ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

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

Country: SWITZERLAND

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Nonylphenols and nonylphenol ethoxylates**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**4-Nonyl phenol (branched); Nonylphenol; 4-Nonyl phenol** **Polyethylene glycol nonylphenyl ether; PEG-X nonyl phenyl ether; Nonoxynol-X (X≥1)** **Poly(oxy-1,2-ethanediyl), α-(4-nonylphenyl)-ω-hydroxy-, branched;**
1.3	**Trade names and names of preparations**	**Marlophen NP9, Imbentin-N/020, Sympatens NP090, Berol 09, Berol 268, Igepal CO 630, Lutensol AP10, Arkopal N090, Dowfax 9N20**
1.4	**Code numbers**	
1.4.1	CAS number	84852-15-3 , 25154-52-3 , 90481-04-2, 104-40-5 37205-87-1, 9016-45-9, 68412-54-4, 127087-87-0, 26027-38-3, 11066-49-2
1.4.2	Harmonized System customs code	2907 13 3402 13
1.4.3	Other numbers (specify the numbering system)	

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 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 2 **FINAL REGULATORY ACTION**

2.1 The chemical is: ☐ banned OR ☒ severely restricted

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

It is prohibited to place the following product types on the market if their content of octylphenol (molecular formula $C_{14}H_{22}O$), nonylphenol (molecular formula $C_{15}H_{24}O$) or ethoxylates of these is equal to or greater than 0.1 % by mass:

a. laundry detergents
b. cleaning products
c. cosmetics
d. textiles processing products;
e. leather processing products;
f. metal working products;
g. auxiliary products for the manufacture of cellulose and paper;
h. agricultural teat dips containing these substances as emulsifiers;
i. biocidal products and plant protection products containing these substances as co-formulants.

Exemptions:

a. spermicides;
b. textile and leather processing products if:
    1. their processing does not result in the disposal of octylphenol ethoxylates or nonylphenol ethoxylates in waste water, or
    2. for installations for special treatment, such as degreasing of sheep skin, the process water is pre-treated to remove the organic fraction completely prior to the biological waste water treatment;
c. metal working products intended for use in closed and controlled systems in which the cleaning liquid is recycled or incinerated.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

On 18 May 2005 the Federal Council adopted a regulatory package on chemicals inter alia the Ordinance on Risk Reduction related to the Use of certain particularly dangerous Substances, Preparations and Articles (SR 814.81), Annex 1.8 severely restricts nonylphenols and nonylphenol ethoxylates.

2.2.3 Date of entry into force of the final regulatory action

1 August 2005 see http://www.admin.ch/ch/f/as/2005/2917.pdf page 2924

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Nonylphenol:

Is used as/in

- monomer in the production of phenol/formaldehyde resins
- catalyst in the curing of epoxy resins
- the production of nonylphenol ethoxylates
- the production of tri-(4-nonylphenyl) phosphite (TNPP)

Nonylphenol ethoxylates:

Mainly used as/in:

- Co-formulant in pesticide products (plant protection and biocide products)
- Surfactant in cosmetics
- Surfactant in industrial and household cleaning products
- Textile and leather processing
- Metal working
- Paper and pulp manufacturing
- Paints, resins, protective coatings

2.3.2 Final regulatory action has been taken for the category ☒ Industrial

Use or uses prohibited by the final regulatory action

Banned uses:

- Institutional and industrial cleaning (severely restricted)
- In household cleaning products (banned)
- In cosmetic products (banned)
- Textile and leather processing (severely restricted)
- In agricultural teat dips (banned)

- Metal working (severely restricted)
- Paper and pulp manufacturing (banned)

Use or uses that remain allowed (only in case of a severe restriction)

- Institutional and industrial cleaning only in:

- 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

- Textile and leather processing only in:

- 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)

- Spermicides
- Metal working only:

- in controlled closed systems where the washing liquid is recycled or incinerated

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Banned uses

- Co-formulant in pesticide products (plant protection and biocide products)

Formulation(s) and use or uses that remain allowed

(only in case of a severe restriction)

Existing national authorisations of plant protection or biocidal products containing NPE as a co-formulant which have been granted before 01/08/2005 (entry into force of the regulatory action) shall remain valid until they expire

