1. the chemical name from the Chemical Abstracts 1972 to 1976 Index of Nomenclature, or other well-defined names;
2. the Chemical Abstracts (CAS) registry number;
3. the product name, trade name, and common name (if established);
4. the experimental or internal code number;
5. the molecular (empirical) formula and the weight or the molecular weight range for each ingredient; and
6. the structural formula for each organic ingredient.

Committee's Comments: It is uncertain whether a firm order of presentation will be established for this information. However, because many substances submitted for approval will be mixtures such as PCBs, the following sequence may be most appropriate for identifying a product:

1. the product name, trade name, and common name;
2. the experimental or internal code number;
3. for each ingredient:

- the chemical name from the Chemical Abstracts Index of Nomenclature;
- the Chemical Abstracts (CAS) registry number;
- the molecular formula and structural formula (for organic, organo-inorganic, and inorganic compounds whenever appropriate); and
- the molecular weight or weight range.

Description of Manufacturing Process Guidelines require that application for approval of manufacture or new use, or both, include information regarding the basic manufacturing process as well as information on the composition of the starting and intermediate materials.

Formation of Unintentional Ingredients An indication of whether unintentional ingredients are formed is required along with information on intentionally added ingredients; identification of components that might reasonably be detected as present in amounts of 0.01 percent or more of product weight are to be included.

Committee's Comments: A variety of chemical contaminants is present in manufactured products in amounts less than 0.01 percent of product weight

(100 µg/g). For example, as shown in Table 3.2, the amount of chlorodibenzofurans (CDFs) reported in individual samples of commercial PCB products is substantially below this limit, and low-level exposures to CDFs have been reported to produce toxic effects in animals (Zitko et al. 1973, Nisbet 1976, Oishi and Hiraga 1978, Oishi et al. 1978, International Agency for Research on Cancer/IARC, in press). Thus a listing of all identifiable "contaminants" or unintentionally added ingredients should be required to make possible a proper evaluation of the potential toxicity of new compounds. For those ingredients known to be or suspected of being hazardous, an expected maximum limit within the product should be stated, even if this limit is less than 100 µg/g of product weight.

Declaration and Certification of Ingredient Limits

Estimates of upper and lower limits should be established for each ingredient as well as for any impurities known to be present. The limits should be presented as percentages of the total product.

Committee's Comments: In addition, quantities should be established for impurities that may be expected to arise during normal use of the product and under specified disposal conditions.

TABLE 3.2 Amounts of Chlorodibenzofurans Detected in Commercial PCB Mixtures

		µg/g
Aroclor	1248	2.0
	1254	1.7
	1260	1.0
	1016	ND (less than 0.001)
Clophen	A-60	8.4
Phenoclor	DP-6	13.6
Kanechlor	300	1.0
	400	18.0
	500	4.0
	600	5.0

ND indicates not detected.

SOURCE: Modified from Nisbet (1976).

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