#### § 158.108

(b) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no inert ingredients are identical in composition to each other and to the technical grade of the active ingredient (TGAI) from which they were derived, and therefore, the data from a test conducted using any one of these as the test substance (e.g., TGAI) is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances (i.e., MP or EP).

## $[49\ FR\ 42881,\ Oct.\ 24,\ 1984,\ as\ amended\ at\ 53\ FR\ 15999,\ May\ 4,\ 1988]$

# § 158.108 Relationship of Pesticide Assessment Guidelines to data requirements.

The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650). The following Subdivisions of the Pesticide Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D E F G I J K L	Product Chemistry Hazard Evaluation: Wildlife and Aquatic Organisms Hazard Evaluation: Humans and Domestic Animals Product Performance Experimental Use Permits Hazard Evaluation: Nontarget Plants Reentry Protection Hazard Evaluation: Nontarget Insect	PB83-153890 PB83-153908 PB83-153916 PB83-153924 PB83-153932 PB83-1539340 PB85-120962 PB83-153957	\$\\$158.150-158.190 \\$158.490 \\$158.340 \\$158.640 \\$\$158.20-158.740 \\$158.540 \\$158.590
M N O R	Biorational Pesticides Environmental Fate Residue Chemistry Spray Drift Evaluation	PB83–153965 PB83–153973 PB83–153961 PB84–189216	§§ 158.690–158.740 § 158.290 § 158.240 § 158.440

[53 FR 15993, May 4, 1988]

### Subpart C—Product Chemistry Data Requirements

Source: 53 FR 15993, May 4, 1988, unless otherwise noted.

### $\S 158.150$ General.

(a) Applicability. This subpart describes the product chemistry data that are required to support the registration of each pesticide product. The information specified in this subpart must be submitted with each application for new or amended registration or for reregistration, if it has not been submitted previously or if the previously submitted information is not complete and accurate. References in this subpart to the "applicant" include the registrant if the information is required for a registered product.

(b) Purpose—(1) Product composition.
(i) Data on product composition are needed to support the conclusions expressed in the statement of formula.

These data include information on the starting materials, production or formulating process, possible formation of impurities, results of preliminary analysis of product samples, a description of analytical methods to identify and quantify ingredients and validation data for such methods. In addition, an applicant is required to certify the limits for ingredients of his product.

(ii) Product composition data are compared to the composition of materials used in required testing under subpart D of this part. This comparison indicates which components of a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product's composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.