IFCS Forum V.

Information Session

Tools and Approaches for Applying Precaution in the Context of Chemicals Safety

Chemical Reviews and Tools U.S. Case Study*

* This case study abstract is for information and illustrative purposes only and is not intended to convey all aspects of EPA's chemicals program, other programs or U.S. views with respect to scientific uncertainty under U.S. law, international commitments, agreements and law.

Overview

- Background
- New Chemical Reviews
  - Process
  - What's involved (tools)
  - Considerations & Outcomes
  - Scenarios
- Other Methods to Reduce Uncertainty & Risk
- Additional Stewardship Tools & Activities

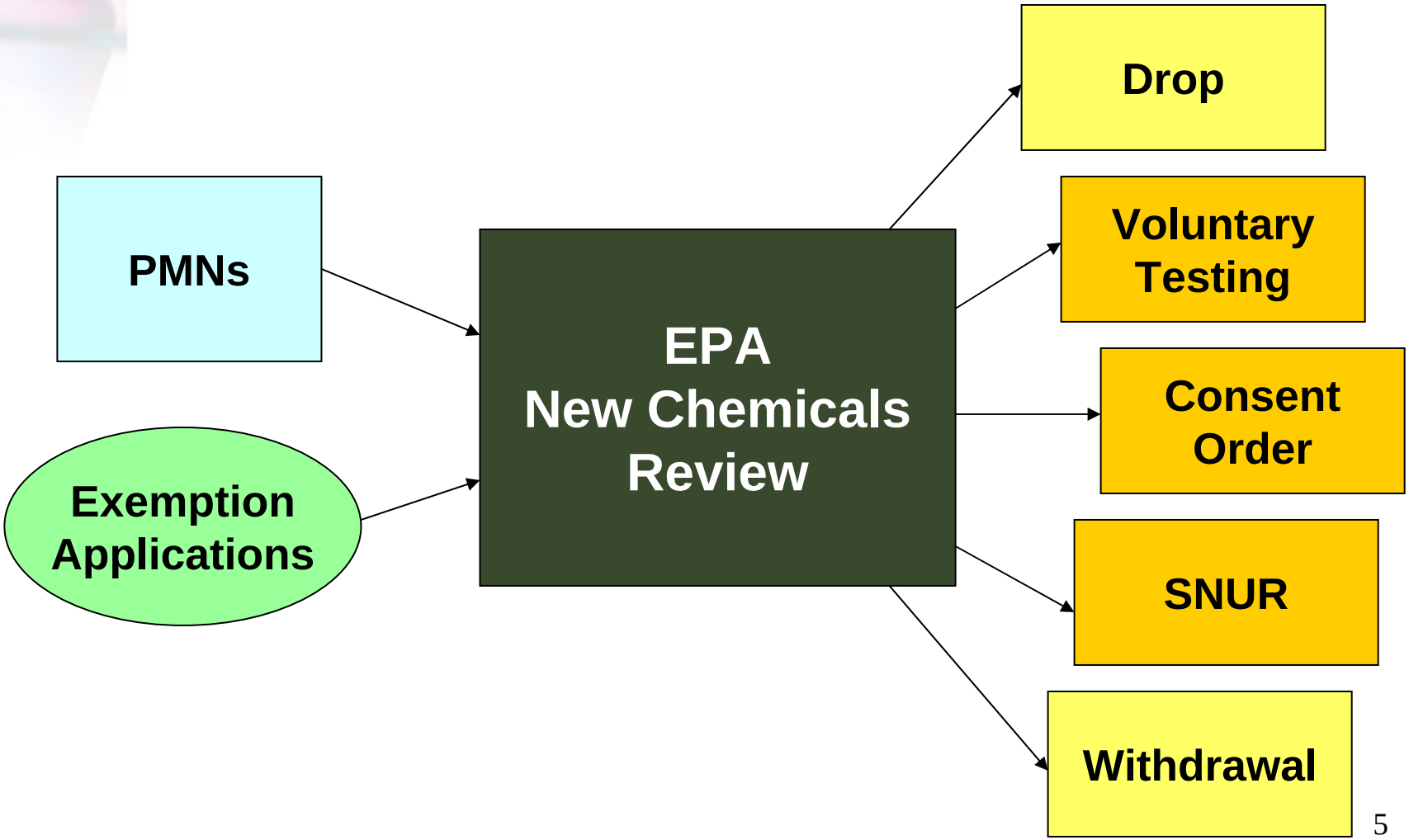
Background – Overall

- Long history of and experience with making decisions in the face of scientific uncertainty
- Approaches vary depending upon the law, context, etc.
- Integral part of our science-based risk assessment and risk management process

