US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

10. If all I am doing is shrink-wrapping a pesticide into a MPPT, does that need to be completed in an EPA establishment?
- Is shrink-wrapping still considered production?
Yes, this is considered pesticide production.
 - If I am not the basic registrant, can I shrink-wrap products together without an agreement?
No, in order to shrink-wrap products together (package a MPPT) that includes a pesticide you would need the following Agreement with the basic registrant. (See question 8)
11. If my MPPT is shrink-wrapped and I add a sticker on the outside of the shrink-wrap (like “value pack”), does this constitute labeling and require that it is done in an EPA Establishment?
- Yes, affixing a sticker to a container is considered labeling and therefore production as defined in 40 CFR 167.3. 40 CFR 167.20(a)(1) requires any establishment where production occurs to be registered. Affixing a sticker must take place in a registered establishment.¹¹
- Exception is bar code stickers: Provided the bar code sticker is not being added to label to meet a labeling requirement and the bar code does not cover or obscure any required label element, EPA does not consider the placement of the bar code sticker on cartons and containers to be production that must occur in a registered establishment.¹²
12. What about online sales and marketing is this considered labeling?
Yes^{13, 14}
13. Alternate brand names (ABNs) / registration. Does EPA review and approve the names of MPPT submitted by companies to add ABNs for EPA-registered products inside the packages?
- With an ABN or Distributor product, EPA does little more than accept the additional name/8570-5 form. Clarification that the name is not false or misleading is not reviewed. **Follow up/confirmation from EPA on the process may be helpful.**
14. **What can State Lead Agencies (SLAs) conclude regarding registration compliance if the name of the MPPT is listed as an ABN in EPA’s Pesticide Product Label System (PPLS), but the MPPT doesn’t have its own unique EPA registration number? For example, “Product X Kit” is listed as an ABN for EPA-registered “Product X”, but “Product X Kit” doesn’t have its own unique EPA Reg. No.**
If “Product X Kit” is listed as an ABN for EPA registered “Product X” then EPA did not require it to have its own unique EPA Reg No.
15. **Can a MPPT contain more than one registrant’s product(s) (whether primary registrant or distributor)? Example: There was a registration submitted that had three different companies represented in a single MPPT. The registrant’s reasoning was that the two distributors represented (one was registering the MPPT) were owned by the primary registrant. We think the answer is NO, but would like EPA to clarify.**

¹¹ US EPA Pesticide Labeling Q&A Website, LC09-0303; 12/10/09

¹² US EPA Pesticide Labeling Q&A Website, LC12-0567; 10/23/12

¹³ EPA Label Review Manual 12.X, page 12-12

¹⁴ US EPA Pesticide Labeling Q&A Website, LC11-0436; 10/6/11

16. Can EPA please clarify the following:

- a. State the registration and labeling requirements for each type of combination product; how do they differ? Keep in mind many of these (kit) products are marketed by supplemental distributors.
 - i. When is separate EPA registration required for each type?
 - ii. Does separate EPA registration mean the combination product must have its own unique EPA registration number, and not just be marketed under an alternate brand name (ABN) for one of the EPA-registered products inside?
 - iii. What are the labeling requirements for each type?
 - iv. When is EPA label review required for each type?
 - v. What can a registrant NOT do with each type?
 - vi. What can a supplemental distributor NOT do with each type?
 - vii. Do registration/labeling requirements differ depending on whether the various components in the package must/can be mixed together?
 - viii. EPA's existing guidance on kits states "If, however, the kit is sold under a separate name from its previously registered contents, the kit must be registered as a separate product and the kit label must be reviewed."
 1. Does this also apply to other types of "multiple products packaged together"?
 2. Does the separate name have to appear on the packaging or outer label in order to trigger the separate registration requirement?
 - a. Some companies market/advertise/sell various combinations of products under names that do not necessarily appear on the actual packaging.
 - b. Examples: "pallets" and "packs" (or "pallet packs") where companies advertise certain combinations of products (e.g. turf fungicides) under new names (e.g. on sell sheets, flyers, websites) and the new names may appear on inventory and distribution records (e.g. invoices, shipping/receiving records).

Current Resources for MPPT:

EPA Pesticide Labeling Q&A Website: <https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers>

EPA Label Review Manual (LRM)

- Chapter 18, IV Multi-packs / co-packs
- *Submit errors or suggestions for the LRM on the [Pesticide Labeling Questions and Answers](#) page, which is a component of the [Pesticide Labeling Consistency](#) Web page.*

Pesticide Devices:

For questions about devices see [Pesticide Registration Manual: Chapter 13 - Devices | US EPA](#) or email OPPDeviceDeterminations@epa.gov