EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Protecting the Natural Environment
ENV.B.4 - Biotechnology & Pesticides
The Deputy Head of Unit

Brussels, 02/12/2005
ENV.B.4 D(05) 24475

Mr J. Whitelaw
Secretariat for the Rotterdam
Convention
UNEP Chemicals
11-13 Chemin des Anémones
CH-1219 Châtelaine, Geneva

Dear Mr Whitelaw,

In line with Article 5 of the Rotterdam Convention, I am pleased to send you herewith a European Community notification concerning a final regulatory action relating to nonylphenol and nonyphenol ethoxylate.

Yours sincerely,

Signed
Klaus BEREND

Cc. Mr N. Van der Graaff, FAO
Ms Sheila Logan, UNEP Chemicals

Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: EUROPEAN COMMUNITY

(Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Nonylphenol (NP)
		Nonylphenol Ethoxylate (NPE)
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	NP: IUPAC: Nonylphenol and 4-nonylphenol, (branched) Einecs: Nonylphenol and phenol, 4-nonyl-, branched
		NPE: IUPAC: No information Einecs: No information
1.3	**Trade names and names of preparations**	NP: There are many different names
		NPE: There are many different names
1.4	**Code numbers**	
1.4.1	**CAS number**	NP: various including 25154-52-3 (phenol, nonyl-), 84852-15-3 (phenol, 4-nonyl-, branched), 11066-49-2 (Isononylphenol) and 90481-04-2 (phenol, nonyl-, branched)

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

		NPE: various including 9016-45-9, 26027-38-3, 37205-87-1, 68412-54-4 and 127087-87-0
1.4.2	**Harmonized System customs code**	No information
1.4.3	**Other numbers (specify the numbering system)**	NP: EINECS: 246-672-0, 284-325-5 CIPAC: 79 RTECS: SM5600000 UN: 3082
		NPE: EINECS: NO INFORMATION ACX: X1003424-3 RTECS: MD0905000 UN: 8027

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	√ This is a first time notification of final regulatory action on this chemical.
1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
UN Classification	NP: UN Hazard class: 9 UN Packing Group: III
	NPE: UN Hazard class: 9 UN Packing Group: NO INFORMATION
Classification of the EC in accordance with Council Directive 67/548/EEC	NP: Xn (Harmful) C (Corrosive) N (Dangerous to the environment) Repro Category 3 (toxic to reproduction) R22-34-50/53- 62 -63 (Harmful if swallowed; Causes burns; Very toxic to aquatic organisms; May cause long-term adverse effects in the aquatic environment; Possible risk of impaired fertility; Possible risk of harm to the unborn child).
	NPE: No harmonised classification at EU level at present. The following self classifications using the rules of Annex VI to Directive 67/548/EEC for the different groups of molecules and depending on the chain lengths have been reported: Nonylphenol(ethoxylates)n, n=2-6 Xi; R36/38 – N; R51-53 Nonylphenol(ethoxylates)n, n=7-10 Xn; R22 – 41 – N; R51-53 Nonylphenol(ethoxylates)n, n=11-19 Xi; R41 – R52/53 Nonylphenol(ethoxylates)n, n=20-40 R52/53 Nonylphenol(ethoxylates)n, n>40 R53
Other classification systems	**Hazard class**

1.7 Use or uses of the chemical	
1.7.1	θ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	None. Used as co-formulant only
1.7.2	√ **Industrial**
	Describe the industrial uses of the chemical in your country:

Nonylphenol is used in the production of nonylphenol ethoxylate, plastics, resins, stabilizers and phenolic oximes.

Nonylphenol ethoxylates are used in a wide range of industries including, chemical (synthesis of nonylphenol ether sulphates and nonylphenol ether phosphates), electrical engineering (in fluxes, dyes, chemical baths, cleaning products), industrial and institutional cleaning, textile auxiliaries, leather auxiliaries, agriculture (as a wetting agent in pesticide formulations), emulsion polymers, speciality paints, pulp and paper, and metal industry (cleaning of metal products). Other miscellaneous uses include additives in lubricating oils, spermicides, surfactants in cosmetic formulations, and as wetting agents in the developing of photographic film.

