

BPPD Old Active Ingredient Checklist

New Product Registration/Existing Product Amendment

Fast Track PRIA Actions B650 , B660 , B670 , B672 , B680 , B681 , B710 ,
B720 , B721 , B730 , B880 , B881 , B890 , & B900

EPA Reg. No.:

RAL:

Application Date:

#	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.		
2.	If amendment, was final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling.		
3.	Confidential Statement of Formula (CSF) EPA Form 8570-4 Basic Formula <input type="checkbox"/> Alternate Formula(s) <input type="checkbox"/> _____		
a.	CSF Review completed? IF YES, SKIP to ITEM 4.		
b.	CSF is signed and dated? IF NO, CALL APPLICANT.		
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?		
d.	Are the totals accurate?		
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).		
f.	Viability (if live microbial, i.e., cfu/gram)? NA <input type="checkbox"/>		
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?		
h.	List 1 inert ingredient(s) present in the formulation? If YES, be sure it is listed on the label.		
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs per 40 CFR 152.43(b)(3). NA <input type="checkbox"/>		
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)		
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? IF YES , RAL must evaluate label directions for compliance with 40 CFR 180.1071.		
4.	Data and Data Matrix present. (EPA Form 8570-35)		
a.	a) Using Selective Method? [IF NO, SKIP to item 5 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.]		
b.	Complete Data Matrix supporting both the product registration and, if applicable, the		

	proposed amendment. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.		
c.	Adequate product specific data submitted?		
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 5. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) IF NO or if use not supported by registered source, generic data is necessary.		
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
5.	Certification with Respect to Citation of Data (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, form is not needed. This is often true for minor amendments.]		
a.	Did applicant check a Method of Support?		
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		
c.	Is the form signed and dated?		
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?		
e.	IF YES, is the required authorization letter included in application?		
6.	Formulators Exemption (EPA Form 5870-27)		
a.	If registrant is using a registered source active ingredient in the formulation (manufacturing-use product), is form filled out completely and signed? NA <input type="checkbox"/>		
7.	Exclusive Use Notice Requirement Prior to Registration (Required per 40 CFR 152.116, separate from permission of an exclusive use data submitter to rely on exclusive use data) Is this an exclusive use active ingredient or mix of active ingredients (registered w/in last 10 yrs)? If YES, go to a) or b) below.		
a.	a) Has a notification of intent to register letter or email been sent to the exclusive use data submitter(s) at least 30 days before registration? (This notification is required for all methods of data support except when the exclusive use data submitter(s)' product is used to formulate and the formulator's exemption is claimed.)		
b.	Has exclusive use data submitter requested during 30 day period the applicants' list of data requirements and method of compliance?		
c.	Has registrant submitted certification from exclusive use data submitter that submitter is aware of the application and does not object to the registration ?		
8.	Science Review completed? Comments:		

9.	Label(s) Review	<u>Date of Label Review:</u>	
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.		
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.		
c.	Nominal concentration of active ingredient shown in ingredients statement.		
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).		
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).		
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES , RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		
h.	Does label bear “National Organic Program”(PR Notice 2003-1) or OMRI claims?		
i.	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer? NA <input type="checkbox"/>		
	Labeling is acceptable. Corrections or changes are NOT necessary.		
j.	Comments:		
10.	If new use sites are being added, are they subject to OPP’s process for public involvement in pesticide registration actions?		
11.	BPPD Registration with Conditions/Terms Logbook		
a.	Type of Registration: Conditional or Unconditional		
b.	Does this registration have terms/conditions (ex: storage stability data)? IF THE REGISTRATION HAS TERMS/CONDITIONS THIS INFORMATION MUST BE ENTERED INTO THE LOGBOOK For BPPD Registrations with Terms/Conditions FOR THE APPROPRIATE BRANCH.		
c.	If there are term/conditions to the registration notice has this information been placed in the <u>LOGBOOK For BPPD Registrations with Terms/Conditions</u>		