§ 158.330 Description of production process.

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him), concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

3. The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) Additional information. On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.335 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient) as required by the following sections:

(a) Section 158.330(b)(2), pertaining to characterization of the process.

(b) Section 158.330(b)(4), pertaining to ingredients used in the process.

(c) Section 158.330(b)(5), pertaining to process equipment.

(d) Section 158.330(b)(6), pertaining to the conditions of the process.

(e) Section 158.330(b)(8), pertaining to quality control measures.

§ 158.340 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA
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§ 158.345 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the technical grade of the active ingredient. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substances are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of the active ingredient must be provided. If the technical grade of the active ingredient cannot...