Background – New Chemicals

- Designed to prevent health and/or environmental risks before they occur
- Regulatory decisions are made within a 90-day review process for premanufacture notices (PMNs)
- Since its establishment in 1979 with the publication of the TSCA Inventory, EPA has reviewed over 45,000 submissions and receives about 1,500 submissions annually.
- Has evolved into two complementary roles: gatekeeper and steward

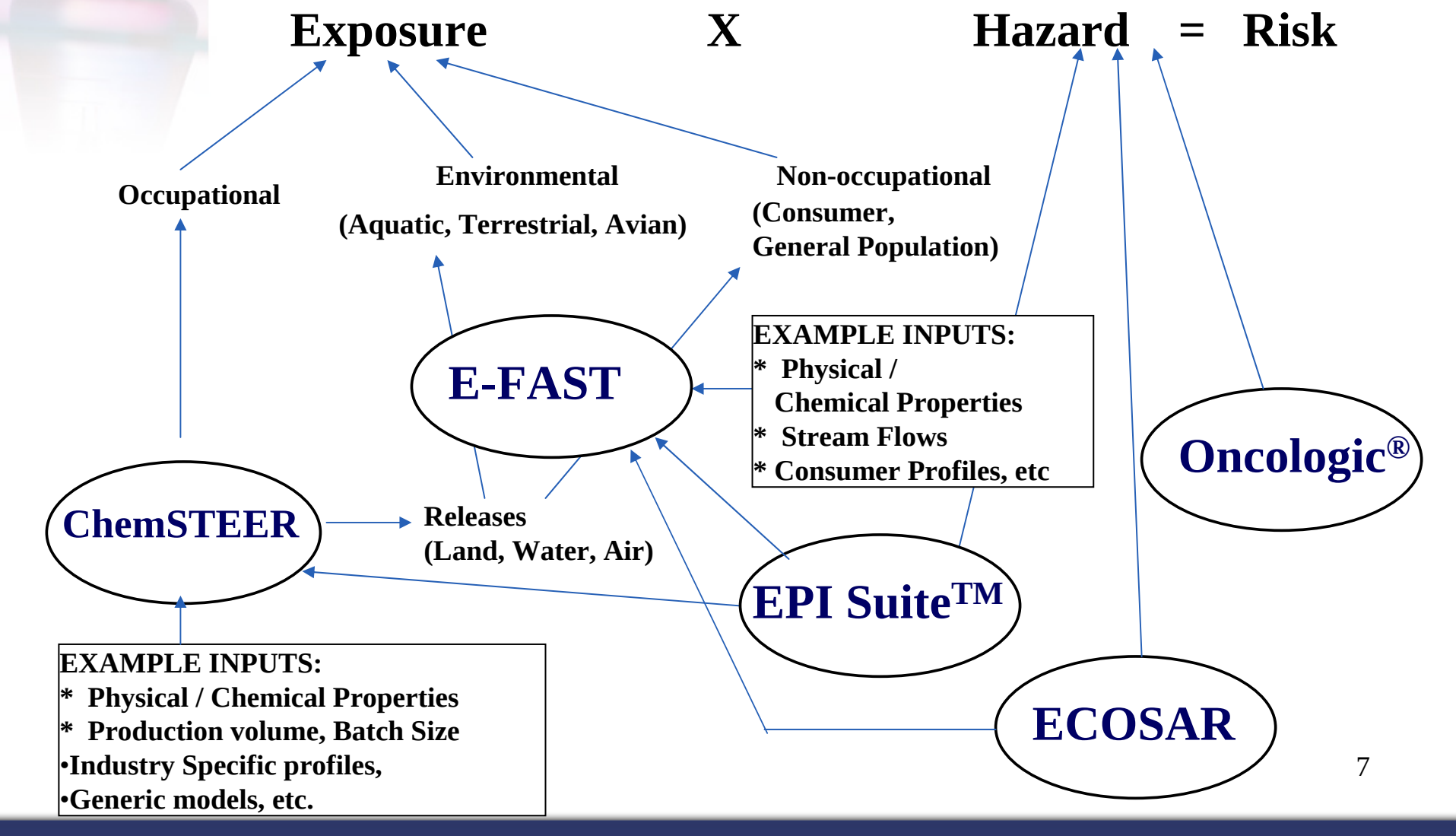
New Chemical Reviews – Process



New Chemical Reviews – Process

- Notices contain –
  - Chemical identity
  - Byproducts
  - Production/Import volume
  - Description of uses
  - Description of human exposure
  - Description of disposal practices
  - Data in submitter's possession or control
- Test data are *not* required to be developed as a condition of notification
- *Hence*, we have developed proficiency with Structure Activity Relationship (SAR) analysis to support hazard and exposure assessment.

New Chemicals – Tools



New Chemical Reviews – Considerations

- Factors in Risk Management
  - Magnitude and type of hazard
  - Magnitude and type of human/environmental exposure
  - Substitutes - relative risk determination
  - Benefits (e.g., energy efficiency, less toxic than existing chemical, etc.)
  - Other uses – potential for increased risks
  - Regulatory history – consistency in risk management decisions

New Chemical Reviews – Statutory Basis for Regulatory Measures

- Consent Orders (TSCA § 5(e))
  - "May present an unreasonable risk", OR
  - Substantial production and exposure
- Significant New Use Rules (SNURs, TSCA § 5(a)(2))
  - Consideration of relevant "factors"

New Chemical Reviews – Outcomes

- Dropped from further review
- Regulate by:
  - consent orders
    - testing requirements
    - exposure/use controls
  - significant new use rule (SNUR)
    - extend consent order requirements to other manufacturers* and/or
    - impose other requirements triggering advance notification to EPA

    * i.e., the notifier is subject per the consent order and the SNUR extends these requirements to any other manufacturer, user, etc.
- Withdrawal in face of action

New Chemical Reviews – Scenarios

- Most regulatory decisions based upon models and some screening level data

1. Conservative upfront ban with voluntary testing. Receipt of additional information indicates that risk was overstated. Initial measure is revised and commercialization can commence. Testing triggered and additional information can lead to further updating of measures.

2. In other cases, controls can be strengthened with improved information on hazard and exposure.

Other Methods to Reduce Uncertainty & Risk

- Information Gathering/Development
  - Targeted testing (regulatory and voluntary)
    - EPA and/or National Toxicology Program (NTP) research
  - Substantial risk information notices
  - Inventory Update Reporting
  - High Production Volume (HPV) Challenge Program

