



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Memorandum

To: Office of Pesticide Programs Staff
Office of Chemical Safety and Pollution Prevention

From: Jeff Herndon, Associate Division Director
Office of Pesticide Programs, Registration Division

Subject: Confidential Statements of Formula for End-Use Products (EPs) and Manufacturing Use Products (MUPs) REVISED

Jeff Herndon
9/11/12

Some registrants of end-use pesticide products (EPs) and manufacturing use products (MUPs) formulated from a **registered source of active ingredient** have proposed a different approach to completing EPA Form 8570-4, the Confidential Statement of Formula (CSF). Instead of providing multiple, alternate CSFs reflecting each potential formulation site (Box 2 of the CSF), each potential country where production may occur (Box 6), and each potential supplier of a specified inert ingredient (Box 11), the registrants have proposed to do the following:

- Identify in Box 2 of the CSF the name, title, company name, address, and telephone number of the appropriate company contact for production-related questions. Optionally, companies can also provide an attachment to the CSF that lists production sites. For the purposes of this attachment, if provided, production is interpreted as mixing, blending, or diluting (see also 40 CFR part 158.300 *Formulation* [1]). Formulation of these products can take place in multiple facilities, including contract manufacturing facilities, but always must be under control of the registrant. Further, production must always occur at a registered establishment. The product label will identify the final production site.
- Provide an attachment to the CSF that lists alternate countries in which the EP is formulated. For the purposes of this attachment, formulation is interpreted as mixing, blending, or diluting (see also 40 CFR part 158.300 *Formulation* [1]) (Box 6 of the CSF).
- Provide an attachment to the CSF that lists alternate suppliers of the inert ingredients (Box 11 of the CSF).

Through discussions with the regulated community, Office of Pesticide Programs (OPP) has determined that this approach will still allow the agency to fully evaluate the proposed products to make a sound regulatory decision. Further, OPP believes this approach can help to alleviate the agency's handling and tracking of many pages of alternate CSFs and help to reduce registrant burden. Therefore, OPP will accept attachments to a basic or an alternate EP/MUP CSF. An alternate CSF may be necessary when different inert ingredients are used or when any component

exceeds the certified limits specified on the basic CSF¹. OPP understands these attachments will provide the same information and assurances that would be needed if submitted as a new, alternate CSF, as follows:

- Any change in ingredient source would not result in a change to the composition of the product as listed on the original (basic or alternate) CSF. In other words, alternate suppliers would be supplying material with the same percentage of the inert ingredient.
- The name(s) and address(es) of any alternate suppliers of inert ingredients used in the formulation will be provided.
- The names of any alternate countries in which product may be mixed, blended, or diluted to obtain an EP/MUP product will be provided.
- Box 6 of the CSF to which the attachment applies will indicate "see attachment," if product is mixed, blended, or diluted in more than one country.
- Box 11 of the CSF to which the attachment applies will indicate "see attachment," if there are alternate suppliers of the specified component.
- The attachments will indicate the date of the CSF to which the attachment applies (the dates will match, as the attachment form would not be appropriate in the absence of a cover CSF), and pages will be numbered consecutively.
- The form and attachment will be identically signed and dated by the registrant.


Attached is an example of the format in which registrants may provide this information. The information in bold and red reflects the conditions above.

Please also note it is not appropriate to require this information of registrants in this format; however, if the information is provided in this format and all conditions are met, OPP has committed to accepting this submission format for end-use products formulated using an EPA-registered source of the active ingredient. It is important to keep in mind that, in cases where this option is used, the CSF form and attachment will represent the complete CSF. Therefore, any CSF changes would require submission and review of both the CSF and the attachment. In addition, if a registrant is using this approach to replace existing CSF(s), they should clearly identify the CSFs the new version is intended to replace.

Please let Jeff Herndon (RD), Debbie McCall (RD), Karen Hicks (AD), Maria Piansay (PRD), or Andrew Bryceland (BPPD) know if you have any questions.

cc: Andrew Bryceland, BPPD
Karen Hicks, AD
Debbie McCall, RD
Maria Piansay, PRD

¹ Insure existing efficiencies continue to be allowed. Examples of these include dyes, fragrances and fertilizers.