1.8 Properties

1.8.1 Description of physico-chemical properties of the chemical

Minimum purity

Purity of commercial NP reported as 90%

FAO specification

No information

Molecular Formula

NP: $C_{15}H_{24}O$

NPE: $C_9H_{19}C_6H_4(OCH_2CH_2)_nOH$

Molecular Mass

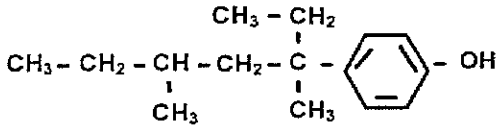
NP: 220.34

NPE: Depends on number of ethoxylate groups.

Structural Formula

NP:

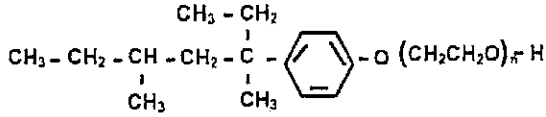
Nonylphenol



NPE:

Nonylphenol Derivative

Nonylphenol Ethoxylate



n = 1 - 100

Appearance

NP: Clear to pale yellow viscous liquid
NPE: White paste

Relative density

0.95 at 20°C (NP)

Melting point

NP: Circa –8°C

NPE: 1°C (varies with ethoxylate number)

Boiling point / decomposition

290-300°C (NP)

	Flash point	141-155°C (NP)
	Vapour pressure	Circa 0.3 Pa at 25°C (NP)
	Henry's law constant	11.02 $Pa.m^3.mol^{-1}$ (NP)
	Solubility in water	NP: 6 mg/l at 20°C NPE: 1 g/l*
	Solubility in organic solvents (at 25°C)	Soluble in methanol and xylene. Insoluble in kerosene. (NPE)
	Partition coefficient (log P_{ow})	NP: Log Kow 4.48 NPE: Log Kow 4-4.6
	Hydrolytic stability (DT_{50})	NO INFORMATION

*Water solubility is increased by alkyl (C_nH_{2n+1}) branching and is directly proportional to the number of ethoxylate groups. NPEs are water-soluble when the number of ethoxylate groups is equal to or above 7.

1.8.2	Description of toxicological properties of the chemical

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Absorption, distribution, excretion and metabolism in mammals:
Nonylphenol is initially absorbed rapidly from the gastrointestinal tract and after intraperitoneal administration. There are no specific data for inhalation exposure but it is assumed that there would be significant absorption via this route. The major metabolic pathways are likely to involve glucuronide and sulphate conjugation and there is evidence of first-pass metabolism. Distribution appears to be widespread with the highest concentration in fat and excretion mainly via the faeces and urine. After oral administration of a 6.6 mg/kg radiolabelled dose to Wistar rats, 70% of the radioactivity was excreted via the faeces and 20% via urine after 4 days. Dermal absorption is limited and the potential for bioaccumulation appears to be low. (Nonylphenol)

Acute toxicity:
LD50 oral rat 1900 mg/kg bw
LD50 oral rat 2462 mg/kg bw
LD50 oral rat 1300 mg/kg bw
LD50 oral rat male 1000-2500 mg/ kg bw
LD50 dermal rabbit 2031 mg/kg bw
(Nonylphenol)

Skin and eye irritation:
Corrosive in liquid form (skin)
Severe irritant (eye)
(Nonylphenol)

Sensitization:
Not sensitizing
(Nonylphenol)

Repeated dose toxicity
Based on results from studies in experimental animals, repeated exposure to nonylphenol may result in histopathological change in the kidney (tubular degeneration or dilation) and minor changes in liver histology (vacuolation in hepatocytes or occasional necrosis).

- Rat (oral, 28 days): NOAEL = 100 mg/kg/day (reduced body weight, reduced food intake, increased liver, kidney and testis weight).
- Rat (oral, 90 day): NOAEL = 50 mg/kg/day (reduced body weight, food consumption and changes in liver and kidney).
- Rat (oral, 3-generation): LOAEL = 15 mg/kg day (histopathological changes in kidneys).

(Nonylphenol)

Genotoxicity:
Based on results from a number of *in vitro* and *in vivo* assays, nonylphenol does not appear to be mutagenic.
(Nonylphenol)

Reproductive and developmental toxicity:
Nonylphenol exposure over several generations can cause minor perturbations in the reproductive system of offspring, although functional changes in reproduction were not produced.
There is no evidence that it is a developmental toxicant in a standard oral developmental toxicity study in the rat.