Other Methods to Reduce Uncertainty & Risk – Examples

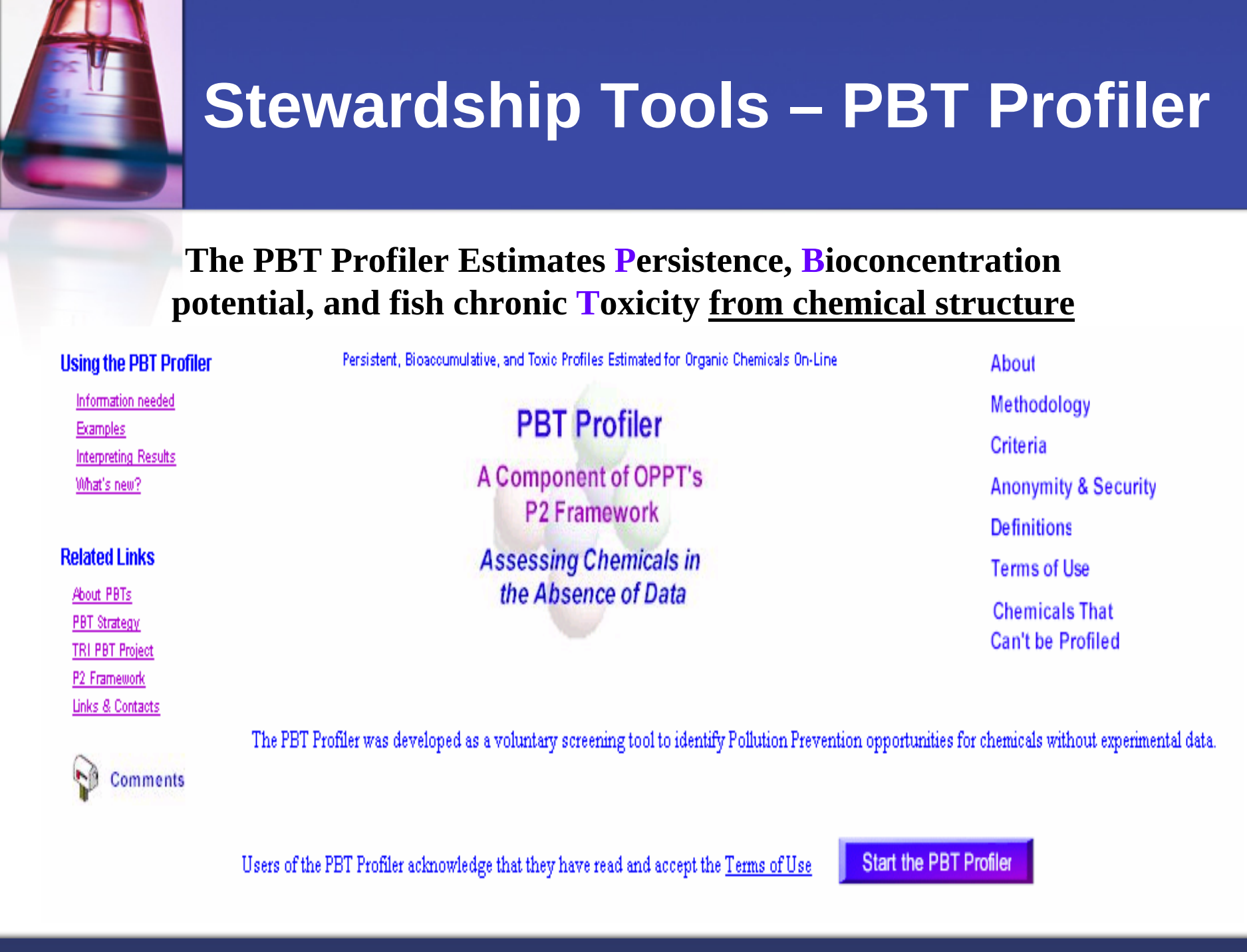
- Perfluorinated Acids
  - PFOS
  - PFOA

Additional Stewardship Tools & Activities

- Pollution Prevention (P2) Framework
- Sustainable Futures
- **PBT Profiler**
- Analogue Identification Methodology (AIM)
- Green Chemistry/Engineering
- **Design for Environment (DfE)**
- Environmentally Preferable Purchasing (EPP)

Stewardship Tools – PBT Profiler

The PBT Profiler Estimates Persistence, Bioconcentration potential, and fish chronic Toxicity from chemical structure



Stewardship Tools – PBT Profiler

Results

(1) Summary Results

Orange or red highlights indicate that the EPA criteria have been exceeded.
Black-and-white version

Persistence | Bioaccumulation | Toxicity

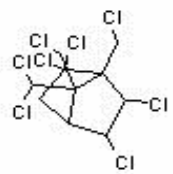
(2) Detailed Results

8001-35-2 Toxaphene

PBT Profiler Estimate = PBT

Screening estimates indicate this chemical may be a PBT - a P2 Assessment may allow further evaluation

Media	Half-Life (days)	Percent in Each Medium	BCF	Fish ChV (mg/l)
Water	180	1%	34,000	0.003
Soil	360	42%		
Sediment	1,600	57%		
Air	7.1	0%		