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Rapport explicatif relatif à l'ordonnance sur la réduction des risques liés à l'utilisation de substances, de préparations et d'objets particulièrement dangereux ; page 39-41 (Ref. 1)

Stoffe mit endokriner Wirkung in der Umwelt, Schriftenreihe Umwelt Nr. 308,Bundesamt für Umwelt, 1999 (Ref. 2):

http://www.bafu.admin.ch/publikationen/publikation/00456/index.html?lang=de

EU nonylphenols Risk Assessment (Ref. 3):

http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/4-nonylphenol_nonylphenolreport017.pdf

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Nonylphenol ethoxylates are microbially degraded. It is mainly the ethoxylate chain that is degraded to yield more stable and smaller molecules such as nonylphenol with 1 and 2 ethoxylate units, their carbonic acids and finally nonylphenols are formed.

Direct exposure of consumer to nonylphenols may occur by using products containing them. The estimated exposure level was low. It is estimated that the main indirect exposure of humans to nonylphenols occurs via food intake (mainly fish and root crops). Local exposure scenarios like vicinity to textile industry give high exposure levels. Contamination of crops with nonylphenols can occur via application of pesticides containing nonylphenol ethoxylates as co-formulant (up to 5%). However there are no data on residue levels in the harvested crops. Concerns for human health for workers in certain processes have been identified (ex. spray application of specialty paint) (see EU Risk assessment[1], Ref 3).

The contamination with nonylphenol ethoxylates metabolites of different fish tissues (from Swiss rivers) has been determined in 1984/85. A range of 0.03-7 mg/kg dw. has been measured (Ref 2).

Two studies on rodents show that subcutaneous injection of nonylphenols induce an increase of the uterus weight with a range of lowest observed effect (LOEL) from 100 to 333 mg/kg/day. Another study on youthful rats report an increase of progesterone receptors in uterus at a LOEL

[1] For the regulation of chemicals Switzerland bases its risk evaluation inter alia on the EU risk assessment. Switzerland takes over most of the EU chemicals regulations and in certain cases adapt them to Swiss circumstances. This is due to the fact that Switzerland is geographically in the middle of Europe and is socially and economically similar to western Europe, EU is the most important trade partner of Switzerland

of 15-30 mg/kg/day.

Another study on rats reports that males show a reduced density of sperm and reduced quantity of spermatids in testicles after oral concentration of 49 and 150 mg/kg/day respectively. Females show an early sexual maturity and reduced weight of ovaries and an extension in the oestrogenic cycle after oral concentration of 49 and 150 mg/kg/day respectively. The NOEL is 15 mg/kg/day.

Statistics on testicular cancer in Switzerland showed an increase of 13% between the periods 1974-1978 and 1983-1993 (Statistics comprised canton Vaud and Neuchatel). A second Study compared the occurrence of testicular cancer in the period 1984-1988 and 1989-1993: no significant increase could be observed (Ref 2).

Epidemiological studies show an increase of certain diseases in the last decades, however the studies often don't show the connection between the causes and the observed effects.

Expected effect of the final regulatory action

Reduction of the risk to humans

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Final regulatory action was taken to protect the environment

Already in 1987 the marketing and use of nonylphenol ethoxylates in laundry detergents had been banned. As a consequence, concentrations of metabolites in waste water have decreased markedly. Because of other still permitted uses, in 1997 the compounds were still detected at concentrations of a few micrograms per litre in effluents from water treatment plants and also in sewage sludge. Elevated values were found in samples of drainage water and flowing water receiving waste water from the textile industry.

The nonylphenol concentrations that are considered to have no effect on aquatic organisms (PNEC= 0.3374 µg/l see Ref 3) are in certain cases exceeded (see Ref 1).

Concentrations of 0.03-0.3µg/l of nonylphenols have been measured in Swiss rivers in 1997. Nonylphenols have also been measured in the effluents of water treatment plants in 1997: the concentration ranged from 0.1 to 3.6 µg/l.

