How to Prepare
a Confidential Statement of Formula (CSF)
for Biochemical and Microbial Pesticides

07/31/02 CSF-for web-3
OPP/BPPD
bmandula

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Confidential Statement of Formula (CSF)–General

Introduction

The Confidential Statement of Formula (CSF), Form 8570-4, is a crucial part of submissions related to new pesticide products. The form lists all the components and their percent by weight in your product, and various additional information. [See previous item for instructions on getting form.]

Note: All **21** items in the form must be addressed, *plus* items A and B at the top. In filling out the CSF, you should:

- Use the information provided in this document, including sample forms
- Consult the instructions provided with Form 8570-4 from the website.
- Contact your BPPD person for clarification

You may fill out the CSF form on-line, with a typewriter, or by hand.

Enforceability

The certified limits in the CSF (Items 14a and 14b) are legally enforceable. Therefore, when you fill out these items, you should be certain that the composition of your end product will be within those expressed limits.

Consistency

Several sections of your full submission rely in part on the same data. You will need to make sure that the data you provide in different sections of your submission agree with each other. Examples of data and information that must be consistent include:

- Label information regarding ingredients and their percentages by weight
- Data on certain physical and chemical properties
- Information provided on the CSF
- Other information, e.g., manufacturing process

It is your responsibility to make sure there are no inconsistencies in your submission. When a reviewer finds such inconsistencies, you will be asked to fix them, which may delay the processing of your submission.

Organization of this document

The remainder of this document provides instructions on filling out Items 1 to 21, and A and B, appearing on the CSF.

Items 1-9. Background Information

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Items 1-3; 6 Provide required information, including zip codes in addresses

Item 4: Registration No. Leave this blank if EPA has not given you a registration number for the product.

Item 5: EPA Project Manager/Team No.

For a biochemical pesticide: Sheryl Reilly, Team No. 91

For a microbial pesticide: Phil Hutton, Team No. 92

Note: If you are not certain, contact: jones.russell@epa.gov

Item 7: Density Use the guidance in the table below to quantify the density of your product.

Note: You may use metric **or** British units throughout the CSF, **but not both**.

IF the product is	THEN provide data as
A liquid	Weight/volume of liquid product, i.e., pounds per gallon. [Pure water is 8.3 pounds/gallon or 1gm/ml]
A solid that is a powder or is granular	Weight/volume of powder or granules, e.g., pounds per cubic foot; grams per cubic centimeter
A tablet, briquette, or other uniformly shaped product	Weight per formulated piece, e.g., grams per tablet

Item 8: pH Needed only for aqueous solutions.

- Otherwise use "N/A" for "Not applicable"

Item 9: Flash point Needed only for pressurized products and those expected or known to burn.

- Otherwise use "N/A"

Item 10: Components of Formulation

10:Introduction

You need to follow directions carefully to fill out Item 10 correctly.

- A component can be a pure ingredient, or a formulation containing more than one ingredient.
- For components that contain one or more active ingredients, you must include the percent by weight of each active ingredient. (As shown in the sample form, 95% of component 1, by weight, is active ingredient.)

- Each component intentionally present in your product must be listed individually if it is present in the product at a concentration of 0.1% or more by weight. These components fall into two general categories:
  - **Active** ingredients. These are ingredients that have some active role in controlling the pest. Active ingredients may be contained in components, or may be pure components themselves.
  - **Other** components (such as water, emulsifiers, preservatives, carriers). These Other components almost always have a purpose in the product, but are not directly active against the pest.

- For components not intentionally present in the product (e.g., contaminants, impurities):
  - Each component that may have toxic effects must be listed separately, even if present at less than 0.1% by weight.
  - Impurities and contaminants that do not have toxic properties can be lumped together on the CSF as "Other ingredients," if each is below 0.1% by weight.

Note: For your product labels, you are required to list each active ingredient and its percentage by weight in the product, but you may lump together all other components as "Other ingredients."

10: Biochemical and chemical components

For each biochemical and chemical component that you list, provide ALL the information that Item 10 calls for, as available

- Common chemical name (s)
- Trade name (s)
- CAS number and CAS name

Next item

If your active ingredient is a biochemical (i.e., is NOT a microbial), proceed to Item 11.

Continued on next page

Item 10: Components of Formulation, Continued

10. Microbial components– special requirements

Background: This section largely assumes that you are working with a viable microbe as your active ingredient. EPA requires you to relate the weight of a microbial active ingredient to a biological characteristic, (e.g., spores/gm).

[**Note**: If you are using non-viable microbes, spent growth media, or culture extracts in your product, consult with your BPPD representative early in the registration process, and certainly before filling out the CSF.]

