

**Sustainable Futures / P2 Framework Manual 2012
EPA-748-B12-001**

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Executive Summary

The models and methods described in this manual are screening-level methods that were developed by the U.S. Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) to predict risk-related properties of industrial chemicals submitted under the Toxic Substances Control Act (TSCA). Industrial chemicals are those that are not drugs, cosmetics, pesticides, or food additives. TSCA requires that anyone wishing to commercialize an industrial chemical must submit it to OPPT for review, but does not require that additional testing be conducted and submitted. As a result most of the chemicals submitted under TSCA are not submitted with enough data to allow a thorough evaluation of risk.

OPPT developed computer-based methods that derive important risk assessment information based on chemical structure, conservative defaults, standard scenarios, and other factors. These methods provide information on physical / chemical properties, environmental fate, and potential carcinogenicity, toxicity to aquatic organisms, worker and general population exposures, among other data. OPPT routinely uses these methods to highlight chemicals of concern, to identify safer substitutes, and to reduce or eliminate risks.

These screening methods were combined into the Pollution Prevention Framework (“P2 Framework”) and presented to stakeholders in an effort to help them generate risk-related information early in the chemical development process. The successes of the P2 Framework lead to the development of P2 Framework-based Eastman Kodak and PPG Project XLs. EPA’s Project XL (eXcellence in Leadership, available at www.epa.gov/projectxl) encouraged innovation in environmental and public health protection. When EPA decided to scale-up several XL Projects and offer the advantages of innovation nation-wide, the P2 Framework-based projects were selected. OPPT developed the Sustainable Futures Pilot Project as the programmatic structure to scale-up the successful XL Projects. OPPT published a Federal Register notice announcing Sustainable Futures on December 11, 2002 (available at www.epa.gov/fedrgstr/EPA-TOX/2002/December/Day-11/t31243.pdf). Through Sustainable Futures OPPT is offering the P2 Framework models, hands-on training in the use of the models, and qualified participants can become eligible for regulatory flexibility in the review of their prescreened PMNs.

The regulatory flexibility will allow submitters of qualifying PMNs to begin manufacture in 45 days, rather than have to wait until the customary 90-day review period ends. This is a powerful incentive for many companies. In addition to getting to market sooner and reducing product development and manufacturing costs, regulatory uncertainty is greatly reduced because the P2 Framework helps anticipate, and engineer away from, chemicals of concern. This is pollution prevention in its purest form.

About this Document

This document has been reviewed and approved for publication by the Risk Assessment Division of the Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency (EPA/OPPT). Approval

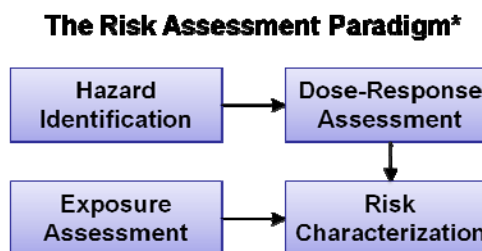
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does not signify that the contents necessarily reflect the views and policies of all Offices/Divisions in the Environmental Protection Agency, nor does the mention of trade names or commercial products constitute endorsement or recommendation for use.

This manual explains the models and methods developed and used by OPPT to identify potential hazards, exposures and risks posed by new chemical notices under the Toxic Substances Control Act (TSCA). These models have been combined into the Pollution Prevention (P2) Framework and are offered to stakeholders through the Sustainable Futures Initiative at <http://www.epa.gov/oppt/sf>.

How the Methods are Presented in This Manual

Each model gives screening-level information that is integrated into an assessment of potential risk to humans and the environment. As a reminder the Risk Assessment Paradigm (*National Research Council, 1983) which is described in Chapter 2 of this document and shown in the graphic here, says Hazard information combined with Exposure information equals Risk. For example, if a chemical kills fish at 1 mg/L (the hazard or toxicity) but the concentration in surface water (the exposure) will only be 0.02 mg/L then the risk should be low.



The models and methods in the manual are presented in the order in which you would use them to do a comprehensive risk assessment. Hazard-related information is presented first followed by Exposure information. Finally information on how to combining Hazard and Exposure information is presented to help the reader estimate Risk. Often the model outputs are used as inputs for subsequent models. Brief overviews of each model are provided which give enough information to successfully run each model. More detailed information on each model is provided in the User's Guide or supplemental documentation for that model.

Sustainable Futures Summary Assessment Worksheet and SF PMN

These models and methods were developed to screen new chemicals submitted under TSCA as Premanufacture Notices (PMNs). This document walks the reader through screening a chemical (isodecyl acrylate CAS RN 1330-61-6) using the models. Readers are instructed on how to interpret and enter the results into a summary assessment worksheet developed for Sustainable Futures training. After readers are instructed in how to use the models and methods to screen a sample chemical (isodecyl acrylate) the reader is presented with an example Sustainable Futures PMN developed using the same chemical. As of April 6, 2011 all new TSCA section 5 PMNs must be submitted electronically and must use e-PMN software which can be downloaded at <http://www.epa.gov/opptintr/newchems/epmn/epmn-index.htm>.



Additional Information

Additional information that we think will be useful is provided in Appendices, including: Useful Terms; Acronyms; Data Sources; Chemicals known to cause local & systemic effects; Information on Assessing

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Unique Chemical Classes; a SMILES Notations tutorial; a case study using ChemSTEER; and a blank Sustainable Futures Summary Assessment Worksheet, and the 1-page SF reporting format.

Sustainable Futures Contacts

We believe the information in this manual will be useful to readers, however if you still have questions after you read this material, technical assistance is available from OPPT contacts to answer those questions.

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EETD = Economics, Exposure and Technology Division

RAD = Risk Assessment Division

Disclosures

The models and methods described in this manual are screening-level methods that were developed by the Office of Pollution Prevention and Toxics (OPPT) to predict risk-related properties of chemicals lacking data. Screening methods are developed with conservative default values and have an inherent degree of uncertainty. They should never be used in place of measured data from properly-conducted laboratory studies. OPPT scientists use these methods to identify chemicals that require more detailed evaluation so that resources can be focused on those chemicals.

These models and methods are not the only methods available to screen chemicals in the absence of data. Readers are strongly encouraged to evaluate other methods as well.

The URLs of certain Internet sites are listed in this document to provide information to readers. Readers are cautioned that due to the dynamic nature of the Internet, these URLs may have been changed from the time of the writing of this document. In case a URL is no longer correct, the user is advised to use any of the publicly available Internet search engines to locate the correct URL.

This document has not been formally released by the U. S. Environmental Protection Agency (USEPA) and should not be construed to represent Agency policy. It has not been subject to internal U.S. EPA review and external technical peer review.

Mention of trade names or commercial products, or services does not convey, and should not be interpreted as conveying official USEPA approval, endorsement, or recommendation.

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