

# Canadian Manufactures of Chemical Specialties Association

*Environmental Committee*  
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# Presentation Overview

- Product Overview
- State of the Science
- Regulatory Status
- NPE Environmental Management Program

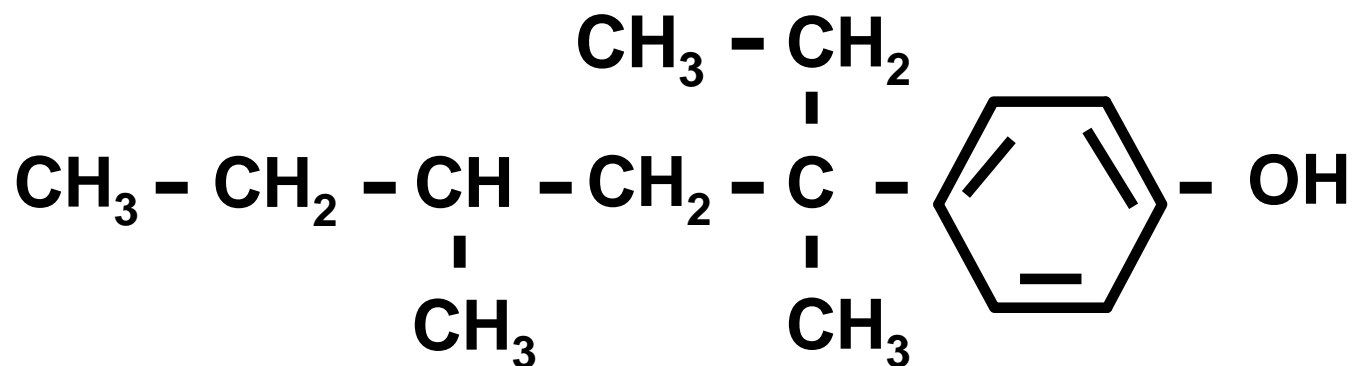
# Product Overview

## Nonylphenol based products

- High performance, cost effective compounds with broad regulatory acceptance
- Safe for the environment when used as intended, handled and disposed of properly
- Not a risk to human health through normal use and exposure

# Nonylphenol

One of the major isomers



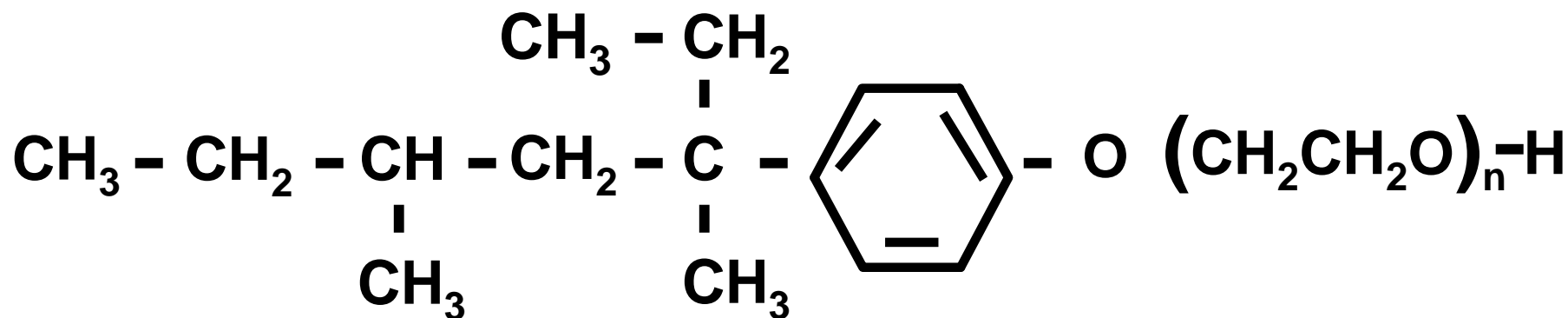
# Product Overview

## NP Applications

- Surfactant precursor (NPE)
- Polymer antioxidant (TNPP)
- Intermediate for PVC plasticizer
- Phenolic resins
- Reclaiming agent for synthetic rubber
- Corrosion inhibitors

# Nonylphenol Ethoxylates

One of the major isomers



$n = 1 - 100$

# Product Overview

## NPE Benefits

- Excellent wetting, emulsifying, dispersant properties
- Good chemical stability
- Cost-effective
- “Workhorse” surfactant

# Product Overview

## NPE Applications

- Household, Industrial & Institutional cleaners
- Textile manufacturing
- Paper and pulp processing
- Emulsion polymerization
- Industrial additive

# State of the Science Discussion Overview

- Environmental Exposure
- Environmental Effects
- Environmental Risk Assessment
- Human Safety

# State of the Science

## Environmental Exposure

- NP and NPE are effectively removed in well-functioning sewage treatment plants.
- Removal rate of NPE from wastewater treatment is on average 95%

# State of the Science

## Environmental Exposure

- Very high concentrations of NPE are degraded efficiently
- NP and NPE are biodegradable.
- NP and NPE do not build up in the food chain

# State of the Science

## Environmental Exposure

- Monitoring studies in North America show low environmental levels of NP and NPE
- Environmental levels of concern exist where effluent treatment is inefficient or inadequate