Expected effect of the final regulatory action

Reduction of the risk to the environment

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	Approx. 990 MT (Nonylphenols)	1993
imported	Approx. 830 MT (Nonylphenols, estimation based on received export notification) Approx. 70 MT (Nonylphenol ethxylates, estimation based on received export notification)	2011 2011
exported	Approx. 2 MT (Nonylphenols, estimation based on sent export notification) Approx. 340 MT (Nonylphenol ethxylates, estimation based on sent export notification)	2011 2011
used		

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

Many of the banned uses of nonylphenol ethoxylates (ex. Co-formulant in pesticides)in Switzerland are still permitted in many countries. Concerns mentioned in the risk evaluation such as water pollution might be relevant in these countries.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

All bans deal with the use of Nonylphenols and nonylphenol ethoxylates as:

cleaning, emulsifying or dispersing agent and uses that are based on the surfactant properties of Nonylphenols and nonylphenol ethoxylates.

Nonylphenols and nonylphenol ethoxylate surfactants are easily replaceable and a large variety of alternatives exist and are being used.

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**

Other classification systems **e.g. EU, USEPA**	**Hazard class**
• Annex I to Directive 67/548/EEC • Regulation (EC) No 1272/2008 • Based on the Ordinance on chemical products, the EU-classification is also valid in Switzerland	**Classification and Labeling of 4-nonylphenol (84852-15-3)** **Classification:** **Repr. Cat. 3; R62-63 - Xn; R22 - C; R34 - N; R50-53** **Labeling :** **C; N** **R: 22-34-62-63-50/53** **S: (1/2-)26-36/37/39-45-60-61** R22 states: Harmful if swallowed R34 states: Causes burns R62 states: Possible risk of impaired fertility. R63 states: Possible risk of harm to the unborn child. R50/53 states: Very toxic to aquatic organisms, may

Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council	cause long-term adverse effects in the aquatic environment S1/2 states: Keep locked up and out of the reach of children S26 states: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S36/37/39 states: Wear suitable protective clothing, gloves and eye/face protection S45 states: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S46 states: If swallowed, seek medical advice immediately and show this container or label S60 states: This material and its container must be disposed of as hazardous waste S61 states Avoid release to the environment. Refer to special instructions/safety data sheets Repr. 2 -H361d Acute Tox. 4* -H302 Skin Corr. 1B -H314 Aquatic Acute 1 -H400 Aquatic Chronic 1 -H410

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Table 1: Physico-chemical properties of 4-nonylphenol:

Property	Value	Comments
Physical state at ntp	Clear to pale-yellow viscous liquid	Slight phenolic odour
Molecular weight	220.34 g/mol	
Melting point	circa –8°C	Approximate only due to nature of th material – may vary according to production process used.
Boiling point	290-300°C	Nonylphenol undergoes thermal decomposition before it reaches its boiling point.
Relative density	0.95 at 20°C	ASTM 3505
Vapour Pressure	circa 0.3 Pa at 25°C (some evidence actual value may be lower)	Extrapolated value - see text
Partition coefficient	log Kow 4.48	See text
Water solubility	6 mg/l at 20°C	See text for discussion of other valu - may be Ph dependent
Flash point	141-155°C (lowest value used for risk assessment)	149-155°C when tested to ASTM D- by Hüls
Autoflammability	circa 370°C	Hüls to DIN 51794
Oxidising properties	not applicable	
Viscosity	2,500 mPa s at 20°C	Hüls

Reference

EU nonylphenols Risk Assessment (Ref. 3):

http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/4-

nonylphenol_nonylphenolreport017.pdf

3.2.2 Description of toxicological properties of the chemical

According to Ref 3

Summary of toxicokinetics, metabolism and distribution

Most of the information on the toxicokinetics of nonylphenol concerns oral exposure and is based on a small number of limited rat and human studies, supported by a read across from data relating to octylphenol, an alkyl phenol with a close structural relationship to nonylphenol. The available data, though sparse, do provide the basis for a general understanding of the main features of the toxicokinetic profile. Absorption from the gastrointestinal tract is initially rapid, and probably extensive. The major metabolic pathways are likely to involve glucuronide and sulphate conjugation, and there is evidence of extensive first pass metabolism of nonylphenol absorbed through the gastrointestinal tract. Because of first pass metabolism, the bioavailability of unconjugated nonylphenol is probably limited following oral exposure, at no more that 10- 20% of the administered dose. Nonylphenol is distributed widely throughout the body, with the highest concentration in fat. Regarding bioaccumulation, considering the available information from both animals and humans, there are insufficient consistent data to allow a conclusion to be drawn on whether or not nonylphenol has this potential. The major routes of excretion are via the faeces and urine.

