

# COMMON PMN MISTAKES & HOW TO BEST PREPARE FOR A PMN SUBMISSION

Global Chem 2009  
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April 6, 2009

- ⦿ Pre-PMN Preparation
- ⦿ PMN Mistakes/Oversights

# PMN Pre-Preparation

# Things to do in advance of Preparing Your PMN

Are there environmental concerns for the chemistry?

- Is your chemical on EPA's Chemicals of Concern List?

- e.g. Acrylates/methacrylates, anhydrides, anilines, charged polymers, imides, esters, diisocyanates, and many others

- EPA "MAY" regulate under TSCA section 5(e)
  - Dependent on Volume, Exposure, and Hazard

- <http://www.epa.gov/opptintr/newchemicals/pubs/chemcat.htm>

- Is the chemical on any governments' list or has it received public scrutiny?

- PFOS/PFOA, Polybrominated diphenylethers, Bisphenol A, REACH SVHC list, Environment and Health Canada's "Challenge" chemicals, PBT, vPvB, etc.





# Consent Order Guidelines for PBTs

EPA has published their Evaluation Criteria and Process for new PBT (Persistent, bioaccumulative and Toxic) chemical substances

[Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances, Federal Register: November 4, 1999 \(Volume 64, Number 213\), pages 60194-60204](#)

5e Order Pending Testing/SNUR	5e Ban Pending Testing
Persistence > 2months	Persistence > 6 months
Bioaccumulation $\geq 1000$	Bioaccumulation $\geq 5000$
Toxicity is based upon concerns for persistence, bioaccumulation, other physical/chemical factors, and toxicity based on existing data	

Example PBT Profiler - 32536-52-0, Octabromodiphenyl ether  
[PBTProfiler.net](http://PBTProfiler.net)

# What does a TSCA 5e action mean?

## Two primary Section 5e Consent Orders

- Risk-based
  - Volume based toxicity or environmental fate testing
  - Worker personal protective equipment
  - Hazard communication
  - Disposal/Release requirements or restrictions
  - Recordkeeping
- Exposure-based
  - Testing
  - Risk Notification
  - Recordkeeping

See EPA website for example Consent Order templates

<http://www.epa.gov/oppt/newchemicals/pubs/boilerpl.htm>

# Processes can help mitigate delays

- ⦿ Training – Educate interested parties about TSCA (R&D, product mgr, some plant and sales personnel)
- ⦿ Get involved early in new chemical development
- ⦿ Use EPA's Tools and Guidance
  - Get trained on EPA's Sustainable Futures (SF) pollution prevention modeling software  
<http://www.epa.gov/oppt/sf/index.htm>
  - Refer to the Guidance Document Webpage  
<http://www.epa.gov/opptintr/newchemicals/pubs/guideman.htm>
- ⦿ Ask for help
  - Call TSCA Hotline - (202) 554-5603
  - Speak to a Prenotice Coordinator

# Common Administrative Mistakes & Oversights

# What happens when PMN is received by EPA?

- PMN is date stamped as soon as it is received
- PMN is checked for completeness
  - Chemical ID and Structure
  - Page 5 for polymers, all components under 2% must be included (don't necessarily need to have included in name)
  - Don't forget free radical initiators, chain transfer agents etc...anything that gets incorporated into polymer must be identified
  - Feedstocks from Page 8 match structure
  - End Use Description – it must be specific enough (e.g. “component” of paint is NOT acceptable, but pigment for paint is OK)
  - If proprietary component – Letter of Support must be received
- Once confirmed Complete – Day 1 begins
  - If EPA found errors – clock is not generally stopped, they will request corrections
- EPA sends letter indicating Day 1

# What happens if PMN is returned Incomplete?

- ⦿ 90 day window to correct and re-submit
- ⦿ PMN fee is not lost if resubmitted within window
  - PMN fee is returned if not resubmitted
- ⦿ Must reference original TS number and indicate in cover letter it is a resubmission
- ⦿ EPA's rejection letter will specify the details

# Chemical Identification Errors and Omissions

- Although CAS IES names are not REQUIRED – they are highly recommended
- It's VERY DIFFICULT to get a PMN through with a non-CAS IES assigned name
  - What happens If there is a structural/name error (name and structure don't match)?
    - IF CAS assigned name – EPA will allow company to Correct
    - IF NOT CAS assigned – EPA will reject and consider as Incomplete
- Branched vs. linear – Branched alkyl chains are much more common especially for nonyl and dodecyl moieties. Be sure name and structure are identified correctly and match
- REMINDER – a Letter of Support must be received by supplier prior to PMN moving on

# Exposure and Release Information (Pages 8-10)

- EPA will assume worst case if not specified for risk evaluation, e.g. release to water, spray application (vs. roll coated)
- If PMN substance is a solid
  - Submit Particle Size Distribution Analysis with PMN; otherwise EPA will assume the worst case inhalation scenarios
  - State that equipment will be wiped down and cleaning media will be disposed of in an approved landfill or incineration – otherwise EPA will assume residual is sprayed off equipment and washed down the site sewer system
- Be as specific as possible and substantiate whenever possible. Don't just state “we expect there will be no release to groundwater”
- Know as much as possible about customers use/exposure/release info
- Most Data Gaps are due to lack of information about Sites Controlled by Others (Page 10, Part II)

# And finally...remember the basics!!!

- ⦿ Don't forget to Sign and Certify your PMN (Page 2)
- ⦿ All information must be in English (including ALL test reports that may be submitted)
- ⦿ Provide US based Technical Contact (Page 3)
- ⦿ If unsure of something, CALL EPA and ASK FOR HELP
  - TSCA HOTLINE NUMBER - (202) 554-5603

## For Additional Information

Please reference a very good and detailed EPA presentation from Global Chem 2007 for additional information

[http://www.socma.com/assets/File/socma1/PDFfiles/gcrc/2007/presentations/TSCA\\_Fundamentals\\_EPA.pdf](http://www.socma.com/assets/File/socma1/PDFfiles/gcrc/2007/presentations/TSCA_Fundamentals_EPA.pdf)

**THANK YOU!**