Viable microbial active ingredients may be in the form of

- bacteria
- fungal spores and mycelia
- virus particles
- protozoan spores
- other

Information Required in Item 10 for each microbe listed (see sample form for a microbial active ingredient)

- Provide genus, species, strain, and any other identifiers.
- Provide ID number for strain assigned by the recognized collection (e.g., DSMZ, ATCC) where the microbe is deposited.
  - EPA requires you to deposit your microbe in such a collection.
- Provide a biologically relevant measure for the activity of your active ingredient, as noted below:
  - Bacteria and most fungi: colony-forming units (CFU) per wt. of active ingredient.
  - Fungi that require a live host for growth: number of spores per wt. of active ingredient.
  - Nucleopolyhedral and granulosis viruses: Number of polyhedral occlusion bodies or granulosis capsules per wt. of active ingredient.
  - Other. If you want to use a different biological measure for your active ingredient, contact your BPPD representative.
- NOTE: When you prepare your product label, you will use this biological measure to calculate number of spores, etc. for a given weight of product, (e.g., 5×10^{10} spores/lb. for a one-pound package, **or** 3×10^{7} CFU/gm of product, regardless of package weight).

NOTE: For the non-microbial components in Item 10, as well as for the remaining Items in the CSF, the same instructions apply whether or not there is a microbial component.

Items 11 and 12

Item 11: Supplier	Provide full name and address, including city, state, zip code, and country (if not U.S.) of supplying company For more than one known supplier, provide the information for each supplier
Item 12: Product registration number	If the component is a registered pesticide product, provide the EPA registration number. Otherwise, leave blank.

Items 13 and 17: Amount and Percentage of Each Component in Your Product

Quantifying the formulation

For each component of your product listed in Item 10, you need to determine

- what percentage by weight of your product, on average, consists of that component (13b), and
- what are the upper and lower limits on that average percentage (14a, b).
  - lower limit must be greater than zero

Special instructions for component that contains active ingredient

As noted earlier in Item 10, the active ingredient (ai) may be

- pure active ingredient (100% ai), or
- active ingredient containing additional substances (less than 100% ai). In the sample form, the active ingredient is 95% of component 1.

For Items 13 and 14, if the active ingredient is **not** 100 % of the component, you must provide the required information for BOTH

- the component, and
- the active ingredient

IMPORTANT: As shown on the sample form, the information for the active ingredient is placed in parentheses, e.g., (10.5%), whereas information for the component is listed without parenthesis, e.g., 11.0%. See sample forms for appropriate footnote to use when needed.

Notes:

- If the active ingredient component is 100% active ingredient, you do not need to use parentheses or a footnote.
- In the PDF format, you may need to use two (or more) cells under Item 10 (and Items 13 and 14)--one cell for the component and the second for the active ingredient contained in it.

Quantification for an EUP

For an Experimental Use Permit (EUP) application, you still need to provide an average percent by weight for each component in your product (13b), as well as upper and lower limits to that average (Items 14a and b), but you need not follow the rigorous process described below.

- For example, you may be able to use a broader range for upper and lower limits, or fewer than five batches.

Continued on next page

Items 13 and 17: Amount and Percentage of Each Component in Your Product, Continued

Quantification for registration

Using appropriate analytical techniques, analyze the percent by weight of each component in at least five batches of your product.

The arithmetic average* of the five measurements provides the percent concentration you will use on the CSF for each component. (**Note**: the five analyses for each component should be close enough in value so that averaging them is statistically valid.)

* An arithmetic average is obtained by adding together the values for each of your measurements, and dividing by the number of measurements.

13a and 13b

For each component listed in column 10, use the results of your five batch analysis (above) to provide the following information:

Item 13a. Weight of component per given weight of product, e.g., 5 lb per 100 lb, or 15 kilograms per 100 kilogram.

Item 13b. Percent by weight of that component in final product

Note: If you use 100 lb or 100 kg as your total weight in Item 17, then the numbers in items 13a and 13b will be identical

Numbers MUST add up

CHECK YOUR ARITHMETIC!

- Make sure that the weights of components in column 13a add up to the total weight listed in Item 17.
- Make sure that the percents of components in column 13b total 100% and are consistent with numbers provided in column 13a.

Item 14: Certified Percent Limits for Components in Your Product

Reminder

Each component in Item 10 can consist of

- a single ingredient, or
- more than one ingredient

Which components need limits?