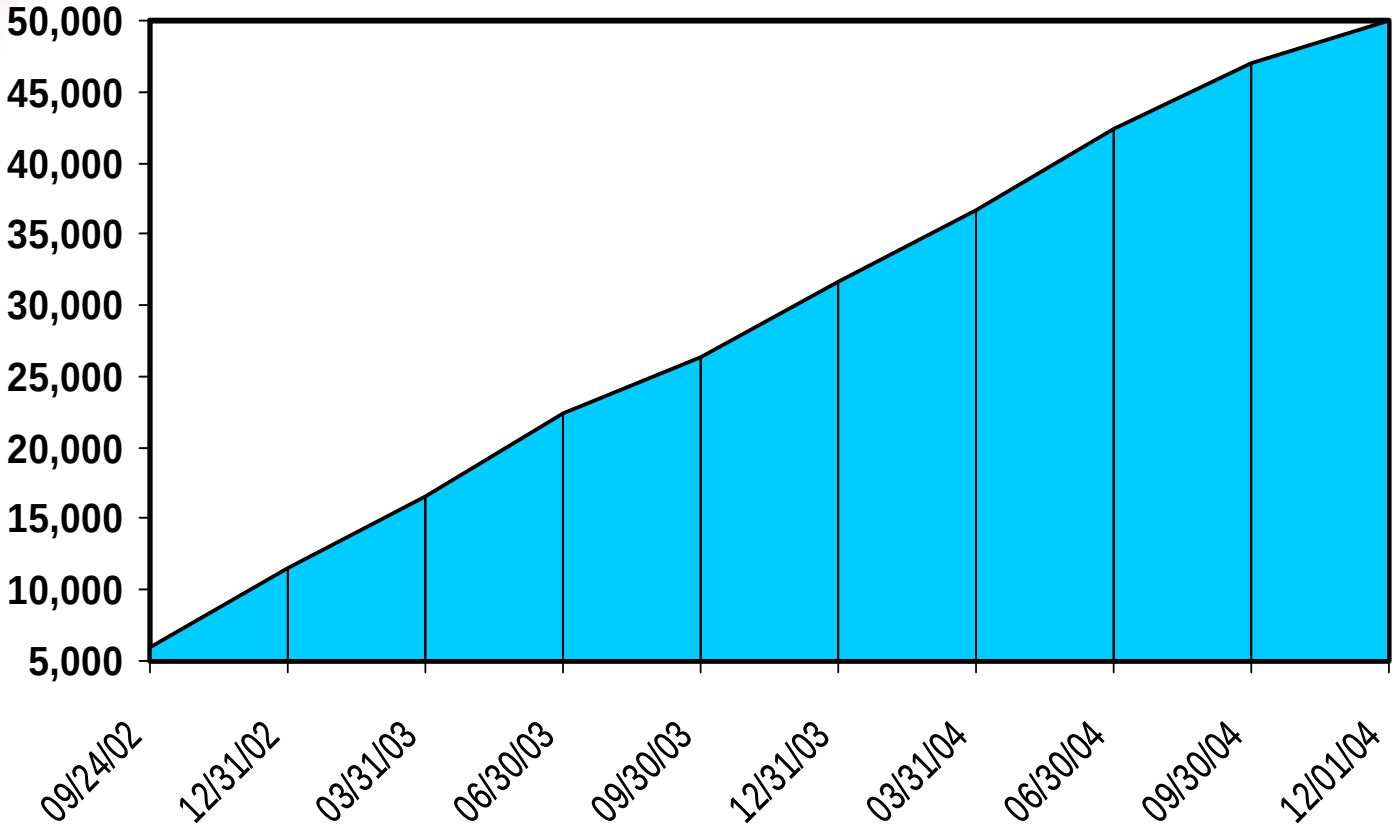


(3) P2 Information

P2 Considerations and more information

Stewardship Tools – PBT Profiler

Steady Increase Seen in Number of Chemicals Evaluated with PBT Profiler Since Public Release on Sept. 25, 2002



Source: PBT Profiler online model www.pbtprofiler.net "What's New" page, click on Details to get the number of chemicals profiled by date.

