

§1308.23 Exemption of certain chemical preparations; application.

(c) An application for an exemption under this section shall contain the following information:

- (1) The name, address, and registration number, if any, of the applicant;
- (2) The name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;
- (3) The exact trade name or other designation of the preparation or mixture;
- (4) The complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and non-controlled substances);
- (5) The form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);
- (6) The dimensions or capacity of the immediate container of the preparation or mixture;
- (7) The label and labeling, as defined in [part 1300](#) of this chapter, of the immediate container and the commercial containers, if any, of the preparation or mixture;
- (8) A brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put;
- (9) The date of the application; and
- (10) Which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the Act ([21 U.S.C. 842\(a\) \(8\)](#)) or any other law restricting public disclosure of information.