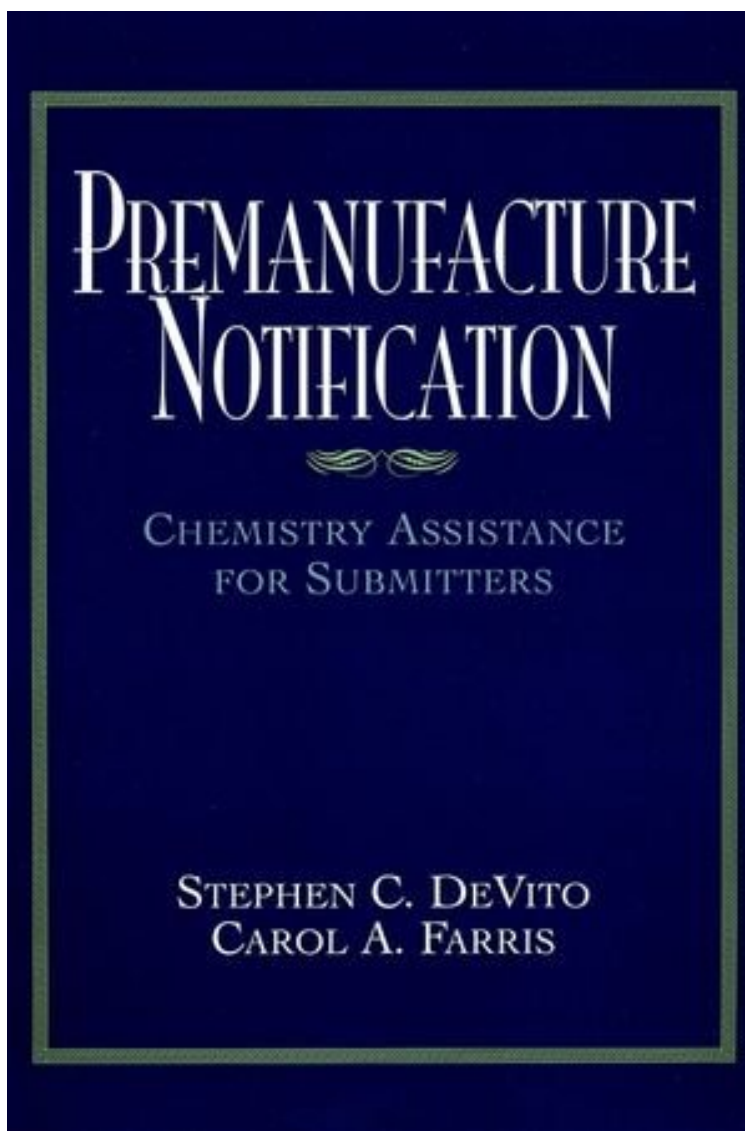


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Premanufacture Notification: Chemistry Assistance for Submitters

Stephen C. DeVito, Carol A. Farris

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Stephen C. DeVito, Carol A. Farris : Premanufacture Notification: Chemistry Assistance for Submitters before purchasing it in order to gage whether or not it would be worth my time, and all praised Premanufacture Notification: Chemistry Assistance for Submitters:

The first and only guidance document to help applicants from chemical manufacturers obtain approval to synthesize

and manufacture a chemical compound. Written by two EPA scientists, it provides coverage of chemical information needed for risk assessment to satisfy the requirements of the PMN review process and comply with the Toxic Substance Control Act.

From the Publisher The first and only guidance document to help applicants from chemical manufacturers obtain approval to synthesize and manufacture a chemical compound. Written by two EPA scientists, it provides coverage of chemical information needed for risk assessment to satisfy the requirements of the PMN review process and comply with the Toxic Substance Control Act. From the Back Cover EPA insiders offer a behind-the-scenes look at Agency review of Premanufacture Notifications (PMNs) for new chemical substances. Each year the EPA receives more than 2,500 PMNs for new chemical substances; under the Toxic Substances Control Act, the EPA may keep a PMN substance off the market if it appears to pose unreasonable risk. In many cases submitters fail to supply the Agency with all of the information necessary to perform a human health and environmental safety assessment to estimate risk. When that happens, Agency scientists fill in the blanks themselves with best estimates--often to the submitter's disadvantage. What chemical information would the EPA like to receive, and how is this information used to assess a PMN chemical? What can you do to avoid the need for Agency estimates and to facilitate accurate Agency assessments and decisions? What impact does the EPA's pollution prevention program have upon the review process, and what can you do about it? Until now, submitters had to learn the answers to these and other crucial questions concerning the PMN process the hard way--through trial and error coupled with minimal technical guidance from the Agency. This valuable technical guide, written by two EPA scientists, helps you reduce the learning curve and facilitates the EPA's accurate review of your new chemical. It provides: * A blow-by-blow account of the EPA scientific review procedure and the rationale behind each step in the process * A detailed review of physicochemical information the EPA uses, how to measure and estimate the critical information, and how the EPA uses the information to assess risk * An in-depth, practical look at the EPA's pollution prevention program as it relates to the PMN review process * Insider tips on additional data--including frequently overlooked product benefits--that help Agency reviewers weigh your product's benefits in their assessments. Avoid conservative estimates and worst-case scenarios that may lead to unnecessary regulation of your new chemical. Find out how to prepare the perfect PMN in Premanufacture Notification. About the Author STEPHEN C. DEVITO, PhD, and CAROL A. FARRIS, PhD, are chemists with the Industrial Chemistry Branch of the Office of Pollution Prevention and Toxics at the U.S. Environmental Protection Agency.