- Rat (oral, multi-generational): NOAEL= 15 mg/kg/day (slight change in oestrus cycle length, vaginal opening, ovarian weight and sperm count).
- Rat (oral gavage, 10 weeks): LOAEL= 100 mg/kg/day (testicular toxicity).
- Rat (oral gavage, days 6-15 of gestation): NOAEL (maternal)= 75 mg/kg /day (reduced body weight, food consumption, changed appearance of kidney and spleen). NOAEL (foetal)= 300 mg/kg /day (no observed effects).

(Nonylphenol)

Endocrine disruption:
Nonylphenol has been shown to have oestrogenic activity in a number of *in vitro* and *in vivo* assays

Endocrine Disruption
There is evidence both *in vitro* and *in vivo* that nonylphenol has oestrogenic activity of 3-6 orders of magnitude less than that of oestradiol. However, the assays demonstrating oestrogenic activity (recombinant yeast, oestrogen sensitive MCF-7 cells and a rodent uterotrophic assay) are not validated as internationally accepted toxicity tests. In the Nobel rat (a strain particularly sensitive to oestrogenic activity), nonylphenol induced cell proliferation in the mammary gland following subcutaneous exposure at levels as low as 0.05 mg/kg body weight/day. The RAR noted that the significance to humans of these oestrogenic effects has yet to be established.
(Nonylphenol)

Carcinogenicity
There are low concerns for carcinogenicity of nonylphenol by a non-genotoxic mechanism. (Nonylphenol)

EU Risk Characterisation:
The key health effects identified in the EU risk characterization for nonylphenol were acute toxicity, corrosivity, repeated dose toxicity and reproductive effects. The values used for comparison are a LOAEL of 1.5 mg/kg/day (repeated dose toxicity) and a NOAEL of 1.5 mg/kg/day (reproductive effects). These figures were reduced by a factor of 10 from animal N(L)OAELs to compensate for limited oral bioavailability (10%).

An estimated maximum combined daily exposure of approximately 6.4 mg/kg/day was provided, from which a margin of safety of 0.2 was calculated for both repeat dose toxicity and reproductive effects. This maximum exposure is expected to occur in an individual who applies specialty paints, uses a pesticide product, uses cosmetics, is exposed via food packaging materials, and lives in the locality of a textile factory. Conclusion (i) was reached for combined exposure to nonylphenol i.e. "There is a need for further information and/or testing". The margin of safety of 0.2 indicates a cause for concern and has been derived by comparing a LOAEL of 1.5 mg/kg body weight/day for repeat dose toxicity and a NOAEL of 1.5 mg/kg body weight/day for reproductive effects, with the maximum combined exposure of 6.4 mg/kg body weight/day.
(Nonylphenol)

Reference
European Union Risk Assessment Report (RAR), 2002 4-nonylphenol (branched) and nonylphenol, Institute for Health and Consumer Protection, European Chemicals Bureau Existing Substances, Joint Research Centre, European Commission

1.8.3	**Description of ecotoxicological properties of the chemical**

Environmental fate (Nonylphenol)

Soil:
There is evidence that substantial biodegradation of nonylphenol will occur in soil, after a period of adaptation. The biodegradation half-life in soil is estimated to be 300 days.

Water:
Nonylphenol appears to be inherently biodegradable with a calculated rate constant of 0.1-1 h in a wastewater treatment plant. The biodegradation half-life in water is estimated to be 150 days.

Air:
Nonylphenol released to the air is likely to be degraded by reaction with hydroxyl radicals with a half-life of approximately 0.3 days.

Ecotoxicology (Nonylphenol)

- Terrestrial invertebrates

Chronic toxicity (21 days)	Springtail	EC50 (reproduction) = 39 mg/kg
Chronic toxicity (21 days)	Springtail	EC50 (reproduction) = 66 mg/kg
Chronic toxicity (21 days)	Springtail	LC50 = 151 mg/kg
Chronic toxicity (21 days)	*Apporertodea calignosa*	EC50 (growth) = 23.9 mg/kg
Chronic toxicity (21 days)	*Apporertodea calignosa*	EC50 (reproduction) = 13.7 mg/kg
Chronic toxicity (21 days)	*Apporertodea calignosa*	EC10 (reproduction) = 3.44 mg/kg