There are no data on the toxicokinetics of nonylphenol following inhalation exposure, but on the basis of the oral absorption data and high partition coefficient, it would be prudent to assume that significant absorption via the inhalation route can occur. Furthermore, because first pass metabolism will not take place following exposure by these routes, the systemic bioavailability is likely to be substantially greater than is associated with the oral route. Concerning the dermal route, *in vitro* data indicate that nonyl phenol is poorly absorbed across skin, although some limited skin penetration, especially to the stratum corneum, can occur

Summary of acute toxicity

No human data are available. In animals, nonylphenol is moderately toxic by the oral route, with LD50 values for the rat in the ranges of about 1200 to 2400 mg/kg for males and 1600 to 1900 mg/kg for females. The dose-response curve for lethality appears to be steep. Erosion of the stomach mucosa is sometimes seen following the administration of a lethal dose. The acute toxicity of nonylphenol by the dermal route is similar, with an LD50 of about 2000 mg/kg in rabbits. No data are available on the acute inhalation toxicity, although the corrosive nature of nonylphenol suggests that toxicity would be elicited following exposure by this route.

Summary of irritation

No information is available from human studies. Animal data indicates that liquid nonylphenol can be corrosive to the skin, although its potency might vary according to source and exact composition. The liquid is also a severe eye irritant. Exposure to the saturated vapour elicited mild sensory irritation of the respiratory tract in mice.

Summary of sensitisation

No human data are available. The results of several guinea pig maximisation tests suggest that nonylphenol does not have significant skin sensitising potential. No information on respiratory tract sensitisation is available, although it can be predicted from its low chemical reactivity that nonylphenol is unlikely to be a respiratory allergen.

Summary of repeated dose toxicity

No useful human data are available. In a multigeneration study in the rat involving oral exposure via the diet for up to 20 weeks, a LOAEL for repeated dose toxicity of 15 mg/kg/day was identified, based on histopathological changes in the kidneys (tubular degeneration or dilatation), although such changes were not apparent at this dose level in a 90-day dietary exposure rat study. At higher dose levels the liver may also be a target organ; minor histopathological changes in the liver (vacuolation in the periportal hepatocytes or occasional individual cell necrosis) were seen at

doses of 140 mg/kg/day and above in some dietary studies. The oral toxicity of nonylphenol appears to be enhanced when dosed by gavage, with mortalities being reported at dose levels of 100 mg/kg/day and above. No studies involving dermal or inhalation exposure have been conducted. Nonylphenol has been reported to induce cell proliferation in the mammary gland of the Nobel rat following subcutaneous exposure at levels down to 0.05 mg/kg/day, but this finding could not be reproduced in a duplicate study; furthermore, there are doubts about the relevance of this finding to humans and regarding the validity of the original study.

Summary of mutagenicity
No human data are available. Nonylphenol tested negative in two bacterial assays and an *in vitro* mammalian cell gene mutation assay. An *in vivo* micronucleus test, conducted using the intraperitoneal route, was negative. A second in vivo micronucleus test, which used the oral route, was also negative, although there were methodological weaknesses in this study. These results show that nonylphenol is not mutagenic.

