

Commodity Inert Ingredients- Guidance for PRIA Category I018

EPA has established a list of inert ingredients that have been designated as Commodity Inert Ingredients (<https://www.epa.gov/pesticide-registration/commodity-inert-ingredients>). This designation will help to streamline and reduce the volume of paperwork associated with the Confidential Statement of Formula (CSF) Form (EPA Form 8570-4). As part of PRIA 5, a new category (I018; decision review time 3 months) was created for a submission requesting the addition of a single inert ingredient (to the Commodity Inert Ingredient List. This document provides guidance for I018 submissions.

For those inert ingredients so designated, applicants for pesticide registration or registration amendments will be afforded the ability to obtain these inert ingredients from various commercial sources without having to provide the Agency with specific supplier name and address information for each such source on the CSF Form. This approach will reduce the amount of information required on the CSF, as well as the need for frequent revisions of the CSF to account for new sources of these inert ingredients. Only those inert ingredients designated as “Commodity Inert Ingredients” would be eligible for this reduced source reporting.

The following definitional criteria should be addressed in any PRIA I018 submission requesting addition of a substance to the list:

1. The substance must be on EPA’s list of approved nonfood inert ingredients or have an established tolerance or exemption from tolerance for use as an inert ingredient published in the 40 CFR §§180.
 - A screenshot of the chemical of interest on InertFinder can be provided as verification of point 1 (<https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1::::1::>).
2. The substance must not be registered by EPA as a pesticide active ingredient.
3. Should EPA’s approval of the inert ingredient and/or the establishment of a tolerance or the exemption from tolerance be supported by any data that are eligible for compensation under FIFRA§§3(c)(1)(F) and 10, and/or FFDCA §408(i), the substance may be considered commodity only for those uses that do not rely on compensable data (e.g. nonfood).
4. The substance must not be an intentionally prepared mixture or proprietary blend and must be identified by a single Chemical Abstracts Service Registry Number (CAS Reg. No.), if one has been assigned.
 - The CAS Reg. No. must be provided, if available, as well as the full chemical name, as approved for inert ingredient use.
5. The substance must be available from a minimum of three commercial sources.
 - A list of suppliers should be provided, including the name and address for each.

- The physical form (e.g., powder, liquid, etc.) and the purity of the proposed substance, as given by each supplier should also be provided.

Based on the review of submitted information, EPA will make a determination of whether the substance is appropriate for inclusion in the Commodity Inert Ingredient List and will add it to the website (<https://www.epa.gov/pesticide-registration/commodityinert-ingredients>) as well as designate it in the InertFinder database (<https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1:0::NO:1>).

Note: Once a substance has been so designated, subsequent CSF submissions should reflect this status. However, previously submitted and accepted CSFs do not need to be revised and resubmitted to the Agency solely to include the Commodity Inert Ingredient designation, as registrants are permitted to obtain such inert ingredients from various sources *via* non-notification.