- Aquatic species

Fish

Acute toxicity (96 hr)	Rainbow trout	LC50 = 0.221 mg/l
Acute toxicity (96 hr)	Winter flounder	LC50 = 0.017 mg/l
Acute toxicity (96 hr)	Inland silversides	LC50 = 0.069 mg/l
Acute toxicity (96 hr)	Fathead minnow	LC50 = 0.135 mg/l
Acute toxicity (96 hr)	Fathead minnow	LOEC (loss of equilibrium) = 0.098 mg/l
Acute toxicity (96 hr)	Fathead minnow	NOEC (mortality) = 0.0831 mg/l
Acute toxicity (96 hr)	Bluegill sunfish	LC50 = 0.209 mg/l
Acute toxicity (96 hr)	Bluegill sunfish	EC50 = 0.203 mg/l
Chronic toxicity (33 days)	Fathead minnow	NOEC (survival) = 0.0074 mg/l
Chronic toxicity (28 days)	Fathead minnow	NOEC (mortality) = 0.0775 mg/l

Invertebrates

Acute toxicity (24hr)	Water flea	EC50 = 0.30 mg/l
Acute toxicity (96hr)	Water flea	EC50 = 0.069 mg/l
Acute toxicity (96hr)	Snail	LC50 = 0.774 mg/l
Acute toxicity (96hr)	Painted shrimp	EC50 (loss of mobility) = 0.0207 mg/l
Chronic toxicity (21 days)	Water flea	NOEC (reproduction)= 0.1 mg/l

Algae

Acute toxicity (72hr)	Green alga	EC50 (biomass) = 0.0563 mg/l
Chronic toxicity (72hr)	Green alga	EC10 (biomass) = 0.0033 mg/l

EU Risk Characterisation (nonylphenol)

In the aquatic compartment, a PNEC of 0.33 µg/l has been derived based on a 72-hour EC_{10} (biomass) of 3.3 µg/l for *Scenedesmus subspicatus* (green alga) and a safety factor of 10. The regional $PEC_{surface\ water}$ is calculated as 0.6 µg/l and therefore the PEC/PNEC ratio is 1.8, indicating concern for the aquatic environment.

In the terrestrial compartment, a $PNEC_{soil}$ of 0.3 mg/kg wet weight has been derived based on a 21-day EC_{10} (reproduction) of 3.44 mg/kg body weight for *Apporectodea calignosa* and a safety factor of 10. Calculated PECs vary according to the source and subsequent PEC/PNEC ratios indicate that for most uses there is a level of concern for the terrestrial environment.

Reference

European Union Risk Assessment Report, 2002 4-nonylphenol (branched) and nonylphenol, Institute for Health and Consumer Protection, European Chemicals Bureau Existing Substances, Joint Research Centre, European Commission

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION			
2.1	**The chemical is:**	θ **banned**	**OR**	☑ **severely restricted**
2.2	**Information specific to the final regulatory action**			
2.2.1	**Summary of the final regulatory action** Nonylphenol (NP) and Nonylphenol ethoxylate (NPE) are included in Annex I to Council Directive 76/769/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Therefore, NP and NPE may only be placed on the market or used subject to the conditions specified in point 46 of Annex I to Directive 76/769/EEC. Point 46 states that NP and NPE may not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0.1 % by mass for a list of purposes (see section 2.5.1). Furthermore, NPE was not included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC and therefore Member States had to withdraw all authorizations for plant protection products containing NPE as an active substance by 25 July 2003. A period of grace for the disposal of existing stocks that could be granted by Member States expired on 31 December 2003 (see section 2.5.2).			
2.2.2	**Reference to the regulatory document** Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003 amending for the 26th time Council Directive 76/769/EEC relating to the restrictions on the marketing and use of certain dangerous substances and preparations (nonylphenol, nonylphenol ethoxylate and cement) (Official Journal of the European Union L178 of 17/07/2003 pp.24-27) http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_178/l_17820030717en00240027.pdf Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (Official Journal L 319 of 23/11/2002 pp.3 – 11)			
2.2.3	**Date of entry into force of the final regulatory action** 17 January 2005. The provisions adopted and published by the Member States to comply with Directive 2003/53/EC had to be applied from 17 January 2005. However, existing national authorisations of pesticides or biocidal products containing NPE as a co-formulant, which had been granted before the entry into force of the Directive (therefore before 18/07/2003) will not be affected by the provisions of the Directive until they expire. Moreover, Member States had to withdraw all authorizations for plant protection products containing NPE as an active substance by 25 July 2003. (see section 2.5.1 and 2.5.2)			

