



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

Octylphenols and Octylphenol ethoxylates

1.2 Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists

4-(1,1,3,3-Tetramethylbutyl)phenol; 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated
4-octylphenol,
(1,1,3,3-Tetramethylbutyl)phenol,
Polyethylene glycol octyl phenyl ether, Octoxynol-X,
PEG-X Octyl phenyl ether (X≥1);

1.3 Trade names and names of preparations

Triton X, Texofor FP 300; Igepal CA 630
Preceptin, Antarox A-200, Alfenol 3, Marlophen 820

1.4 Code numbers

1.4.1 CAS number

140-66-9, 1806-26-4, 27193-28-8

9002-93-1, 68987-90-6, 9036-19-5

1.4.2 Harmonized System customs code

2907 198

3402 131

1.4.3 Other numbers (specify the numbering system)

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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 octylphenols and octylphenol 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

Octylphenol:

Is used as/in

- monomer in the production of phenol/formaldehyde resins
- rubber additive
- the production of octylphenol ethoxylates
- Stabilizer, antioxidant
- Fungicide, bactericide

Octylphenol 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
- Production of octylphenol based resins.

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 octylphenol ethoxylated 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 Yes
or hazard evaluation?

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)

SIDS Initial Assessment Report for 3rd SIAM, Williamsburg, Virginia 13th – 16th February 1995
<http://www.inchem.org/documents/sids/sids/140669.pdf> (Ref. 2)

- 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

Expected effect of the final regulatory action

- 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

Octylphenol ethoxylates are released to waste water and a considerable part is converted to octylphenol at sewage treatment plants (STP) which partly leaves the STP via effluent.

Octylphenol is acutely very toxic for water organisms: LC50 (72h) Pimephales promelas: 0.25 mg/l. In long-term tests rainbow trout is the most sensitive species: NOEC (60d) Salmo gairdneri: 0.006 mg/l. This results in a PNEC of 0.0006 mg/l.

In 1983 a maximum concentration of 0.03 mg/l of nonylphenol in Swiss STP effluents has been measured. Assuming a nine-fold higher consumption of nonylphenol ethoxylated than octylphenol ethoxylated a concentration of 0.003 mg/l for octylphenol can be estimated. A ten-fold dilution in the river gives an estimated surface water concentration of 0.0003 mg/l.

The possibility that estrogenic effects could occur at concentrations below the derived PNEC values cannot be excluded.

Octylphenol shows a moderate tendency to bioaccumulate, having a calculated BCF of 331

(Ref 2).

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. 248 MT (Octylphenol)	1993
imported	Approx. 129 MT (Octylphenol)	1993
exported	Approx. 45 MT (Octylphenol ethoxylates, Estimation based on received export notifications)	2011 2010
used	Approx. 1500 MT (Octylphenol ethoxylates, Estimation based on received export notifications)	

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 octylphenol ethoxylates (ex. in house hold or personal cleaning products) are still in use in many countries. Concerns mentioned in the risk evaluation such as water pollution might be encountered 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 octylphenols and octylphenol ethoxylates as: cleaning, emulsifying or dispersing agent and uses that are based on the surfactant properties of octylphenols and octylphenol ethoxylates.

octylphenols and octylphenol ethoxylate surfactants are easily replaceable and a large variety of alternative exist and are being used.

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

Besides that the final regulatory action has been based on a risk evaluation, the final regulatory action was also taken to avoid octylphenol and its ethoxylates being taken as substitutes for nonylphenol and its ethoxylates.

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

All octylphenols and octylphenol ethoxylates have been severely restricted. Risk evaluation is based on 4-(1,1,3,3-tetramethylbutyl)-phenol (CAS 140-66-9) since it is the most commonly commercialized octylphenol and it is also being ethoxylated.

