BPPD Substantially Similar and Technical Screen checklist for a B660 or B674

Please first review any appropriate guidance, including the PRIA fee category interpretation, the Label Review Manual, Pesticide Registration Manual (including Chapters 2, 6, and 10), etc. After determining substantial similarity or 100% repack (or not), complete the technical screen checklist.

B660 PRIA Fee Category Interpretation: An application for registration of an end-use or a manufacturing-use microbial or biochemical pesticide product which contains a registered source of active ingredient (i.e., the active ingredient in the proposed product is derived from an EPA-registered product), and the product is identical, or substantially similar, in its uses and formulation to products that are currently registered and for which the Agency must make a determination of similarity to a registered product.

If a review of data other than product chemistry is needed, the application does not fall in this category. For proposed new products for which product-specific data or waiver requests beyond product chemistry (e.g., efficacy, acute toxicity, companion animal safety, and/or child resistant packaging), must be submitted and reviewed to support the application, see category B670. For proposed new products containing an unregistered source of active ingredient or new generic (active ingredient) data, see category B672. For 100% repacks, see category B674.

All applications require the following:

- The active ingredient in the proposed product must be derived from an EPA-registered product.
- The applicant must identify the currently registered similar product, and this must be accurately reflected on the CSF.
- A data matrix (if data are cited or submitted)
- Product chemistry data (Group A and B). In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.
- Acute toxicity requirements must be addressed by using only: (1) the cite-all method, (2) selective data citation where the applicant owns all required data, or (3) applicant submits specific authorization letter from the data owner.

A formulator's exemption for generic data requirements can be claimed when the registered source of the active ingredient is owned by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, a formulator's exemption is not applicable, and the generic data used to support the active ingredient is instead referenced on the applicant's data matrix.

Substantially Similar: Product must have the same active ingredient, in substantially the same proportion, same chemical form (solid, liquid, granular), and substantially similar composition (inert ingredients) as the already registered product. In addition, substantially similar means that the proposed product bears the same use pattern. Adding to or changing existing use

patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.

Identical: Same composition and use patterns as a currently registered product.

B674 PRIA Fee Category Interpretation: An application for registration of an end-use or a manufacturing-use microbial or biochemical pesticide product that is a 100% repack of a registered end-use product, a 100% repack of a registered manufacturing-use product, or a repack of a registered end-use product as a manufacturing-use product.

All applications require the following:

- A formulator's exemption statement (or if the registered source of the active ingredient is owned by the current applicant, the data used to support the registered source must be referenced on a data matrix).
- The applicant must identify the currently registered product being repacked for this application in a CSF listing the original product in Box 10, the EPA registration number in Box 12, and "100% repack" in Box 13.

Submission of data or requests to waive data is not allowed in this category. Products that require a "substantially similar" determination fall under PRIA Category B660.

If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see PRIA fee category Table 12 for applicable new use categories).

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Date:

Review Date:

File Symbol:

EPA Reg No. application is claiming substantial similarity to:

Comments:

Determination of similarity (Yes/No): *Note: if **not** substantially similar give detailed summary as to why.*

If the product is a 100% repack, go to 100% repack checklist.

Checklist for Substantial Similarity					
	Checklist Item	**Yes**	**No**	**N/A**	**Comments**
1.	Is the product that the applicant is claiming to be substantially similar to currently registered? Note: The product that the applicant that is claiming to be substantially similar to must be currently registered. They cannot claim to be substantially similar to a cancelled or pending pesticide product.				

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2.	Is the active ingredient of the pending application from a registered source? There should be an EPA Reg. No. on the pending product's CSF for the active ingredient. The active ingredient(s) must be currently registered and the CSF must include its EPA Registration Number(s). If multiple AIs all need to be from a registered source.				
3.	Amount of Active Ingredient: Is the amount of AI of the pending product lower than the amount of AI of the cited product? A judgement call on the toxicity of the inert ingredients would be needed here from the science reviewer (for example water is the added inert). **FYI:** RD does take this into consideration for its Similarity Clinic.				