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☑ **Yes**	θ **No**
	If yes, give information on such evaluation Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of existing substances provides a systematic framework for the evaluation of the risks to human health and the environment for each substance on the priority lists if they are produced or imported into the Community in volumes above 10 tonnes per year with a view to establish a strategy for limiting risks in respect to these substances. Nonylphenol (NP) and Nonylphenol ethoxylate (NPE) were part of the priority list and within this context, a Member State volunteered to act as rapporteur to undertake an in-depth risk assessment for both chemicals. The assessment report identified a need to reduce those risks. The assessment report was presented to a meeting of Member States technical experts for endorsement and was peer-reviewed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). The opinion of the CSTEE was expressed at the 22nd plenary meeting (Brussels 6/7 March 2001), confirming the conclusions of the assessment report. The evaluation was based on the review of scientific data generated on the releases, exposure and		

	effects of nonylphenol (NP) and nonylphenol ethoxylate (NPE) and major products of nonylphenol. (which consists of an isometric mixture of variable composition) in the context of the current practices related to the life-cycle of the substance produced or imported into the European Community. Only data that had been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures. It was concluded that NP and NPE posed an unacceptable risk to the environment. The following areas of concern were identified: effects on local and regional aquatic environmental spheres including sediment, effects for terrestrial spheres and effects on secondary poisoning to fish and earthworm predators, as a consequence of exposure arising from the production, formulation and uses of NP or NPE. According to Regulation 793/93, the Commission proposed in Commission Recommendation 2001/838/EC of 7 November 2001 a risk limitation strategy for NP and NPE, recommending in particular that restrictions be placed on their marketing and use. NPE had also been included in the programme of work under Directive 91/414/EEC for the evaluation of existing active substances used in plant protection products which were already on the market on 25 July 1993, with a view to their possible inclusion in Annex I to that Directive. However in the event no dossier was put forward by industry for examination, apparently because the substance was not used as an active ingredient in such products.
	Reference to the relevant documentation European Union Risk Assessment Report 4-nonylphenol (branched) and nonylphenol, final report 2002 http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/4-nonylphenol_nonylphenolreport017.pdf Commission Recommendation of 7 November 2002 on the results of the risk evaluation and the risk reduction strategies for the substances acrylaldehyde; dimethyl sulphate; nonylphenol, phenol, 4-nonyl-branched; ter-butyl methyl ether C(2001)3380 (Official Journal of the European Union of 4/12/2001, L319 pp.30-44 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_319/l_31920011204en00300044.pdf Opinion on the results of the Risk Assessment of: 4-nonylphenol-CAS No.:84852-154-3, 25154-52-3-EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1. Opinion expressed at the 22nd CSTEE plenary meeting, Brussels 6/7 March 2001 http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out91_en.htm Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the results of the Risk Assessment of Nonylphenol, straight chain [CAS N° 25154-52-3- EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1— Opinion expressed at the 13th CSTEE plenary meeting, Brussels 4 February 2000 http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out54_en.htm

2.4	**Reasons for the final regulatory action**		
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	**Yes**	**☑No**
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers		

The final regulatory action was taken in order to protect the environment. However the risk evaluation concluded that:

- There were some concerns with respect to the workers of the industry sectors involving the manufacture of NP and its use as an intermediate, the margin between the actual exposure and the N(L)OEALs for repeated dose toxicity and reproductive effects are low, giving rise to concerns for risks to human health. The corrosivity of the substance in relation to skin and eye is unlikely to be expressed when good occupational hygiene practices are in operation. However, because of the variation in hygiene practice for the spraying of paints, there are concerns for corrosivity, and the conclusion was reached that there was a need to limit risks. These results give rise to concerns for risks to human health.
- Indirect environment exposure: there were some concerns for human health with respect to local exposure, based on MOSs of about 3 for repeated dose toxicity and reproductive effects.