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

<ul style="list-style-type: none">Annex I to Directive 67/548/EECRegulation (EC) No 1272/2008 Based on the Ordinance on chemical	Classification and Labeling of octylphenol (140-66-9) Classification: Category of danger : irritant, corrosive R-phrases : 36/38, 48/22, 50/53
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<p>products, the EU-classification is also valid in Switzerland</p> <p>Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council</p>	<p>Labeling : N; Xn R: 36/38, 48/22, 50/53 S: 26, 28, 35, 36, 56, 60, 61</p> <p>R36/38: Irritating to eyes and skin R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed R50/53 states: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment</p> <p>S26 states: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28 states: After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer) S35 states: This material and its container must be disposed of in a safe way S36 states: Wear suitable protective clothing S56 states: Dispose of this material and its container at hazardous or special waste collection point 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</p> <p>Skin Irrit. 2 -H315 Eye Dam. 1 -H318 Aquatic Acute 1 -H400 Aquatic Chronic 1 -H410</p>

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 on 4-(1,1,3,3-tetramethylbutyl)-phenol:		
Property	Value	Comments
Molecular weight	206.33 g/mol	
Melting point	80.5 °C	
Boiling point	280-283°C	
Relative density	950 kg/m ³	
Vapour Pressure	0.001 kPa at 20°C	
Partition coefficient (log Pow)	3.7	HPLC method
Water solubility	19 mg/l at 22°C	HPLC method
pKa	10.33 at 25 °C	Calculated

Reference

SIDS Initial Assessment Report for 3rd SIAM, Williamsburg, Virginia 13th – 16th February 1995

<http://www.inchem.org/documents/sids/sids/140669.pdf> (Ref. 2)

3.2.2 Description of toxicological properties of the chemical

According to Ref 2

Acute Toxicity

Oral: LD50: >2000 mg/kg (rat)

LD50 3210 mg/kg (mouse)

Inhalation: LD100 (24h): =<116 mg/l (rat, 89% OP)

Dermal: LD50: 1880 mg/kg (rabbit)

Intra-peritoneal: LD50: 25 mg/kg (mouse)

Skin irritation: slightly irritating index 4.5/8 (rabbit)

Eye irritation: highly irritating 63.0 scores in 24h (rabbit)

Sensitization: not sensitizing according to Magnussen & Illigman protocol (guinea pig); OP concentration: 20% in corn oil.

Repeated Dose Toxicity

OECD 407 repeated dose 28 days oral toxicity study:

The test substance was administered at dosages of 15, 150 and 250 mg/kg/day, once daily for a period of 29 days. Target organs were liver and kidney.

Kidney: In the kidneys of high dosages group rats, microscopic changes seen were basophilic epithelium with occasional mitotic figures in proximal tubules (males: 4 of 5, females 5 of 5; control: females: 1 of 5, males 0 of 5) and interstitial inflammation (males: 4 of 5, females 1 of 5, compared to control: males: 1 of 5, females: 2 of 5). Associated with these findings were increased kidney weights for females. For male rats of the intermediate dosage group, basophilic epithelium with occasional mitoses were also seen. Increased water consumption for rats of the high dosage group was considered to be related to the kidney effects.

Liver: In the liver of high dosage group female rats, minimal centrilobular hepatocyte enlargement with associated increased liver weight. These findings were considered to be adaptive and related to the metabolism of the test substance.

The finding in the kidney at the high and intermediate dosages was considered to be an adverse effect. There were no treatment related effects on the low dosage of 15 mg/kg bw/day. Based on these findings, a LOAEL of 150 mg/kg bw/day and a NOEL of 15 mg/kg bw/day was derived.

Toxicity for Reproduction

A reproduction/developmental screening test has been conducted in the rat. The test substance was administered at dosages of 125, 250 or 500 mg/kg/day, once daily by gavage for two weeks prior mating, throughout the two weeks mating period and until litters reached day 4 post partum. Slight impairment of the mating performance and development of the conceptus, observed as a reduced conception and implantation rate, a prolonged duration of pregnancy and a developmental delay, only occurred at 500 mg/kg/day. This dosage produced a marked parental toxic effect resulting in the death of 13 out of 24 adult animals during the treatment period. There was a clear, though less marked, treatment-related effect at 250 mg/kg/day upon the treated adults, although reproductive performance and development of the offspring was unaffected. The only changes noted at 125 mg/kg/day were post dose salivation and slightly elevated water consumption.

The NOAEL for parental toxicity was 125 mg/kg bw/day. The NOEL for reproductive performance and development of the offspring was 250 mg/kg bw/day.

Depigmentation study

Subcutaneous injections (6 times a week/7 months) of o-tert.-octylphenol in black mice (0.05 ml of a 0.01 M solution in olive oil) caused depigmentation of the skin 9 weeks after starting.