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4.	Is the pending product composition similar to the registered product the applicant claiming substantial similarity too? The CSF of the pending product will need to be compared to the most recent CSF of the registered product. A science reviewer will need to do this. The pending product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product.				
5.	Labeling/ Use Sites: Are the use site/rates of the pending product the same as the registered product? Note: Substantially similar also means that the proposed product bears the same use pattern. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.				
6.	A data matrix is required with the application if it is not a 100% re-packaged product.				

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7.	Product chemistry data (Group A and B) unless the product is identical (e.g., 100% repackaged product) is required. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.				
8.	Acute toxicity requirements must be addressed by using: a. The cite-all method. b. Selective data citation where the applicant owns all required data, or c. Applicant submits specific authorization letter from the data owner				
9.	Does the application contain efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data or waiver requests for these data? **Note:** The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data.				

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10.	Does the application require review of review of cited or submitted data other than product chemistry? **Note:** An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category.				

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Date:

File Symbol:

EPA Reg No. application is claiming 100% repack of:

Comments:

Determination of 100% repack (Yes/No): *Note: if **not** a 100% repack, give detailed summary as to why.*

If the product is a claiming substantial similarity, go to substantially similar checklist.

Checklist for 100% Re-pack (B674)					
	Checklist Item	**Yes**	**No**	**N/A**	**Comments**
1.	Is the product that the applicant is claiming to be substantially similar to currently registered? Note: The product that the applicant that is claiming to be substantially similar to must be currently registered. They cannot claim to be substantially similar to a cancelled or pending pesticide product.				
2.	Labeling: Is the pending product label identical to the product label which is being repackaged? The only differences should be the company name, address, name of product, and registration number.				

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BPPD Substantially Similar/100% Repack

45 Day Technical Screen

Date:

File Symbol:

Comments: *note if any calls to the registrant were made*

Pass/Fail:

Technical Screen Checklist for Substantially Similar/100% Repack					
	Checklist Item	**Yes**	**No**	**N/A**	**Comments**
1.	**Forms**				
a.	8570-1: Application for Registration				
b.	8570-4: CSF				
c.	8570-27: Formulator's Exemption				
d.	8570-34: Certification with Respect to Data				
e.	8570-35: Data Matrix (Not required for 100% repack) Has the Offer to Pay Box on the Certification with Respect to Citation of data Form? Does the Matrix Indicate Pay? Are any of the data that you are citing compensable? Has an Offer To Pay been made? Is documentation of said offer included in this application (Refer to 40 CFR 152.86 Cite All Method and/or 152.90 Selective Method)?				
2.	**Confidential Statements of Formula (CSFs)**				
a.	Signed and dated				
b.	Food-use? (If no, skip to 1e.)				
c.	Active cleared for food-use				*List exemption*
d.	Units in all applicable boxes				
e.	Is Reg. No. of source of AI on CSF?				

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f.	Does CSF indicate that the product is a repack of an existing product and list registration number?				
g.	Does CSF indicate supplier of repackaged product?				
3.	**Label**				
a.	For 100% repack: is proposed label identical to registered product label, except for brand name, file symbol, address(es).				
b.	Restricted Use Pesticide statement (If applicable)				
c.	Product name, brand or trademark				
d.	Ingredient statement correct? Microbial: strain designation Microbial: potency designation				
e.	"Keep Out of Reach of Children" (KOOROC) Statement				
f.	Signal word				
g.	First aid statement				
h.	Net contents/net weight				
i.	EPA Reg. No. and Establishment No.				
j.	Company name and address				
k.	Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement				
l.	Environmental hazards				
m.	Physical and chemical hazards (if app.)				
n.	Directions for use				
o.	Storage and disposal				
p.	Warranty statement				
q.	Worker protection				
r.	Batch code				