Reference to the relevant documentation

European Union Risk Assessment Report 4-nonylphenol (branched) and nonylphenol, final report 2002
http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/4-nonylphenol_nonylphenolreport017.pdf
Commission Recommendation of 7 November 2002 on the results of the risk evaluation and the risk reduction strategies for the substances acrylaldehyde; dimethyl sulphate; nonylphenol, phenol, 4-nonyl- branched; ter-butyl methyl ether C(2001)3380 (Official Journal of the European Union of 4/12/2001, L319 pp.30-44
http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_319/l_31920011204en00300044.pdf
Opinion on the results of the Risk Assessment of: 4-nonylphenol-CAS No.:84852-154-3, 25154-52-3- EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1. Opinion expressed at the 22nd CSTEE plenary meeting, Brussels 6/7 March 2001
http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out91_en.htm
Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the results of the Risk Assessment of Nonylphenol, straight chain [CAS N° 25154-52-3- EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1— Opinion expressed at the 13th CSTEE plenary meeting, Brussels 4 February 2000
http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out54_en.htm

Expected effect of the final regulatory action

Reduction of risks to human health

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☑ **Yes**	θ **No**

If yes, give summary of the known hazards and risks to the environment

Final regulatory action was taken to protect aquatic and terrestrial ecosystems.
Concerns were identified with regards to effects on local and regional environmental spheres as well as fish and earthworms predators:

- **Aquatic compartment:** the risk evaluation calculated predicted environmental concentrations (PECs) using default release estimations from the Technical Guidance Document (TGD), use category documents, information supplied by industry and from consultations with end users. The Regional $PEC_{surface\ water}$ is calculated as 0.60 µg/l. When compared to the PNEC of 0.33µg/l the PEC/PNEC ratio is 1.8 indicating concern for the aquatic environment. The measured data suggest that local concentrations may be higher where waters are receiving inputs from industries which use either NP or NPE. NP in water courses is strongly adsorbed to sediments and sludges. The $PNEC_{sediment}$ is 0.039 mg/kg. This has been calculated from the $PNEC_{water}$ using an equilibrium partition method. The comparison of the PECs and PNECs and subsequent PECs/PNECs rations suggest that the NP may have adverse effects on sediment dwelling species.
- **Terrestrial compartment:** The calculated PECs imply high concentrations of NPE in all the soil types due to the application of sewage sludge. In calculating the PECs default estimations based on the TGD and information on use supplied by industry have been used. NP is strongly absorbed to sludge in the WWT process. High concentrations of NP may therefore occur in soils where sewage sludge is applied. A $PNEC_{soil}$ of 0.3 mg/kg was calculated using terrestrial

toxicity data. A comparison of the calculated PEC/PNEC ratios indicates that for other uses there is a level of concern for the terrestrial environment. The reported levels on soil (arising from sludge application) range from 0.3-4.7 mg/kg following application. This would give PEC/PNEC ratios of 1 to 15.6

- **Risk for fish and earthworm predators by secondary poisoning:** NPEOs show a high bioconcentration potential in aquatic organisms. A PEC_{oral} of 10 mg/kg food was derived for the secondary poisoning scenario. The experiments carried out indicate bioconcentration factors for fish of 10-1,300 (with most values > 100) on a whole body fresh weight basis and of <0.03 to 1.65mg/kg dry weight. The average concentration of NP in the river during the sampling period was 3.9 µg/l. EUSES has been used to calculate the concentration of NP in fish and earthworms resulting in similar figures. Much higher values were calculated for local concentrations based on the default emissions to water. A further possible route of exposure for higher animals which might be considered is the consumption of plants sprayed with pesticide containing NPEOs. This gave a PEC in food of 6 mg/kg. Compared to the PNEC, the PEC/PNEC ratio is 0.6. As this calculation includes several additive worst-case assumptions, this indicates there should not be any concern for exposure via consumption of plants.

The risk evaluation conclusion reached for the environment is that there is a need for limiting the risks to the **aquatic (surface water)** compartment for the following life cycle stages:
Production of nonylphenol, phenol/formaldehyde resins, epoxy resins, other plastic stabilizers, phenolic oximes, nonylphenol ethoxylates formulation and production
Nonylphenol ethoxylate use in all applications i.e. agriculture except veterinary medicines, captive use by the chemical industry, civil and electrical engineering, industrial and institutional cleaning, leather processing, metal extraction and processing, mineral fuel and oil industry, paint production and use, photographic industry, polymer industry, pulp, paper and board industry, textile industry.