Summary of toxicity to reproduction
No human data are available. Nonylphenol has been shown to have oestrogenic activity in a number of *in vitro* and *in vivo* assays. The potency of this oestrogenic activity in these assays ranged from 3 to 6 orders of magnitude less than that of oestradiol. The effects of nonylphenol on fertility and reproductive performance have been investigated in a good quality oral (dietary administration) multigeneration study in the rat. This study provided evidence that nonylphenol exposure over several generations can cause minor perturbations in the reproductive system of offspring, namely slight changes in the oestrous cycle length, the timing of vaginal opening and possibly also in ovarian weight and sperm/spermatid count, although functional changes in reproduction were not induced at the dose levels tested. The NOAEL for these changes was 15 mg/kg/day. The observed perturbations in offspring are compatible with the predictable or hypothesised effects of exogenous oestrogenic activity. Evidence of testicular toxicity, seen as seminiferous tubule vacuolation, cell necrosis and a reduction in tubule diameter, was reported at exposure levels which also cause mortality in a repeated dose gavage study in rats. The LOAEL for testicular toxicity was 100 mg/kg/day. The toxicity of nonylphenol appears to be enhanced by gavage administration in comparison to dietary administration, presumably because higher peak blood concentrations of nonylphenol are achieved by gavage. No evidence that nonylphenol is a developmental toxicant was seen in a standard oral developmental toxicity study in the rat; maternal and foetal NOAELs were 75 and 300 mg/kg/day, respectively. In contrast, in a gavage study involving *in utero*, lactational and direct post-weaning exposure, there was a reduction in sperm count at 250 mg/kg/day, although it is not possible to state whether this is a developmental effect or as a result of direct exposure after weaning. In an intraperitoneal study designed to investigate the effects of nonylphenol on male reproductive tract development of neonatal rats, evidence of impaired development was observed. However, this study was difficult to interpret, such that these results carry little weight in the overall assessment of the available data. Overall, the observations of oestrogenic activity in the *in vitro* and *in vivo* assays, minor perturbations in the reproductive system of offspring in the multigeneration study, and testicular changes in gavage studies collectively raise concerns for reproductive toxicity, possibly mediated through action on the oestrogen receptor. These concerns for reproductive toxicity are addressed in the risk characterisation, although there are uncertainties. The oestrogenic activity assays are merely screening tests. The effects on reproduction-related parameters in the multigeneration study were marginal and there was no evidence of functional changes in reproduction; furthermore any changes that were seen occurred at exposure levels in excess of the LOAEL for repeated dose toxicity (LOAEL for renal toxicity is 15 mg/kg/day, NOAEL for reproductive changes is 15 mg/kg/day). Evidence of testicular toxicity was reported in two repeated exposure studies designed specifically to investigate the effects on this organ, but only at doses which also caused mortality. No evidence of testicular toxicity was seen in standard repeated dose studies involving dietary administration. Development was not affected in a standard rat oral developmental toxicity study.

According to Ref 2

Endocrine effect: two studies on rodents show that subcutaneous injection of nonylphenol induce an increase of the uterus weight with a range of lowest observed effect (LOEL) from 100 to 333

mg/kg/day. Another study on youthful rats report an increase of oestrogen receptors in uterus at a LOEL of 5-10 mg/kg/day.

Reference

EU nonylphenols Risk Assessment (Ref. 3):

http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/4-nonylphenol_nonylphenolreport017.pdf

Stoffe mit endokriner Wirkung in der Umwelt, Schriftenreihe Umwelt Nr. 308 (Ref. 2):

http://www.bafu.admin.ch/publikationen/publikation/00456/index.html?lang=de

3.2.3 Description of ecotoxicological properties of the chemical

Exposure to environment: Nonylphenol ethoxylate and their degradation products (e.g., nonylphenol) are not produced naturally. Their presence in the environment is only a consequence of anthropogenic activity. Local releases of nonylphenol to the environment may occur during production, use as a chemical intermediate and from the breakdown of nonylphenol ethoxylates in wastewater treatment plants. Nonylphenol enters the aquatic compartment directly as nonylphenol or as the breakdown product of nonylphenol ethoxylates. Nonylphenol in water courses is strongly adsorbed to sediments and sludges. The concentration of nonylphenol is generally low in treated effluents, as it degrades and sorbs to sludge particles; however, nonylphenol sorbed to sediments may represent an alternative route of exposure that may result in chronic toxicity to sediment-dwelling organisms. Nonylphenol shows a high bioconcentration potential in aquatic organisms.
Direct releases of nonylphenol to the terrestrial compartment are unlikely to occur given its production method and use pattern. The exception is the use of nonylphenol ethoxylates in pesticide formulations. Nonylphenol in sewage treatment plants can come from direct discharges of nonylphenol or from the breakdown of products containing nonylphenol, such as nonylphenol ethoxylates, in the waste water treatment plant. High concentrations of nonylphenol may therefore occur in soils if sewage sludge is applied (it should not be the case in Switzerland, because it is forbidden by law). Nonylphenol released to soil either directly or indirectly will be strongly bound to the soil. It is therefore unlikely to enter groundwater or be transported a considerable distance. Moreover, studies show that nonylphenol is rapidly eliminated in soils treated with sewage sludge containing nonylphenol.
Nonylphenol is not released in any significant quantities to the atmosphere. In the atmosphere nonylphenol is relatively short lived, based upon its reaction with hydroxyl radicals. It is therefore unlikely to be transported very far from its point of emission. It is unlikely to move from the troposphere to the stratosphere and contribute to ozone depletion. Nonylphenol is not thought to contribute to low level ozone formation nor act as a greenhouse gas and neither is it thought to contribute to low level ozone formation.
According to Ref 3:
Toxicity for aquatic organisms:
- Freshwater fish species: in flow system studies the 96h LC_{50} range from 0.128 to 0.221 mg/l and the 96h EC_{50} from 0.096 to 0.109 mg/l. One long term study reports a no observed effect concentration on survival ($NOEC_{survival}$) of 0.0074 mg/l and a lowest observed effect concentration on survival ($LOEC_{survival}$) of 0.014 mg/l
- Saltwater fish species: one valid study reports a 96h LC_{50} of 0.31 mg/l (flow system study).
- Freshwater aquatic invertebrates species: the acute toxicity values in static system studies on are 24h and 48h LC_{50} of 0.30 and 0.19 mg/l respectively, and 24h and 48h $EC_{50\ (immobilization)}$ of 0.218 and 0.14 mg/l respectively. A long term study on *Daphnia magna* shows a range of 0.10 to 0.12 mg/l for the 7day and 21day LC_{50} respectively. Studies with other invertebrate species in flow system show a range of 96h LC_{50} between 0.17 to 0.774 mg/l, and 96h EC_{50} between 0.15 to 0.378 mg/l.
- Seawater aquatic invertebrates species: a valid study in a flow system show a 96h LC_{50} of 0.043 mg/l and 96h NOEC of 0.018 mg/l, and 28day $LOEC_{length}$ and 28day $NOEC_{length}$ of 0.0067 and 0.0039 mg/l respectively.
- Aquatic algae and plants species: different studies on freshwater species report 72h EC_{50} of 0.0563, 0.323 and 1.3 mg/l for effects on biomass, growth rate, and cell growth respectively.

Another study on *Lemna minor* reports a 96h $LOEC_{(frond\ production)}$ of 2.08 mg/l and a 96h NOEC 0.901 mg/l. And a study on alga shows a 96h $LOEC_{(cell\ production)}$ of 1.480 and a NOEC of 2.08 mg/l. Finally, a study on a marine alga show a value for 96h $EC_{50(cell\ growth)}$ of 0.027 mg/l.

- Micro-organisms: Cultures of the bacterium *Pseudonomas putida* show an EC_{10} of >10 mg/l for oxygen consumption when exposed to nonylphenol for 30 minutes. In a test of activated sludge respiration inhibition an EC_{50} of 950 mg/l was reported.
- Amphibians: A study done over 30 days in a sediment/water system shows a 30day LC_{50} of 260 mg/kg dry weight and a 30day EC_{50} of 220 mg/kg dry weight. At 10, 20 and 30 days the lowest observed effect level (LOEL) was 390 mg/kg dry weight and the no observed effect level (NOEL) was 155 mg/kg dry weight.

Field studies on the effects observed on zooplankton and macroinvertebrates populations show that the lowest $NOEC_{(population\ decrease)}$ over all the species studied is 5 □g/l and the lowest LOEC is 76 □g/l.

Two long term studies on terrestrial plants show a 21day $NOEC_{(growth)}$ of 100 mg/kg and 7day, 14day and 21day $EC_{50(growth)}$ of 559, 625 and 1000 mg/kg respectively. Two other long term studies on terrestrial invertebrates show a 21day $EC_{10(reproduction)}$ range of 3.44 to 48 mg/kg of nonylphenol, and a 21day $EC_{10(mortality)}$ range of 40 to 75 mg/kg.

There are no data on the effects of nonylphenol through aerial exposure of non-mammalian organisms. Biotic or abiotic effects are unlikely to occur because of the limited direct release, low volatility and rapid atmospheric degradation of nonylphenol. But nonylphenol has been shown to bioconcentrate in aquatic species.

Endocrine disruption of aquatic organisms

The oestrogenic effect of nonylphenol on fish and Daphnids has been studied by a number of authors. Generally the work shows that nonylphenol and nonylphenol ethoxylates do exhibit oestrogenic activity. For nonylphenol ethoxylates the activity was found to increase with decreasing chain length, with nonylphenol showing the greatest activity. Most of the tests indicate that oestrogenic effects may start to occur at around 10-20 µg/l. Nonylphenol is, however, 100 to 100'000 times less potent than oestradiol.

Vitellogenin is a yolk protein normally produced in response to oestrogen and is a good biomarker for environmental oestrogen. *In vitro* studies with hepatocytes show that nonylphenol stimulate the production of vitellogenin with a mean EC_{50} of 3.56 mg/l, and a LOEC of 0.2 mg/l. In long term studies, fish exposed to nonylphenol for 3 weeks show significant stimulation of blood vitellogenin at 20.3 g/l with a NOEC of 5.02 g/l. In two other studies, fishes were exposed to nonylphenol by intraperitoneal injection. Vitellogenin was detected in plasma at a dose of 10 mg/kg and at a significant dose of 237 mg/kg.

In a flow through system study on fish (3 weeks assay), a significant reduction in testes size was found at 54.3 g/l nonylphenol with a NOEC of 20.3 g/l. After an acute exposure to nonylphenol of 48h, a study indicate that nonylphenol is capable of significantly perturbing components of androgen metabolism in daphnids at concentrations of 25 g/l, and a reduction in the number of off-spring was found with a mean LOEC of 71 g/l. Moreover, the same study on daphnids also show that a long term exposure of nonylphenol (30 days) can cause a deformed offspring at a EC_{11} of 10 g/l. Another study on the effects of nonylphenol on steroid-metabolising enzymes of fishes concluded that nonylphenol may increase the activity of steroid-metabolising enzymes at low concentrations (1 mg/kg injected intraperitoneally) but decrease the activity of theses enzymes at high concentrations (25 mg/kg).

The relative importance and significance of estrogenic responses in aquatic organisms to the individual or population are not currently well understood.

Table 2: Toxicity to aquatic organisms

Tropic level	Species	End point	Concentration (mg/l)	Reference
Freshwater fish	Fathead minnow Primephales promelas	96hr LC_{50}	0.128	Brooke (1993a)
		33 day $NOEC_{survival}$	0.0074	Ward and Boeri (1991b)
Saltwater fish	Sheepshead minnow Cyprinodon variegatus	96hr LC_{50}	0.31	Ward and Boeri (1990d)
Freshwater	Ceriodaphnia dubia	96hr EC_{50}	0.069	England (1995)

invertebrates		7 day NOECreproduction	0.0887		
	Daphnia magna	48hr EC_{50}	0.085	Brooke (1993a)	Vali
		21 day NOECsurviving offspring	0.024	Comber et al (1993)	Vali
	Hyalella azteca	96hr EC_{50}	0.0207	Brooke et al (1993)	Vali
Saltwater invertebrates	Mysidopsis bahia	96hr LC_{50}	0.043	Ward and Boeri (1990c)	Vali
		28 day $NOEC_{length}$	0.0039	Ward and Boeri (1991c)	Vali
Fresh water algae	Selenastrum capricomutum	96hr EC_{50}(Cell growth)	0.41	Ward and Boeri (1990b)	Vali
	Scenedesmus subspicatus	72hr EC50 (Biomass) 72hr EC10 (Biomass) 72hr EC50 (Growth rate) 72hr EC10 (Growth rate)	0.0563 0.0033 0.323 0.0251	Kopf (1997)	Val
Saltwater algae	Skeletonema costatum	96hr EC_{50}(Cell growth)	0.027	Ward and Boeri (1990a)	Vali
Mesocosm study		20 day NOEC 20 day LOEC	0.005 0.023	Liber et al (1999)	Use Car

Table 3: Toxicity to terrestrial plants

Species	Test subtance	Soil type	Endpoint and effect concentration (wet weight)	Reference
Lettuce (Lactuca sativa)	4-nonylphenol	Agricultural loam	7 day EC_{50} (Growth) 559 mg/kg 14 day EC_{50} (Growth) 625 mg/kg	Hulzebos et al (1993)
Sorghum (Sorghum bicolor)	nonylphenol	Grit/loam soil	21 day NOEC (Growth) 100 mg/kg 21 day EC_{50} (Growth) 1,000 mg/kg	Windeatt and Tapp (1987)
Sunflower (Helianthrus rodeo)			21 day NOEC (Growth) 100 mg/kg 21 day EC_{50} (Growth) 1,000 mg/kg	
Soya (Glycine max)			21 day NOEC (Growth) 100 mg/kg 21 day EC_{25} (Growth) 1,000 mg/kg	

Table 4: Toxicity to terrestrial invertebrates

Species	Test subtance	Soil type	Endpoint and effect concentration (wet weight)	Reference
Springtails (Folsomia fimetaria)	nonylphenol	sandy soil	21 day EC_{10} (Reproduction) 27 mg/kg 21 day EC_{50} (Reproduction) 39 mg/kg	Holm
	4-nonylphenol in sludge		21 day EC_{10} (Reproduction) 48 mg/kg 21 day EC_{50} (Reproduction) 59 mg/kg	
	nonylphenol	LUFA soil	21 day EC_{10} (Reproduction) 24 mg/kg 21 day EC_{50} (Reproduction) 66 mg/kg 21 day EC_{10} (Mortality) 75 mg/kg 21 day EC_{50} (Mortality) 151 mg/kg	Krogh et al (1996)
Earthworms (Apporec-todea calignosa)	nonylphenol	LUFA soil	21 day EC_{10} (Mortality) > 40 mg/kg 21 day EC_{50} (Growth) 23.9 mg/kg 21 day EC_{10} (Reproduction) 3.44 mg/kg 21 day EC_{50} (Reproduction) 13.7 mg/kg	

According to Ref 2:

Endocrine effect of nonylphenol, studies on fish:

In vivo studies report induction of vitellogenin synthesis in a LOEC range of 20 to 100 g/l depending on the fish species, and stimulation of the vitellogenin mRNA synthesis in a concentration range of 10 to 100 g/l. Another study reports that fish males exposed to nonylphenol during 3 months develop a testis-ova, characterized by the presence of both testicular and ovarian tissue in the gonads, at a LOEC of 50 g/l.

In vitro studies with hepatocytes show stimulation of vitellogenin synthesis, and also competition for the oestrogenic receptor at IC_{50} of 2 mg/l.

Reference

EU nonylphenols Risk Assessment (Ref. 3): http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/4-nonylphenol_nonylphenolreport017.pdf Stoffe mit endokriner Wirkung in der Umwelt, Schriftenreihe Umwelt Nr. 308 (Ref. 2): http://www.bafu.admin.ch/publikationen/publikation/00456/index.html?lang=de

SECTION 4 **DESIGNATED NATIONAL AUTHORITY**

Institution	Federal Office for the Environment FOEN Waste Management, Chemicals and Biotechnology Division
Address	Worblentalstr. 68, 3063 Ittigen, Switzerland Postal address: 3003 Bern, Switzerland
Name of person in charge	**Dr. Sarah Maillefer**
Position of person in charge	Designated National Authority Rotterdam Convention
Telephone	Tel. +41 (0)31 322 83 44
Telefax	Fax +41 (0)31 323 03 69
E-mail address	picdna@bafu.admin.ch

Date, signature of DNA and official seal: 23.07.12 S Maillefer

Federal Office for the Environment FOEN
Waste Management, Chemicals
and Biotechnology Division
Industrial Chemicals Section
CH - 3003 Bern

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.