Product chemistry Tips for Antimicrobials

1. Complete form 8570-1 (Application for Pesticide Product). Make sure this form is signed and dated.

2. Include a transmittal document (cover letter) that details the purpose for submission.

3. Follow PR Notice 86-5 (Standard Format for Data Submitted Under FIFRA).

4. Complete form 8570-4 (Confidential Statement of Formula). Follow the instructions on the back of the form.

A. Make sure a box is checked for the basic or alternate formulation. If there is more than one alternate formulation, include a special designation or identification such as; alt #1, alt a,b,c, etc… In reference to alternate formulations, the following must apply:

1. The identity of the active ingredients must be the same as the basic.
2. The alternate formulation should not have a toxic inert or impurity of toxicological significance that is not present in the basic formulation.
3. The certified limits of the active ingredients must be the same on the basic and alternate formulation.
4. Inerts must be the same or substantially similar between the alternate and basic formulations.
5. The label claim and label text of an alternate formulation must be the same as the basic formulation.
6. Any precautionary statement must be the same on the basic and alternate formulation.

B. Cleared inerts should be identified in the transmittal document.

C. If inerts are not cleared for use in pesticide formulations, registrants must request that suppliers submit the complete chemical identification of all components in the ingredient, CAS numbers of each component and the percentage of each component used in the formulation directly to the Agency. Registrants should provide suppliers with associated EPA Reg. No., barcode number and Product Manager (PM) to enable ease in location of the associated submission.

D. To avoid delays in review, the exact name must be entered for a chemical (e.g. fragrance, dye) for each entry; otherwise a new CAS number is associated (which may delay time).

E. The Active Ingredient (AI) must be the ingredient that causes the product to be efficacious.

F. The names and addressed of the suppliers should always be provided. The term “commodity chemical” is not acceptable as a replacement for names and addresses of suppliers.

G. Verify the weight percentage of each component. Note that the weight percentage in formulated products when multiplied by chemical purity would result in the label claim nominal concentration. The nominal of the AI on the CSF must exactly match

that on the label (per PR Notice 91-2). CSFs will be rejected if PR Notice 91-2 is not followed. It is quite common that the registrant include the nominal concentration of the AI between parenthesis below the percentage by weight in column 13b and the corresponding certified upper/lower limits in columns 14(a) and 14(b), respectively.

H. Upper and lower certified limits are required for each active and inert ingredient of a pesticide product. The certified limit for the AI should be based on the nominal concentration in pure form, not on the percentages by weight. The certified limits are calculated according to "The Table of Standard Certified Limits." See 40 CFR 158.350(b)(2). The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit, with a justification.

The certified lower limits may not be lower than the minimum level to achieve efficacy. Therefore, zero is not acceptable as a lower limit.

I . The CSF must be signed and dated.

5. All required studies must be addressed per 40 CFR Part 158. If a guideline study is not applicable, the registrant must indicate such by adding "N/A" next to the guideline number.

6. Product Chemistry Data (Master Record Identification Document (MRIDs) – guideline studies – Refer to the OPPTS Test Guideline Series 830. Each study should have a MRID number and a date pin-punched by the front-end processing center.

7. In reference to Good Laboratory Practices (GLP), registrants are advised to refer to 40 CFR § 160.135. GLP applies totally to those studies listed in (a) and partially to the remaining physical and chemical characterizations studies listed in (b).