This conclusion also applies to the following life cycle stages for the **terrestrial** compartment and for **secondary poisoning**:
Production and formulation of nonylphenol ethoxylates, production of paint containing nonylphenol ethoxylates
Nonylphenol ethoxylate use in all applications (including veterinary medicines), captive use by the chemical industry, civil and electrical engineering, industrial and institutional cleaning, leather processing, metal extraction and processing, mineral fuel and oil industry, paint production and use, photographic industry, polymer industry, pulp, paper and board industry, textile industry.

Reference to the relevant documentation

European Union Risk Assessment Report 4-nonylphenol (branched) and nonylphenol, final report 2002
http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/4-nonylphenol_nonylphenolreport017.pdf
Commission Recommendation of 7 November 2002 on the results of the risk evaluation and the risk reduction strategies for the substances acrylaldehyde; dimethyl sulphate; nonylphenol, phenol, 4-nonyl- branched; ter-butyl methyl ether C(2001)3380 (Official Journal of the European Union of 4/12/2001, L319 pp.30-44
http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_319/l_31920011204en00300044.pdf
Opinion on the results of the Risk Assessment of: 4-nonylphenol-CAS No.:84852-154-3, 25154-52-3-EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1. Opinion expressed at the 22nd CSTEE plenary meeting, Brussels 6/7 March 2001
http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out91_en.htmOpinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the results of the Risk Assessment of Nonylphenol, straight chain [CAS N° 25154-52-3- EINECS No.: 284-325-5, 246-672-0. Report version (Human Health effects): November 2000 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances1— Opinion expressed at the 13th CSTEE plenary meeting, Brussels 4 February 2000
http://europa.eu.int/comm/health/ph_risk/committees/sct/docshtml/sct_out54_en.htm

Expected effect of the final regulatory action

Reduction of risks to the environment

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	**Final regulatory action has been taken for the chemical category**	☑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Placing on the market or use as a substance or constituent of preparations in concentrations equal or higher than 0.1% by mass for the following purposes: (1) industrial and institutional cleaning except: - Controlled closed dry cleaning systems where washing liquid is recycled or incinerated, - Cleaning systems with special treatment where the washing liquid is recycled or incinerated; (2) domestic cleaning; (3) textiles and leather processing except: - Processing with no release into waste water, - Systems with special treatment where the process of water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin); (4) emulsifier in agricultural teat dips; (5) metal working except: - Uses in controlled closed systems where the washing liquid is recycled or incinerated; (6) manufacturing of pulp and paper; (7) cosmetic products; (8) other personal care products except: - Spermicides; (9) co-formulants in pesticides and biocides	
	Use or uses that remain allowed	
	Existing national authorization of pesticides or biocidal products containing NPE as a co-formulant which have been granted before 18/07/2003 (entry into force of the regulatory action) shall remain valid until they expire.	

2.5.2	Final regulatory action has been taken for the chemical category	☑ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All applications of NPE as an active ingredient in plant protection products are not allowed. It is prohibited to place on the market or use NP and NPE as a substance or constituent in concentrations equal or higher than 0.1% by mass as a co-formulant in pesticides and biocides.	
	Formulation(s) and use or uses that remain allowed	
	Existing national authorization of pesticides or biocidal products containing NPE as a co-formulant which have been granted before 18/07/2003 (entry into force of the regulatory action) shall remain valid until they expire.	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	**Year**
Produced	73,500	1997
Imported	8,500	1997
Exported	3,500	1997
Used	78,500	1997

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	Similar concerns to those identified are likely to be encountered in other countries where the substances are used, particularly in developing countries.

2.7	Other relevant information that may cover:	
2.7.1	**Assessment of socio-economic effects of the final regulatory action**	
	Not applicable	
2.7.2	**Information on alternatives and their relative risks**	
	Not applicable	
2.7.3	**Relevant additional information**	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 48 60
Telefax	+322 296 7617
E-mail address	klaus.berend@cec.eu.int
Designated National Authority	

Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Name of person in charge	Klaus BEREND
Position of person in charge	Deputy Head of Unit
Telephone	+322 299 48 60
Telefax	+322 296 76 17
E-mail address	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: