



# **US Environmental Protection Agency Office of Pesticide Programs**

**PRIA 2 – 21 Day Content Screen Review Worksheet**  
(EPA/OPP Use Only)  
April 9, 2008

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4/9/08

21 Day Screen Start Date: \_\_\_\_\_

Experts In-Processing Signature: \_\_\_\_\_ Date \_\_\_\_\_ Fee Paid: Yes \_\_\_

Division management contacted on issues: No \_\_\_\_\_ Yes \_\_\_\_\_ Date \_\_\_\_\_

EPA Reg. Number:		EPA Receipt Date:						
Items for Review						Yes	No	N/A*
1	<b>Application Form</b> signed & complete including package type ( <a href="#">EPA Form 8570-1</a> )							
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated ( <a href="#">EPA Form 8570-4</a> )							
	All <u>inerts</u> , except fragrances, approved for food and non food proposed uses (see Footnote A)				yes	no		
3	<b>Certification with Respect to Citation of Data</b> completed and signed (N/A if 100% repack) ( <a href="#">EPA Form 8570-34</a> )							
	Certificate and data matrix consistent							
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)				yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.							
4	<b>Formulator's Exemption Statement</b> completed and signed (N/A if source is unregistered or applicant owns the technical) ( <a href="#">EPA Form 8570-27</a> )							
5	<b>Data Matrix</b> both internal and external copies completed and signed (N/A if 100% repack) ( <a href="#">EPA Form 8570-35</a> ) ( <a href="#">PR 98-5</a> )							
	a) Selective Method (Fee category experts use)				yes	no		
	b) Cite-All (Fee category experts use)							
	c) Applicant owns all data (Fee category experts use)							
6	<b>5 Copies of Label</b> ( <b>Electronic labels on CD are encouraged</b> ( <a href="#">guidance</a> ))							
7	Is the data package consistent with <a href="#">PR Notice 86-5</a>							
8	<b>Notice of Filing included with petitions</b> ( <a href="#">tolerances</a> and <a href="#">tolerance petitions</a> )							

9	If applicable for conventional applications, <a href="#">reduced risk</a> rationale			
	<a href="#">Required Data</a> and/or data waivers. (See Footnote C)			
10	a) List study (or studies) not included with application			

**Comments:**

\* N/A – Not Applicable

## Footnotes

A. This consideration does not apply to PRIA applications that include a request to approve an inert in the fee category. For these PRIA actions, information needs to be submitted to enable the Agency to review the inert approval request and will be a subject of the 21 day content screen. For other types of actions and for fragrances, the answer is only for the Agency's information and current policies, processes, and procedures should be consulted. This worksheet will be updated in the future to be consistent with current policies.

If brand, trade, or proprietary names are being used for some inert ingredients listed on the CSF, alternate names or additional information on the nature of the ingredient(s) should be provided to allow the Agency to determine whether the inert has been approved.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.