# State of the Science Environmental Effects

- Aquatic studies with NP
  - dozens of species covering fish, amphibians, mollusks, insects, annelids, crustaceans, algae, protozoa, and microorganisms
- Aquatic studies with NPE and NPEC
  - acute and chronic data for fish and crustaceans

# State of the Science

## Environmental Effects

- Tests conducted on NP covering:
  - ✓ mechanisms of toxicity (VTG, blood steroids, transitory changes in growth)
  - ✓ acute and long term mortality
  - ✓ growth
  - ✓ reproduction

# State of the Science Environmental Effects

- Endocrine issue is understood
- Toxicity, not endocrine issues, drive risk assessment conclusions

# State of the Science

## Environmental Risk Assessment

- Extensive toxicity database for NPE, NPEC and NP
- Numerous environmental monitoring studies
- Environmental levels in Canadian\US waters pose insignificant risk to aquatic life.

# State of the Science

## Human Safety - Exposure

- Limited human exposure to NP and NPE
- NPE and NP products do not penetrate the skin *in vitro*
- NP oral bioavailability is low

# State of the Science

## Human Safety - Studies

- Hundreds of animal toxicity studies on NP, NPE.
- NPE - low toxicity.
- NP is rapidly metabolized and excreted.

# State of the Science Human Safety -Studies

- NP does not accumulate in the body at doses below metabolic saturation
- No effect on the fetus at doses below maternal toxicity.
- NPE unlikely to form NP *in vivo*.

# State of the Science

## Human Safety -Conclusions

- NP is not a selective, reproductive or developmental toxicant
- Normal exposure to NP and NPE does not pose a significant risk to human health.
- No link has been established between NP exposure and any adverse effect on humans due to endocrine (hormone) disruption.

# Regulatory Status Canada

## Environment Canada\Health Canada

- NP and NPE included in second Priority Substances List (1995)
- Draft Assessment Report published (4/2000)
- Final risk determination required by CEPA (12/2000)

# Regulatory Status Canada -Draft Conclusions

- **Section 64(b)** – No Danger to Environment on Which Life Depends – NP/NPE are not entering the environment ... under conditions that constitute a danger to the environment
- **Section 64(c)** – No Danger to Human Health from Environmental Exposure – NP/NPE are not considered a priority ... to reduce public exposure through control of sources that are addressed under CEPA

# Regulatory Status

## Canada – Draft Conclusions

- **Section 64(a)** – CEPA Toxic to the Environment – NP/NPE are entering the environment ... under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity

# Regulatory Status Canada-Draft Conclusions

## Section 64(a)

- NP and its ethoxylates from untreated or partially treated textile mills that discharge directly to the environment occur at levels that are likely to be causing harmful effects on aquatic organisms.”
- “Discharges from municipal wastewater treatment plants and pulp and paper mills contribute NP and NPEs to the environment at levels that are of concern at a limited number of sites.”

# Regulatory Status Canada

## After CEPA “toxic”

- Identify and implement risk management options to reduce or eliminate the risks that the substances pose to human health or the environment.
- Stakeholder consultation

# Regulatory Status Canada

## Toronto Sewer Use By-law

- Approved June 8, 2000
- Discharge limits
  - 0.001 mg/L NP
  - 0.01 mg/L NPE
- Phase in schedule by industry sector
  - June 30, 2001 to June 30, 2002

# Regulatory Status Canada

## Toronto Sewer Use By-Law

- Requires Pollution Prevention (P2) Planning:
  - Filing P2 plan with City every 2 years
  - Update P2 Plan every 6 years.
- Review of limits within 4 years

# Regulatory Status Canada

## Toronto Sewer Use By-Law

- Regulation politically motivated, not scientifically based
- Regulation intended to create *de facto* ban
- Grassroots initiatives to push By-Law to surrounding municipalities and to the Provincial level

# Regulatory Status

## United States

- No present or pending regulatory restrictions on use
- Broad approval of food-contact applications under FDA
- EPA to establish water quality criteria for nonylphenol

# Regulatory Status United States

## EPA Risk Management Findings (RM1)

- NP risk to aquatic organisms does not appear to be widespread in US waters
  - NP degrades better than previously thought
  - Wastewater treatment facilities are highly efficient in removing NP discharge into wastewater

# Regulatory Status

## European Union

- EU Risk Assessment of nonylphenol near completion
  - Modeling versus monitoring, overestimated environmental levels
  - Used worst-case, conservative assumptions
  - Draft proposal restricts nonylphenol ethoxylates in some applications
- Few unilateral actions by member states

# Regulatory Status Japan

- Japan's Environment Agency monitoring chemicals in the environment, including NP, NPE and other APEs

# Conclusion

- Alkylphenol-based products are high performance, cost effective compounds with broad regulatory acceptance worldwide
- Alkylphenol-based products are safe for the environment and pose no significant human health risk when used as intended, handled and disposed of properly

# NPE Environmental Management Program

- Program Goals:
  - Responsible environmental management
  - Provide guidance on pollution prevention and control
  - Complement existing and planned regulations
  - Avoid product bans or substitutions
- Visit [www.aperc.org](http://www.aperc.org) for more information

# For More Information

Alkylphenols & Ethoxylates  
Research Council

[www.aperc.org](http://www.aperc.org)