Tools and Models Being Widely Used

- New Chemicals
  - PMN Reviews
  - Sustainable Futures
- Existing Chemicals
  - Design for the Environment
  - PBT Initiative
  - HPV Chemicals
- Office of Pesticide Programs - Inerts
- Office of Air Quality Planning and Standards
  - Hazardous Air Pollutants
- Other Federal Agencies
  - Customs & Border Protection
  - Dept. of Defense
  - Food & Drug Admin.
  - Fed. Aviation Admin.
- International
  - European Union
  - Canada
  - The Netherlands

Stewardship Tools –

- Design for the Environment (DfE)
  - Flame Retardant Alternatives Project
    - Facilitate industry decision-making for choosing alternatives to pentaBDE
      - Focus on “drop-in” substitutes
    - Drive innovation toward environmentally safer flame retardancy methods
    - Develop a model for alternatives assessment
      - Current alternatives assessment focuses on use of new chemicals program models and methods to screen potential alternatives

Stewardship Tools –

Design for the Environment U.S. EPA

Furniture Flame Retardancy Partnership Summary Table

Company	Chemical	% in Formulation[6]	Human Health Effects							Ecotoxicity		Environmental		Potential Routes of Exposure							Reactive or Additive?
														Worker			General Population				
			Cancer Hazard	Skin Sensitizer	Reproductive	Developmental	Neurological	Systemic	Genotoxicity	Acute	Chronic	Persistence	Bioaccumulation	Inhalation	Dermal	Ingestion	Inhalation	Dermal	Ingestion	Aquatic	
Albemarle	SAYTEX RZ-243																				
	Proprietary E Tetrabromophthalate diol diester		L	L	L*	L*	L	M*	L	L	H	L▲	L	N	Y	Y	N	N	Y	Y	Additive
	Proprietary B Aryl phosphate		L	L	M*	M*	M	M*	L	H	H	L	M	N	Y	Y	N	Y	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	H	H	L	L	Y	Y	Y	Y	Y	Y	Y	Additive
Ameribrom	FR513																				
	Tribromoneopentyl Alcohol CAS # 36483-57-5		M	L	M	M	M	M	M	M	M	L	L	Y	Y	Y	N	N	Y	Y	Reactive
Great Lakes	Firemaster 550																				
	Proprietary F Halogenated aryl ester		L	L	M	M	L	M	L	H	H	L▲	L	N	Y	Y	N	Y	Y	Y	Additive
	Proprietary G Triaryl phosphate, isopropylated		L	L	M*	M*	M	M*	L	H	H	L	M	N	Y	Y	N	Y	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	H	H	L	L	Y	Y	Y	Y	Y	Y	Y	Additive
	Proprietary H Halogenated aryl ester		L	L	M	M	L	M	L	H	H	L▲	L	N	Y	Y	N	Y	Y	Y	Additive

Summary & More information

Overview of EPA's chemicals program and new chemicals review process

http://www.epa.gov/oppt/pubs/opptabt.htm
(click on "Overview of OPPT Programs" PDF file and "Overview Appendices)
http://www.epa.gov/opptintr/newchems/

Hazard and Exposure Assessment Tools

EPI Suite - http://www.epa.gov/oppt/exposure/pubs/episuite.htm
ChemSTEER - http://www.epa.gov/oppt/exposure/pubs/chemsteer.htm
E-FAST - http://www.epa.gov/oppt/exposure/pubs/efast.htm
ECOSAR - http://www.epa.gov/oppt/newchems/tools/21ecosar.htm
OncoLogic Cancer Expert System - http://www.epa.gov/oppt/newchems/pubs/sustainablefutures.htm
(available soon at above site)

Information Gathering

Substantial Risk Reporting - http://www.epa.gov/opptintr/tsca8e/
Inventory Update Reporting - http://www.epa.gov/opptintr/iur/
High Production Volume Challenge Program - http://www.epa.gov/chemrtk/
Perfluorinated Acids - http://www.epa.gov/opptintr/pfoa/index.htm

Stewardship Tools

Sustainable Futures - http://www.epa.gov/oppt/newchems/pubs/sustainablefutures.htm
PBT Profiler - http://www.pbtprofiler.net/
Design for Environment (DfE) - http://www.epa.gov/opptintr/dfe/
Green Chemistry - http://www.epa.gov/greenchemistry/
Green Engineering - http://www.epa.gov/opptintr/greenengineering/
Environmentally Preferable Purchasing - http://www.epa.gov/opptintr/epp/

See also our abstract for additional descriptions of many of these tools