 United States Environmental Protection Agency Washington, DC 20460		A. <input checked="" type="checkbox"/> Basic Formulation <input type="checkbox"/> Alternative Formulation		B. See Instructions on Back Page 1 of 3	
Office of Pesticide Programs (7505C) – Confidential Statement of Formula					
1. Name and Address of Applicant/Registrant (Include ZIP Code) ABC Company 123 Any Street Anytown, ST, USA 12345		2. Name and Address of Producer (Include ZIP Code) Name and Address of appropriate company contact for production-related questions (i.e. party responsible for production) See attachment			
3. Product Name Pesticide End Product		4. Registration No./File Symbol 00000-99		5. EPA Product Mgr/Team No.	
6. Country Where Formulated USA (see also attachment)		7. Pounds/Gal or Bulk Density Xx		8. pH xx	
9. Flash Point/Flame Extension xx		10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number)		11. Supplier Name and Address	
11. EPA USE ONLY		12. EPA Reg No.		13. Each Component in Formulation	
Active ingredient chemical (50% ai) CAS No. xxx-xx-xxx Everyday Chem® ABC (chemical ABC) CAS No. 1234-56-7		9999-99		a. Amount (lb) b. % by weight 25 25.0 (12.5) 26.5 26.5	
Best Stuff® Proprietary mixture				14. Certified Limits a. Upper Limit b. Lower Limit (12.88) (12.12)	
Common Stuff CAS No. 99-88-7				25.70 25.70	
				15. Purpose in Formulation Active ingredient Surfactant	
				0.5 0.55 0.45 48 49.44 46.56	
				Fragrance Diluent/ balance	
16. Typed Name of Approving Official Same as the person signing and dating the attachment.		17. Total Weight 100		100%	
18. Signature of Approving Official		19. Title		20. Phone No. (Include Area Code) 21. Date Same as date of attachment	

CONFIDENTIAL BUSINESS INFORMATION – Example ABC Company

ATTACHMENT [A] – ALTERNATE LIST
 TO [DATE must match associated CSF and signature below]
 CONFIDENTIAL STATEMENT OF FORMULA [EPA Form 8570-4]
 Page 2 of 3

PESTICIDE END PRODUCT
 EPA REGISTRATION NUMBER: 00000-99

Basic Alternate

CSF BOX 2 (Please note that registrants may provide name and address of appropriate company contact for production-related questions (i.e, party responsible for production) in lieu of or in addition to the following table)

Name and Address of Additional Producer(s)	EPA Establishment Number
Contact Name, Title, Phone Number Company Name and Address: Pete's Example Site 12345 Example Lane Anytown, Anystate Zip, USA	00000-AS-1
Contact Name, Title, Phone Number Company Name and Address: Pete's Sample Location 23456 Sample Court Anytown, Anystate Zip, USA	00000-AS-3
Contact Name, Title, Phone Number Company Name and Address: Pete's NEW Location 34567 New Street Anytown, Mexico	00000-Mexico-4
Contact Name, Title, Phone Number Company Name and Address: Pete's Sample Site 34567 Exotic Ave. Downtown, Australia	00000-Australia- 5

CSF BOX 6

Alternate Country(ies) Where Formulated
Mexico, Australia

 Typed Name and Title of Registrant
 Approving Official

 Signature of Registrant Approving
 Official

 Date [must match associated CSF]

Attachments to [date] EPA Memorandum
Example documents; do not contain Confidential Business Information

CONFIDENTIAL BUSINESS INFORMATION – Example ABC Company

ATTACHMENT [A] – ALTERNATE LIST
TO [DATE must match associated CSF and signature below]
CONFIDENTIAL STATEMENT OF FORMULA [EPA Form 8570-4]

Page 3 of 3

PESTICIDE END PRODUCT
EPA REGISTRATION NUMBER: 00000-99

Basic Alternate

CSF Box 11
Alternate Supplier List

Ingredient: Everyday Chem® ABC
CAS No.: 1234-56-7
Common Trade Name: chemical ABC

Supplier	Address
West Coast Ltd.	Downtown, Australia
Generis Distributors	Anytown, Mexico

Ingredient: Best Stuff®
CAS No.: Proprietary

Supplier	Trade Name	Address
AB Manufacturing	Best Stuff AU®	Downtown, Australia
ALVO Distribution	Mejores Coses®	Anytown, Mexico

Ingredient: Common stuff
CAS No.: 99-88-7
Common Trade Name: stuff

Supplier	Address
Westman Chemical	Anytown, Anystate USA
Southside Supply	Anytown, Anystate USA
Outback Ltd.	Downtown, Australia

Typed Name and Title of Registrant
Approving Official

Signature of Registrant Approving
Official

Date [must match associated CSF]