

Confidential Statement of Formula (CSF) Screening

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Ingredient
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CSF Inert Ingredient Screening

- Applications for product registrations and product registration amendments submitted to the Registration Division (RD) are checked for completeness
- For PRIA actions this is part of initial 21-day review
- Completeness check includes a screen of the Confidential Statement of Formula (CSF) form submitted with registration application

CSF Inert Ingredient Screening (con't)

Elements of CSF Inert Ingredient Screen

- Determination of acceptability for proposed use for all inert ingredients listed on CSF
- Verification that the trade name inert ingredients/inert mixtures full compositional information is on file with Agency
- Verification of correctness of chemical names/CAS Reg. Nos.
- Deficiencies are noted and applicant is informed of results of screen

CSF Inert Ingredient Screening (con't)

- Began as pilot in RD in May 2007
- To date some 3000 products have been subject to the CSF Inert Ingredient Screening process

CSF Inert Screening Results: Year 1 vs. FY '09

	Year 1 of Screen	FY 2009
Deficiency/error rate (before corrections)	37%	15%
% of deficient submissions corrected	28%	54%
Net deficiency rate (after corrections)	26%	7%

CSF Inert Ingredient Screening (con't)

Conclusions

- Screening process has improved quality of CSF submissions
- Significantly lower error rate results in more efficient review process
- Resource savings to the Agency and to industry

Mixture Database

- Company Letterhead
- Product name
- Chemical name
- CAS number
- Complete list of components
- Weight percentage of each component (Must total 100%)

Impurities

- Impurities are generally defined as a by-product of the manufacturing process and are assessed for the active ingredient at the time of registration.
- By law no new toxicologically significant impurities will be allowed in the proposed product.

Impurities (continued)

- All impurities in the active ingredient or product that are greater than 0.1 percent must be listed on the Confidential Statement of Formula and any changes to the initial impurity profile must be assessed and approved by EPA.

Impurities (continued)

- Impurities in inert ingredients are considered as part of the overall evaluation of the inert ingredient.

How to find an Approved Inert

- For pesticide products with nonfood uses, all inert ingredients must appear on the list of inert ingredients permitted for nonfood use:
<http://www.epa.gov/opprd001/inerts/lists.html>
- For pesticide products with food uses, all inert ingredients must also have appropriate tolerances or tolerance exemptions:
<http://www.gpoaccess.gov/ECFR/>