Experience with human exposure

Two female workers suffered depigmentation of the skin after they were exposed to two alkaline detergents containing polyoxyethylene alkylphenylether. Analysis of the detergents revealed the contamination with free alkylphenol, possibly octylphenol.

Some cases of vitiligo are reported among workers exposed to resins and detergents containing octylphenol (Russian and Japanese experiences).

Estrogenic effects of octylphenol on human cells

Experiments show that octylphenol may displace 17-beta-estradiol (a natural estrogen) from its receptors in a competitive manner and can promote cell proliferation in estrogen dependent cells. OP was able to stimulate these biological responses to the same extent as 17-beta-estradiol itself, albeit at a 1000-fold greater concentration.

Reference

SIDS Initial Assessment Report for 3rd SIAM, Williamsburg, Virginia 13th – 16th February 1995
<http://www.inchem.org/documents/sids/sids/140669.pdf> (Ref. 2)

3.2.3 Description of ecotoxicological properties of the chemical

The main source for OP in the environment is the degradation of octylphenol-exhoxylates to octylphenol in STPs, following either release with polluted secondary effluents or sewage sludge used in agriculture.. Their presence in the environment is only a consequence of anthropogenic activity.

Octylphenol is acutely very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. The environmental hazard assessments with the available exposure data shows that OP may represent a risk to the hydrosphere. The main reason for this risk is not the use of OP itself, but the use of octylphenol-ethoxylates which may be degraded back to OP in the aquatic environment.

Environmental Fate

Biodegradation: 0% biodegradation after 28 days (OECD 302C, modified MITI II test)
20% biodegradation after 28 days at 27.5 mg/l (BODIS test with activated sludge)

Photodegradation: In the surface layer of natural waters 30% of the octylphenol can be degraded within one day. The half-life of OP in a shallow (20-25 cm depth) creek at asunny day is 13.9 h.

Toxicity to aquatic organisms

Tropic level	Species	End point	Concentration (mg/l)	Comments
Freshwater fish	Fathead minnow Primephales promelas	96hr LC ₅₀ 72hr LC ₅₀ 48hr LC ₅₀ 24hr LC ₅₀ 96hr NOEC	0.25 0.25 0.25 0.29 0.077	Flow-through conditions
	Rainbow trout Salmo gairdneri	6 day LC ₅₀ 14 day LC ₅₀ 14 day NOEC 60 day NOEC	0.17 0.12 0.084 0.0061	Flow-through conditions
Freshwater invertebrates	Daphnia magna	24hr LC ₅₀	0.26	Flow-through conditions Acetone has been used as a cosolvent
		48hr LC ₅₀ 48hr NOEC 21 day EC ₅₀	0.27 0.11 0.34	
Fresh water algae	Selenastrum capricornutum Printz	96hr EC ₅₀ 96hr NOEC	1.9 < 1.0	Static conditions
	Scenedesmus subspicatus	72hr EC ₁₀ 72hr EC ₅₀	0.3 1.1	Other method (see Huels)

		72hr EC90	4.2	report No. AW 176, 1989)
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An estrogenic potential of octylphenol has been reported in several publications. The following estrogenic effects have been observed experimentally:
 Octylphenol stimulates the secretion of vitellogenin in cultivated hepaocytes of rainbow trout. It may displace 17-beta-estradiol (a natural estrogen) from its receptors in a competitive manner and can promote cell proliferation in estrogen dependent cells.
 Octylphenol has been able to stimulate these biological responses to the same extent as 17-betaestradiol itself, albeit at a 1000-fold greater concentration.

(Ref. 2)

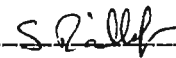
Reference

SIDS Initial Assessment Report for 3rd SIAM, Williamsburg, Virginia 13th – 16th February 1995
<http://www.inchem.org/documents/sids/sids/140669.pdf> (Ref. 2)

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
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Date, signature of DNA and official seal: 23.07.12  **Federal Office for the Environment FOEN**

**Waste Management, Chemicals
and Biotechnology Division
Industrial Chemicals Section
CH - 3003 Bern**

PLEASE RETURN THE COMPLETED FORM TO:

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OR

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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.