



## New Chemicals



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# What Information Must Be Submitted About New Chemical Substances?

PMN submissions require all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. If the identity of some reactants for substance synthesis, or of the substance itself, is unknown to the manufacturer, a [letter of support](#) can be used to provide the Agency with full identity information.

Submissions must be made on **EPA Form 7710-25** using the new [electronic PMN software](#). EPA requires that the following information be submitted with the PMN: all existing health and environmental data in the possession of the submitter, parent company, or affiliates, and a description of any existing data known to or reasonably ascertainable by the submitter. Information frequently requested by the New Chemicals Program for groups of chemicals with common characteristics is identified in the [Chemical Categories](#) document. All of this information is considered by Agency risk assessors during the notice review process.

The New Chemicals Program can require submission of any additional data, including development of new data through testing, when the information included with the PMN, coupled with that available to EPA risk reviewers from internal archives is not adequate to determine potential risk. The [Instruction Manual for Premanufacture Notification of New Chemical Substances \(PDF\)](#) (51 pp, 721K, [about PDF](#)) explains the PMN reporting requirements in detail. The instruction manual information can also be found in the help sections of the e-PMN software. For further assistance, contact the [Toxic Substances Control Act \(TSCA\) Hotline](#). A document is available on how to avoid incomplete PMNs.

A chemistry assistance manual has also been written by Agency personnel and is available in several formats:

- Hardcover book by John Wiley and Sons as *Premanufacture Notification: Chemistry Assistance for Submitters*, by Steven C. DeVito and Carol A. Farris (ISBN: 0-471-19151-5). The book can be ordered through 1-800-225-5945 at a price of \$45.00.
- Photocopies of the Manual are available from the [TSCA Hotline](#) under the title: *Chemistry Assistance for Premanufacture Notification Submitters*
- The [Chemistry Assistance Manual for Premanufacture Notification Submitters](#) can be downloaded directly from the EPA Website.

Note to submitters: if, during the section 5 notice review period, you receive or become aware of the existence of reasonably ascertainable test data or other information that adds to or makes more complete the determination of the potential unreasonable risk, you are obliged to send that information to the address shown on the section 5 notice form within ten days of its receipt, but not later than five days before the end of the review period. If such information becomes available within five days of the end of the review period, you must inform your EPA contact by telephone.

This obligation is described at [40 CFR Section 720.40\(f\)](#), and includes additional toxicological information, details on manufacture, processing, use, and disposal; likely worker exposures and environmental releases; and facts on innovations and improvements in product chemistry and safety practices.

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Last updated on Friday, August 20, 2010