The certified percent limits apply to

- each component containing an active ingredient (as well as to the active ingredient itself.)
- each Other component that is intentionally present (you must use a lower limit greater than 0%.
- each impurity present in the product at greater than 0.1% by weight (needs only upper limit)

These certified percent limits are legally enforceable.

Active ingredients get VIP treatment

- As shown in the sample form, if an active ingredient is part of a component that includes other ingredients, you must calculate the percent of each active ingredient in your final product (13b) so that you can calculate upper and lower limits in 14a and 14b.
- To estimate percent of active ingredient in final product, multiply percent of component in product (13b) by percent of the component that is active ingredient.
  - In the sample form for component 1, 95% x 11% gives 10.5%.

Estimating percent limits–generic

The percent limits on the components above depend on their percent by weight in your product, as shown in tables below. The following table (modified slightly from 40 CFR 158.175), tells you how to calculate the permissible upper and lower percent limits that you need. A sample table follows the generic table.

- If you want to request limits other than the standard ones, consult the CFR reference above (40 CFR 158.175) and your BPPD contact. Broader limits are often appropriate for microbial active ingredients and for some biochemicals.

Continued on next page

Item 14: Certified Percent Limits for Components in Your Product, Continued

Definition: N is the average (or nominal) percentage by weight of a component (or an active ingredient that is part of a component).

Generic table for estimating upper and lower percent limits for Item 14 of the CSF

N (% listed in column 13b)	**Formula for estimating % limits**	**Upper limit (% by weight)**	**Lower limit (% by weight)**
Less than or equal to 1%	N plus or minus 10% N	N x 1.1	N x 0.9
Greater than 1% but less than or equal to 20%.	N plus or minus 5% N	N x 1.05	N x 0.95
More than 20%	N plus or minus 3% N	N x 1.03	N x 0.97

Sample of actual calculation of percent limits for Item 14 of Biochemical Sample CSF

N (% listed in column 13b)	**Formula for estimating % limits**	**Upper limit (% by weight)**	**Lower limit (% by weight)**
11.0%	11.0% plus or minus (5% x 11.0%)	11.0% x 1.05 =11.55%	11.0% x 0.95 =10.45
0.5%	0.5% plus or minus (10% x 0.5%)	0.5% x 1.1 = 0.55%	0.5% x 0.9 = 0.45%
6.0	6.0 % plus or minus (5% x 6%)	6.0% x 1.05=6.3%	6.0% x 0.95 = 5.7%
82.5%	82.5. plus or minus (3% x 82.5%)	82.5% x 1.03= 85%	82.5% x 0.97 = 80%

Notes on upper and lower limits

- Make sure that you put the UPPER limit in column **14a**, and the LOWER limit in column **14b**.
- If you want to use wider limits than those described, provide your BPPD contact with data and a rationale for the alternate limits you are proposing.

Remaining Items (15, 16, 18-21, A, B)

Item 15: Purpose of component

OPP is responsible for ensuring that the components in your product are approved for the purposes you are using them.

For each component, state its purpose in the formulation.

- Purposes include: active ingredient, emulsifier, preservative, solvent.
- For Other ingredients, the purpose must be consistent with purposes EPA has already approved, as listed in 40 CFR, Section 180.1001.
  - Your BPPD contact can provide guidance.

Items 16; 18-21: Signature, date, etc.

You must fill in these items for the CSF to be considered complete.

Items A and B (top of form)

Item A will normally be a basic formulation unless you have reason to believe it is an alternative formulation (check with BPPD)

Fill in Item B as appropriate, depending on number of CSF pages you are submitting.

Sample CSF Forms

Sample Biochemical CSF form: filled out

Sample Microbial CSF form filled out

U.S. Environmental Protection Agency, DC 20460	A. x9 Basic Formulation 9 Alternative Formulation	B. Pg 19 of 1 9	See Instructions

Biopesticides and Pollution Prevention Division (7511C)–Confidential Statement of Formula

1. Name and Address of Applicant/Registrant *(include ZIP code)* **XYZ Chemical Company, 1234 Water Street, Suite 555, City, State 00000-0000**				2. Name and Address of Producer *(include ZIP code)* **QXR Manufacturers, 5678 Raptor Road, Suite 543, City, State, 00000-0000**			
3. Product Name **Flyaway-Flee** Sample: BIOCHEMICAL Active Ingredient				4. EPA Registration No./ File Symbol (if known) **00000-E**		5. Team Leader/Team No. **Sheryl Reilly–91**	6. Country where Formulated **United States**
				7. Density (wt/vol or wt/unit) **0.85 g/cc**		8. pH **6-7**	9. Flash Point/Flame Extension **NA**
EPA Use Only	**10.** Components in Formulation *	11. Supplier Name and Address	12. EPA Registration No. (if there is one)	13. Each Component in Formulation		14. Certified Limits: % by Weight	15. Purpose in Formulation
				a. Amount	b. % by Weight	a. Upper Limit / b. Lower Limit	
	Component 1 (95% active ingredient) CAS No 0000-00-0/name	**Company Name, Street Address, ZIP**	**00000-00**	**110.0 (104.5) ****	**11.0 (10.5)****	**11.55 (11.0)**** / **10.45 (10.0)****	**Active Ingredient**
	Water: CAS No. 7732-18-5	**Company Name (even if local source) Street Address, ZIP**		**60.0**	**6.0**	**6.3** / **5.7**	**Diluent**
	Component 3 CAS No 00000-00-0 /name	**Company Name, Street Address, ZIP**		**5.0**	**0.5**	**0.55** / **0.45**	**Antioxidant**
	Component 4 CAS No 000-00-0/name	**Company Name, Street Address, ZIP**		**825**	**82.5**	**85.0** / **80.0**	**Carrier**
16. Typed Name of Approving Official **Jesse Q. Smith**				17. Total wt. **1000 gm**	100%		
18. *Signature* of Approving Official Jesse Q Smith		19. Title of Approving Official **Manager, Regulatory Affairs**				20. Phone No. (include area code) **000-000-0000**	21. Date **April 1, 2002**

* *Biochemical/Chemical*: common chemical name; trade name; CAS No. and CAS name

* *Viable microbe*: full identifying scientific name; ID No. in recognized collection; biological activity (e.g., CFU/gm)

** Values in ( ) refer to the amount or percent of pure active ingredient in the product, e.g., Flyaway-Flee. The percent in ( ) in column 13b will appear on the product's label as percent active ingredient.

U.S. Environmental Protection Agency, DC 20460	A. x9 Basic Formulation 9 Alternative Formulation	B. Pg 19 of 1 9	

Office of Pesticide Programs (7511C)–Confidential Statement of Formula

1. Name and Address of Applicant/Registrant *(include ZIP code)* **XYZ Chemical Company, 1234 Water Street, Suite 555, City, State 00000-0000**	2. Name and Address of Producer *(include ZIP code)* **QXR Manufacturers, 5678 Raptor Road, Suite 543, City, State, 00000-0000**		
3. Product Name **BugaBoo-Hoo** Sample: MICROBIAL	4. EPA Registration No./ File Symbol (if known) **00000-G**	5. Team Leader/Team No. **Phil Hutton–92**	6. Country where Formulated **United States**
	7. Density (wt/vol or wt/unit) **0.5 g/cc**	8. pH **6-7**	9. Flash Point/Flame Extension **NA**

EPA Use Only	**10.** Components in Formulation *	11. Supplier Name and Address	12. EPA Registration No. (if there is one)	13. Each Component in Formulation		14. Certified Limits: % by Weight		15. Purpose in Formulation
				a. Amount	b. % by Weight	a. Upper Limit	b. Lower Limit	
	***Streptococcus pesticidus* strain AHR-999 (95% active ingredient); ATCC # 00000; minimum 10^8 CFU/gm**	**Company Name, Street Address, ZIP**		**110.0 (104.5) ****	**11.0 (10.5)****	**11.55 (11.0)****	**10.45 (10.0)****	**Active Ingredient**
	Component 2 (CAS No 0000-00-0/name	**Company Name, Street Address, ZIP**		**825**	**82.5**	**85.0**	**80.0**	**Carrier**
	Component 3 CAS No 000-00-0/name	**Company Name, Street Address, ZIP**		**60.0**	**6.0**	**6.3**	**5.7**	**Preservative**
	Water: CAS No. 7732-18-5	**Company Name (even if local source) Street Address, ZIP**		**5.0**	**0.5**	**0.55**	**0.45**	**Unremovable moisture**
Active	Ingredient							
16. Typed Name of Approving Official	**Jesse Q. Smith**			17. Total wt. **1000 gm**	100%			

18. Signature of Approving Official Jesse Q Smith	19. Title of Approving Official **Manager, Regulatory Affairs**	20. Phone No. (include area code) **000-000-0000**	21. Date **April 1, 2002**

* *Biochemical/Chemical*: common chemical name; trade name; CAS No. and CAS name

* *Viable microbe*: full identifying scientific name; ID No. in recognized collection; biological activity (e.g., CFU/gm)

** Values in ( ) refer to the amount or percent of pure active ingredient in the product, e.g., BugaBoo-Hoo. The percent in ( ) in column 13b will appear on the product's label as percent active ingredient.